BIOENVISION INC
Form 10QSB
May 17, 2004

FORM 10-QSB

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

[X] QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2004
Commission File # 0-24875

BIOENVISION, INC.

(Exact name of small business issuer as specified in its charter)

| Delaware | 13-4025857 |
|---|---|
| State or other jurisdiction of incorporation or organization | IRS Employer ID No. |

509 Madison Avenue Suite 404 New York, N.Y. 10022
(Address of principal executive offices)

(Issuer's Telephone Number) (212) 750-6700

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past twelve months (or 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

As of May 14, 2004, there were 26,002,829 shares of the issuer's common stock, par value $.001 per share (the "Common Stock") outstanding.

Traditional Small Business Disclosure Format (Check One): YES [ ] No [X]

C O N T E N T S

Bioenvision, Inc. and Subsidiaries
CONDENSED CONSOLIDATED BALANCE SHEETS

| | March 31, 2004 |
|---|---|
| ASSETS | (unaudited |
| Current assets | |
| Cash and cash equivalents | $17,558,813 |
| Restricted cash | 290,000 |
| Deferred costs | 178,027 |
| Accounts receivable | 2,640,263 |
| Other assets | 187,604 |
| Total current assets | 20,854,708 |
| Property and equipment, net | 37,757 |
| Intangible assets, net | 14,801,470 |
| Goodwill | 3,902,705 |
| Security deposits | 79,111 |
| Other long term assets | 30,001 |
| Deferred costs-long term | 2,776,186 |
| Total assets | $42,481,937 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| Current liabilities | |
| Accounts payable | $1,133,000 |
| Accrued expenses | 493,369 |

| | |
|---|---|
| Accrued dividends payable | 1,597,118 |
| Deferred revenue | 434,181 |
| Total current liabilities | 3,657,667 |
| Deferred revenue-long term | 6,166,152 |
| Deferred tax liability | 5,914,774 |
| Total liabilities | 15,738,593 |
| Stockholders' equity | |
| Preferred stock - $0.001 par value; 20,000,000 shares authorized; 4,698,333 and 5,916,966 shares issued and outstanding at March 31, 2004 and June 30, 2003, respectively (liquidation preference $14,094,999 and 17,750,898 at March 31, 2004 and June 30, 2003, respectively) | 4,698 |
| Common stock - par value $0.001; 70,000,000 shares authorized; 23,017,950 and 17,122,739 shares issued and outstanding at March 31, 2004 and June 30, 2003, respectively | 23,018 |
| Additional paid-in capital | 64,240,092 |
| Accumulated deficit | (37,676,811 |
| Accumulated other comprehensive income | 152,346 |
| Stockholders' equity | 26,743,344 |
| Total liabilities and stockholders' equity | $42,481,937 |

The accompanying notes are an integral part of these financial statements.

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three months ended March 31, | | Nine months e March 31 | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | |
| | (unaudited) | (unaudited) | (unaudited) | ( |
| Licensing and royalty revenue | $224,772 | $45,753 | $361,308 | |
| Research and development contract revenue | 621,722 | - | 1,396,722 | |

| | | | |
|---|---|---|---|
| Total revenue | 846,494 | 45,753 | 1,758,030 |
| Costs and expenses | | | |
| Research and development | 994,307 | 319,760 | 2,545,128 |
| Selling, general and administrative (includes stock based compensation expense of $2,526,943 and $256,056 for the three months ended March 31, 2004 and 2003, respectively, and $3,625,535 and $678,556 for the nine months ended March 31, 2004 and 2003, respectively) | 3,721,937 | 1,050,172 | 7,079,367 |
| Depreciation and amortization | 343,456 | 338,688 | 1,023,325 |
| Total costs and expenses | 5,059,698 | 1,708,620 | 10,647,818 |
| Loss from operations | (4,213,205) | (1,662,867) | (8,889,789) |
| Interest income (expense) | | | |
| Interest and finance charges | - | - | - |
| Interest income | 14,576 | 27,875 | 49,465 |
| Net loss before income tax benefit | (4,198,628) | (1,634,992) | (8,840,325) |
| Income tax benefit | 134,351 | 152,100 | 402,928 |
| Net loss | (4,064,277) | (1,482,892) | (8,437,397) |
| Cumulative preferred stock dividend | (175,704) | (216,415) | (587,971) |
| Net loss available to common stockholders | $(4,239,982) | $(1,699,307) | $(9,025,369) |
| Basic and diluted net loss per share of common stock | $(0.21) | $(0.10) | $(0.50) |
| Weighted average shares used in computing basic and diluted net loss per share | 19,912,396 | 16,887,786 | 18,122,445 |

The accompanying notes are an integral part of these financial statements.



Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Nine months ended March 31, | |
|---|---|---|
| | 2004 | 2003 |
| | (unaudited) | (unaudited |
| Cash flows from operating activities | | |
| Net loss | $(8,437,397) | $(4,198,688 |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 1,023,325 | 1,005,710 |
| Deferred tax benefit | (402,928) | (456,300 |
| Compensation costs - shares and warrants issued to nonemployees | 1,009,290 | 678,556 |
| Compensation costs - re-pricing of options | 2,597,796 | - |
| Compensation costs-options issued to employees | 18,449 | |
| Changes in assets and liabilities | | |
| Deferred costs | (2,706,549) | 184,091 |
| Deferred revenue | 5,362,012 | (368,182 |
| Accounts payable | 721,608 | (109,623 |
| Other current assets | (81,628) | (45,529 |
| Other long term assets | 96,868 | 4,247 |
| Accounts receivable | (2,615,263) | (79,111 |
| Other accrued expenses and liabilities | (237,353) | (772,834 |
| Net cash used in operating activities | (3,651,771) | (4,157,663 |
| Cash flows from investing activities | | |
| Purchase of intangible assets | (30,772) | (161,183 |
| Capital expenditures | (3,116) | (59,405 |
| Restricted cash | - | (290,000 |
| Net cash used in investing activities | (33,888) | (510,588 |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock | 12,157,240 | - |
| Proceeds from exercise of options, warrants and other convertible securities | 1,157,546 | - |
| Net cash provided by financing activities | 13,314,786 | - |
| Net increase (decrease) in cash and cash equivalents | 9,629,127 | (4,668,251 |
| Cash and cash equivalents, beginning of period | 7,929,686 | 12,882,521 |
| Cash and cash equivalents, end of period | $17,558,813 | $8,214,270 |

The accompanying notes are an integral part of these financial statements.

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2004

(Unaudited)

NOTE A - Description of Business

Bioenvision, Inc. ("Bioenvision" or the "Company") is an emerging biopharmaceutical company whose primary business focus is the development and distribution of drugs to treat cancer. The Company has a broad range of products and technologies under development, but its two lead drugs are Clofarabine and Modrenal(R). Modrenal(R)is approved for marketing in the U.K. for advanced post-menopausal breast cancer. The Company' has filed an IND in the United States to test Modrenal(R) in a Phase II clinical trial for the treatment of androgen independent prostate cancer which clinical trial is expected to commence in Q2 of calendar 2004. The Company's future plans within the U.S. include development of Modrenal(R) in the U.S. for the treatment of advanced post-menopausal breast cancer. Most of the Company's other drugs are now in clinical trials in various stages of development including Clofarabine, a drug which we believe to be effective for the treatment of pediatric and adult acute leukemia, and potentially solid tumors and chronic leukemia.

NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments (consisting only of normal recurring accruals) necessary to present fairly the consolidated financial position as of March 31, 2004 and the consolidated results of operations for the three months and nine months ended March 31, 2004 and 2003, and cash flows for the nine months ended March 31, 2004 and 2003.

The condensed consolidated balance sheet at June 30, 2003 has been derived from the audited financial statements at that date, but does not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. For further information, refer to the audited consolidated financial statements and footnotes thereto included in the Form 10-KSB filed by the Company for the year ended June 30, 2003.

The condensed consolidated results of operations for the three months and nine months ended March 31, 2004 and 2003 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

NOTE C - Stock Based Compensation

At March 31, 2004, the Company has stock based compensation plans which are described more fully in the Company's annual report on Form 10-KSB for the year ended June 30, 2003. As permitted by SFAS No. 123, "Accounting for Stock Based Compensation," the Company accounts for stock based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees." Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. Under APB 25, no stock based employee compensation cost is reflected in reported net loss, when options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant. For the three months and nine months ended March 31, 2004, the Company recognized stock based employee compensation expense of $1,943,888 and

$2,597,796, respectively, as a result of the March 31, 2003 re-pricing of 380,000 options granted to an employee pursuant to the terms of his employment contract. For each of the three months and nine months ended March 31, 2004, the Company recorded compensation expense of $18,499, as a result of the 288,600 options granted to certain employees on January 20, 2004.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services," as amended by EITF No. 00-27. Under EITF No. 96-18, where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument. The Company expects to continue applying the provisions of APB Opinion No. 25 for equity issuances to employees.



The following table illustrates the effect on net loss and loss per share as if the fair value based method had been applied to all outstanding and unvested awards in each
period.

| | Three months ended March 31, | | Nine months March 31 | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | |
| Net loss available to common stockholders, as reported | $(4,239,982) | $(1,699,307) | $(9,025,369) | $( |
| Add: Stock based employee compensation expense included in reported net income, net of tax effects | $ 18,499 | - | $ 18,499 | |
| Deduct: Total stock based employee compensation expense determined under fair value based method for all awards; net of related tax effects | $ (159,528) | $(152,042) | $ (284,959) | $( |
| Pro forma net loss | $(4,381,011) | $(1,851,349) | $ (9,291,829) | $( |
| Loss per share | | | | |
| Basic and diluted - as reported | $ (0.21) | $ (0.10) | $ (0.50) | $ |
| Basic and diluted - pro forma | $ (0.22) | $ (0.11) | $ (0.51) | $ |

The fair value of options at the date of grant was established using the Black-Scholes model with the following assumptions:

| | Three months ended March 31, | | Nine months March 31 |
|---|---|---|---|
| | 2004 | 2003 | 2004 |

| | | | |
|---|---|---|---|
| Expected life (years) | 4 | 4 | 4 |
| Risk free interest rate | 3.00% | 3.00% | 3.00% |
| Expected volatility | 80.00% | 80.00% | 80.00% |
| Expected dividend yield | 0.00 | 0.00 | 0.00 |

NOTE D - Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options and warrants to purchase 13,145,020 and 6,054,544 shares of common stock have not been included in the calculation of net loss per share for the nine months ended March 31, 2004 and 2003, respectively, as their effect would have been anti-dilutive.

NOTE E - License And Co-Development Agreements

Clofarabine

The Company has a license from Southern Research Institute ("SRI"), Birmingham, Alabama, to develop and market purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. The lead compound of these purine-based nucleosides is known as Clofarabine. The Company is developing Clofarabine initially for the treatment of pediatric and adult leukemias, lymphomas and solid tumors.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

To facilitate the development of Clofarabine, the Company entered into a co-development agreement with ILEX Oncology,



Inc. ("ILEX") in March 2001. Under the terms of the co-development agreement, the Company granted ILEX an option to market Clofarabine in the United States and Canada. ILEX is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the United States and Canada (excluding Japan and Southeast Asia). The Company also granted Ilex an option to purchase $1 million of Common Stock after completion of the pivotal Phase II clinical trial, and ILEX has an additional option to purchase $2 million of Common Stock after the filing of a new drug application in the United States for the use of Clofarabine in the treatment of lymphocytic leukemia. The exercise price per share for each option is determined by a formula based around the date of exercise. Under the co-development agreement, ILEX also pays royalties to Southern Research Institute based on certain milestones. Also, the Company is obligated to pay milestones and royalties to Southern Research Institute in respect to Clofarabine sales outside the United

State and Canada. On September 12, 2003, ILEX paid the Company approximately $775,000 in respect of Research and Development costs incurred by the Company for European drug development through August 31, 2003. The Company recognized additional revenue of $622,000 from ILEX for Research and Development costs incurred by the Company during the three months ended March 31, 2004.

The Company received a nonrefundable, upfront payment of $1.35 million when they entered into the agreement with ILEX and is entitled to receive milestone payments of $2.5 million upon completion of management designed pivotal Phase II clinical trials of Clofarabine and $5.0 million after submission of a new drug application with the FDA. The upfront payment was deferred and recognized as revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company recognized revenues of $0 for the three and nine months ended March 31, 2004 and $0 and approximately $368,000 for the three and nine months ended March 31, 2003 in connection with the up-front payment under the ILEX agreement.

Deferred costs represents royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology. The Company also defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with Ilex agreement.

Modrenal(R)

The Company holds an exclusive license, until the expiration of existing and new patents related to Modrenal(R), to market modrenal in major international territories, and an agreement with a United Kingdom company to co-develop Modrenal(R) for other therapeutic indications. Management believes that Modrenal(R) currently is manufactured by third-party contractors in accordance with good manufacturing practices. The Company has no plans to establish its own manufacturing facility for Modrenal(R), but will continue to use third-party contractors.

Anti-Estrogen Prostate. The Company has received Institutional Review Board approval from the Massachusetts General Hospital for a Phase II study of Modrenal(R) for the treatment of androgen independent prostate cancer. The study will be conducted by The Dana Faber Cancer Institute and currently is intended to commence in May 2004.

Operational Developments

On April 27, 2004, the Company entered into a Clinical Development Agreement with Covance Inc., pursuant to which Covance has agreed to perform certain clinical investigatory services for the development of Clofarabine in Europe including, without limitation, performing CRO activities in connection with the Company's ongoing Phase II clinical trial of Clofarabine for the treatment of adults with Acute Myeloid Leukemia for which chemotherapy is not considered suitable ("BIV 121"). The Company's management acknowledges that BIV 121 could possibly be the basis for a regulatory submission in the adult AML indication; although several factors beyond management's control may affect the development of Clofarabine in this indication.

On March 31, 2004, ILEX Oncology, Inc., our U.S. co-development partner for the development of Clofarabine, filed a New Drug Application ("NDA") with FDA for approval of Clofarabine in the U.S. for the treatment of pediatric ALL and AML (the "NDA Filing"). The Company has taken the NDA filing and currently is in the process of converting the filing to a Common Technical Document (the "CTD") for filing with the EMEA as the basis potentially for European approval of Clofarabine for the treatment of pediatric ALL and AML. The Company expects to file the CTD with the EMEA in the third quarter of calendar year 2004.

On December 30, 2003, the Company converted ILEX's option to a sublicense and ILEX paid the Company $3.5 million constituting an acceleration of milestone payments required pursuant to the co-development agreement. Further, ILEX agreed to pay an additional $2 million upon filing an NDA and a further $2 million six months thereafter. Pursuant to the original co-development agreement, ILEX was obligated to pay the Company $2.5 million upon completion of the pivotal phase II clinical trials; an additional $500,000 on filing an NDA for acute leukemias; and an additional $4.5 million within



twelve months thereafter. These non-refundable fees that were received pursuant to license and other collaborative agreements where the Company has continuing involvement are recorded as deferred revenue and recognized over the estimated service period through March 2021. The related costs paid to SRI were also deferred and are being amortized over the same service period. ILEX filed the NDA with FDA in March 2004 and in April 2004, ILEX paid the Company $2 million, representing the payment due to be paid upon filing of the NDA. The Company expects to receive the final $2 million payment from ILEX Oncology in Q3 of calendar year 2004.

In September 2003, the Company and ILEX entered into an amendment to the co-development agreement, pursuant to which the Company collaborated with ILEX to co-develop an oral formulation for clofarabine; the rights and related costs of which will be shared equally.

In August 2003, the Company entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, the Company succeeded to Stegram the United Kingdom marketing rights to Modrenal.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from Clofarabine in Japan and Southeast Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

In June 2003, the Company entered into a supply agreement with Ferro-Pfanstiehl Laboratories ("Ferro"), pursuant to which Ferro has agreed to manufacture and supply 100% of Bioenvision's global requirements for Clofarabine-API. Subject to certain circumstances, this agreement will expire on the fifth anniversary date of the first regulatory approval of Clofarabine drug product.

In June 2003, the Company entered into a development agreement with Ferro, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply CTM and GMP supplier qualifications of the API-Clofarabine. Subject to certain circumstances, this agreement expires upon the completion of the development program. The development agreement is milestone based and payments are to be paid upon completion of each milestone. If Ferro has not completed the development agreement by December 2007, the development agreement will automatically terminate without further action by either party. The Company paid and capitalized $50,000 related to development costs.

In May 2003, the Company entered into a sub-license agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Dechra has been granted a sub-license for all of Bioenvision's rights and entitlements to market and

distribute Modrenal in the United States and Canada solely in connection with animal health applications. Subject to certain circumstances, this agreement expires upon expiration of the last patent related to modrenal or the completion of the last royalty set forth in the agreement. The Company received an upfront non-refundable payment of $1.25 million upon execution of this agreement and may receive up to an additional $3.75 million upon the achievement by Dechra of certain milestones set forth in the agreement. The upfront payment received from Dechra has been deferred and will be recognized as revenues on a straight-line basis over the term of the license agreement through May 2014. The Company recognized revenues of $29,000 and $87,000 for the three and nine months ended March 31, 2004 in connection with this sublicense agreement with Dechra. As of March 31, 2004, deferred revenues include approximately $1,153,000 related to this agreement.

In May 2003, the Company entered into a master services agreement with Penn-Pharmaceutical Services Limited ("Penn"), pursuant to which Penn has agreed to label, package and distribute Clofarabine on behalf of and at the Company's request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three months prior written notice.

In April 2003, we entered into an exclusive license agreement with CLL-Pharma ("CLL"), pursuant to which CLL has agreed to perform certain development works and studies to create a new formulation of Modrenal in the form of a soft gel capsule. CLL intends to use its proprietary MIDDS.-patented technology to perform this service on behalf of the Company. This new formulation, once in hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell modrenal throughout Europe. Through June 30, 2003, the Company paid an advance of $175,000 related to development services to be provided by CLL over an eighteen month period, which advance was recorded as a prepaid development cost by the Company.



NOTE F - Equity Transactions

In June 2002, the Company granted options to an officer of the Company to purchase 380,000 shares of common stock at an exercise price of $1.95 per share, which equaled the stock price on the date of grant. Of this amount 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003, the Company entered into an Employment Agreement with such officer of the Company, pursuant to which, among other things, the exercise price for all of the 380,000 options were changed to $0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of $.735 per share which vest immediately. As a result of the repricing of all of the 380,000 options, the Company will remeasure the intrinsic value of these options at the end of each reporting period and will record a charge for compensation expense to the extent the vested portion of the options are in the money. For the three months and nine months ended March 31, 2004, the Company recognized stock based compensation expense of $1,943,888 and $2,597,796, respectively.

During the three months ended March 31, 2003, the Company also issued 20,000

options to another employee to purchase 20,000 shares of common stock at an exercise price of $1.42 per share. Of this amount, 10,000 options vest on January 9, 2004 and the remaining 10,000 options will vest on January 9, 2005.

On April 2, 2003, the Company granted RRD International, a regulatory consultant to the Company, a warrant to acquire 175,000 shares of the Company's common stock at an exercise price of $2.00 per share, which warrant vests ratably upon satisfaction of five milestones included in the warrant and includes registration rights under certain circumstances. In connection therewith, for the three month and nine month periods ended Match 31, 2004, the Company recognized consulting expense of approximately $485,000 and $611,000, respectively.

During the three months ended December 31, 2003, the Company issued options to another employee to purchase 25,000 shares of common stock at an exercise price of $3.53 per share. Of this amount, 12,500 options vest on November 11, 2004 and the remaining 12,500 will vest on November 11, 2005.

During the three and nine months ended March 31, 2004, certain holders of 760,000 shares of the Company's preferred stock converted such shares into 1,520,000 shares of the Company's common stock. In addition, during the three and nine months ended March 31, 2004, certain warrant holders of the Company exercised their warrants to acquire 433,000 and 608,000 shares of the Company's common stock, respectively. The Company received proceeds of approximately $867,000 and $1,129,000 during the three and nine months ended March 31, 2004, respectively from the exercise of these warrants.

During the three and nine month periods ended March 31, 2004, certain holders of options to purchase an aggregate of 1,025,000 and 2,113,000 shares, respectively of the Company's common stock were exercised pursuant to the cashless exercise feature available to such option holders and the Company issued approximately 847,000 and 1,738,000 shares of its common stock in connection therewith.

On January 3, 2004, the Company issued 14,510 restricted shares of its common stock to a consultant to the Company for certain executive placement services rendered to the Company. The Company recorded compensation expense of approximately $60,637 for the three months ended March 31, 2004 in connection with such issuance.

On January 20, 2004, the Company granted 20,000 options to Dr. Michael Kauffman, for serving as a member of the Board of Directors, at an exercise price of $4.55 per share which vest ratably on the first and second anniversaries of the grant date.

On January 20, 2004 the Company recorded a compensation expense of $18,499 as a result of the 288,600 options granted to certain employees.

On February 4, 2004, the Company issued 20,000 shares of its common stock to an employee of the Company in connection with the exercise of options issued prior to that date.

On March 22, 2004, the Company consummated a private placement transaction, pursuant to which we raised $12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of $7.50 per share. The Company recorded proceeds of $12,151,240 net of all legal, professional and financing fees incurred in connection with the offering. The Company consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional $3.5 million from the second closing and issued an additional 558,384

shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of $7.50 per share.



NOTE G - Related Party Transactions

In May 2002, we completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for $3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock and in March of 2004 we consummated a private placement pursuant to which we raised $12.8 million with a second closing in May 2004 in which we raised an additional $3.5 million (See "Note F-Equity Transactions" above). An affiliate of SCO Capital Partners LLC, one of our stockholders, served as financial advisor to the Company in connection with these financings and earned a placement fee of approximately $1.2 million in connection with May 2002 private placement and a placement fee of $1.1 million and warrants to purchase 260,291 shares of common stock for $6.25 per share for the March and May 2004 financings. This affiliate of SCO Capital Partners LLC continues to serve as a financial advisor to the Company.

NOTE H - New Accounting Pronouncements

In January 2003, the FASB issued Financial Interpretation No. 46, "Consolidation of Variable Interest Entities" ("FIN 46"), which addresses consolidation by business enterprises of variable interest entities (VIEs). The accounting provisions and disclosure requirements of FIN 46 are effective immediately for VIEs created after January 31, 2003, and are effective for the Company's fiscal period ending March 31, 2004, for VIEs created prior to February 1, 2003. In December 2003, the FASB published a revision to FIN 46 ("FIN 46R") to clarify some of the provisions of the interpretation and to defer the effective date of implementation for certain entities. Under the guidance of FIN 46R, public companies that have interests in VIE's that are commonly referred to as special purpose entities are required to apply the provisions of FIN 46R for periods ending after December 15, 2003. A public company that does not have any interests in special purpose entities but does have a variable interest in a VIE created before February 1, 2003, must apply the provisions of FIN 46R by the end of the first interim or annual reporting period ending after March 14, 2004. During the quarter ended March 31, 2004 the Company adopted the provisions of FIN 46R. Adoption of FIN46R did not have a material effect on the Company's financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" ("SFAS 150"). The objective of SFAS 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. Adoption of SFAS 150 did not have a material impact on the results of operations or financial position of the Company.

In May 2003, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be

allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations, but could affect the timing or pattern of revenue recognition for future collaborative research and/or license agreements.

NOTE I - Litigation

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleged a breach of contract by the Company and demanded judgment against the Company for $112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary judgment and RLB filed its response on October 27, 2003. In December 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. In March 2004, the complaint and two counterclaims asserted by the Company were dismissed with prejudice.

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the "Tessman Defendants") in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously.



BIOENVISION, INC. AND SUBSIDIARIES

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION OR PLAN OF OPERATION

Except for historical information contained herein, this quarterly report on Form 10-QSB contains forward-looking statements within the meaning of the Section 21E of the Securities and Exchange Act of 1934, as amended, which involve certain risks and uncertainties. Forward-looking statements are included with respect to, among other things, the Company's current business plan an " Managements Discussion and Analysis of Results of Operations". These forward-looking statements are identified by their use of such terms and phrases as "intends," "intend," "intended," "goal," "estimate," "estimates," "expects," "expect," "expected," "project," "projected," "projections," "plans," "anticipates," "anticipated," "should," "designed to," "foreseeable future," "believe," "believes" and "scheduled" and similar expressions. The Company's actual results or outcomes may differ materially from those anticipated. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis of significant factors affecting the Company's operating results, liquidity and capital resources and should be read in conjunction with the accompanying financial statements and related notes.

Overview

We have several products and technologies under development, but our two lead drugs are Clofarabine and Modrenal(R).

Clofarabine is a purine nucleoside analogue, or a small molecule, which, based on our own clinical studies and studies conducted by others on our behalf, we believe is effective in the treatment of leukemia. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I/II clinical trials performed to date. In the United Kingdom, we are currently conducting clinical trials with Clofarabine for the treatment of pediatric and adult acute leukemias. In the U.S., Clofarabine is currently in Pivotal Phase II clinical trials for pediatric acute leukemias. In January, 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for Clofarabine. The drug has also been granted orphan drug status and "fast track" treatment by the United States Food and Drug Administration (the "FDA"). Further, in August 2003, we obtained the exclusive, irrevocable option to sell, market and distribute Clofarabine in Japan and Southeast Asia from the inventor of Clofarabine. These rights were not previously granted by Southern Research Institute and fall outside the scope of the Company's then current licensing and development contracts with respect to Clofarabine. We originally obtained an exclusive license from Southern Research Institute to sell, market and distribute Clofarabine throughout the world, except for Japan and Southeast Asia, for all human applications, pursuant to a co-development agreement, dated August 31, 1998, between the Company and Southern Research Institute. On March 12, 2001, we granted an exclusive option to sell, market and distribute Clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute Clofarabine in the U.S.

Modrenal(R) is a hormonal agent with a novel mode of action, that makes it an effective agent in patients with advanced breast cancer who have acquired resistance to other hormonal agents. We launched Modrenal(R) in May 2003 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. In the first half of 2004, we intend to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such territory. We anticipate receiving approval in each such territory in the first half of calendar year 2005. Further, we filed an IND for prostate cancer clinical trials in the US in February 2004 and intend to commence our first US clinical trial in the second quarter of calendar year 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.

Our primary business strategy relates to our two lead drugs, Clofarabine and Modrenal(R). With Clofarabine, our strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory

authorities to market and distribute Clofarabine for the treatment of pediatric and adult acute leukemias. We anticipate receiving approval early in 2005, subject to our obtaining approval of the regulatory authorities. We will continue clinical trials in other indications with the intention of seeking label extensions after Clofarabine's first approval. With Modrenal, our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to sell Modrenal(R) throughout Europe. We anticipate receiving mutual recognition from major European Community member states by mid-2005. Our secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from Clofarabine and Modrenal(R) will permit us to further develop our portfolio of ancillary products and technologies.

Although our primary business strategy is to develop and commercialize our two lead drugs, Clofarabine and Modrenal(R) for sale in the territories within which we have licensed the right to sell, market and distribute these drugs, our board of directors continues to evaluate other strategic alternatives for the Company and its products, including the potential disposition of all or a portion of our business, potential licensing and/or co-development arrangements with other pharmaceutical companies and certain financing strategies.

Company Status

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this emerging stage. We anticipate that revenues derived from the two lead drugs will permit us to further develop our other products and potential products currently in our development portfolio. On March 29, 2004, ILEX Oncology, Inc. filed a New Drug Application with the FDA for approval of Clofarabine in the U.S. for the treatment of pediatric ALL and AML (the "NDA Filing"). The Company has taken the NDA filing and currently is in the process of converting the filing to a Common Technical Document (the "CTD") for filing with the EMEA as the basis potentially for European approval of Clofarabine for the treatment of pediatric ALL and AML. The Company expects to file the CTD with the EMEA in the third quarter of calendar year 2004. We have commenced marketing one of our lead products, Modrenal(R), and we intend to continue developing our existing platform technologies with a primary business focus on drugs to treat cancer, and commercializing products derived from such technologies. A key element of our business strategy is to continue to develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. As a result of the acquisition of Pathagon Inc., in February 2002, we have several anti-infective technologies. These include the OLIGON(R) technology, an advanced biomaterial that has been approved for certain indications by the FDA in the United States, and is being sold by a product co-development partner, and the use of thiazine dyes, such as methylene blue, which are used for in vitro and in vivos inactivation of pathogens (viruses, bacteria and fungus) in biological fluids. It is not the Company's strategy to sell devices or to expand into the anit-infective market per se, but the technology obtained in the Pathagon acquisition has specific application for support of the cancer patient and oncology treatment. We have had discussions with potential product co-development partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans.

In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are

outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. In May 2003, we entered into a Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed to Dechra the marketing and development rights to modrestane, solely with respect to animal health applications, in the United States and Canada. We received $1.25 million in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try to exploit these types of opportunities as they arise.

You should consider the likelihood of our future success to be highly speculative in light of our limited operating history, as well as the limited resources, problems, expenses, risks and complications frequently encountered by similarly situated companies. To address these risks, we must, among other things:

- satisfy our future capital requirements for the implementation of our business plan;
- commercialize our existing products;
- complete development of products presently in our pipeline and obtain necessary regulatory approvals for use;
- implement and successfully execute our business and marketing strategy to commercialize products;
- establish and maintain our client base;



- continue to develop new products and upgrade our existing products;
- respond to industry and competitive developments; and
- attract, retain, and motivate qualified personnel.

We may not be successful in addressing these risks. If we are unable to do so, our business prospects, financial condition and results of operations would be materially adversely affected. The likelihood of our success must be considered in light of the development cycles of new pharmaceutical products and technologies and the competitive and regulatory environment in which we operate.

Results of Operations

We have acquired development and marketing rights to a portfolio of six platform technologies developed over the past fifteen years, from which a range of products have been derived and additional products may be developed in the future. Although we intend to commence marketing our lead product, Modrenal (TM), and to continue developing our existing platform technologies and commercializing products derived from such technologies, a key element of our business strategy is to continue to develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. Once a product or technology has been launched into the market for a particular disease indication, we plan to work with numerous collaborators, both pharmaceutical and clinical, in the oncology community to extend the permitted uses of the product to other indications. In order to market our products effectively, we intend to develop marketing alliances with

strategic partners and may co-promote and/or co-market in certain territories.

The Company recorded revenues for the three months ended March 31, 2004 and 2003 of approximately $846,000 and $46,000, respectively, representing an increase of $800,000. The Company recorded revenues for the nine months ended March 31, 2004 and 2003 of approximately $1,758,000 and $464,000, respectively, representing an increase of $1,294,000. Approximately $620,000 and $1,390,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, relates to reimbursement for Clofarabine research and development costs incurred by the Company for European drug development (partially offset, for the for the nine months ended March 31, 2004, by an extension of the time period within which the Company recognizes Clofarabine milestone revenues, which has the effect of reducing revenue recognized for such milestones by approximately $300,000 during the period). Revenues reflect our agreement with our co-development partners and/or licenses in connection with our platform of drugs and technologies and includes sales of Clofarabine in Europe pursuant to the Company's Named Patient Program.

Research and development costs for the three months ended March 31, 2004 and 2003 were $994,000 and $320,000, respectively, representing an increase of $674,000.

Research and development costs for the nine months ended March 31, 2004 and 2003 were $2,545,000 and $1,162,000, respectively, representing a increase of $1,383,000.

Our research and development costs include costs associated with six projects for which the Company devotes significant time and resource. Clofarabine research and development costs for the nine months ended March 31, 2004 and 2003 were $1,612,000 and $730,000, respectively, representing an increase of $881,000. The increase primarily reflects the costs associated with our having commenced clinical trials in Europe to develop Clofarabine. Modrenal research and development costs for the nine months ended March 31, 2004 and 2003 were $744,000 and $561,000, respectively, representing a decrease of $183,000. Gossypol research and development costs were $152,000 and $27,000, respectively, representing a increase of $124,000. Gene Therapy research and development costs for the nine months ended March 31, 2004 and 2003 were 0 and $(158,000), respectively, representing a decrease of $158,000. The decrease primarily reflects an accrued expense in the year ended 2002 of $200,000 which was determined to be less than originally estimated by the Company in the year ended June 30, 2003. The clinical trials and development strategy for the Clofarabine and Modrenal projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, Clofarabine and Modrenal , over the next two years.

Selling, general and administrative expenses for the three months ended March 31, 2004 and 2003 were $3,722,000 and $1,050,000, respectively, representing an increase of $2,672,000. Selling, general and administrative expenses for the

nine months ended March 31, 2004 and 2003 were $7,080,000 and $2,743,000, respectively, representing an increase of $4,337,000. Approximately $1,943,000 and $2,597,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, relates to stock based compensation recorded during the period resulting from the repricing of the options issued to an officer of the Company. Approximately $57,000 and $155,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, was due to the expansion of the internal management team from one full time employee to eight full time employees during the three and nine month periods then ended. Approximately $98,000 and $532,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, was due to an increase in investor and public relations expenses related to pre-marketing activities with Clofarabine and marketing costs associated with Modrenal. Approximately $2,000 and $107,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, was related to increases in travel related expenses incurred in order to successfully manage our more active drug development activities during the three and nine month periods then ended. Approximately $562,000 and $817,000 of the increase in Selling, general and administrative expense for the three and nine month periods ended March 31, 2004, respectively, was due to increases in our consulting and legal expenses as the result of our recent growth internally and operationally during the three and nine month periods ended March 31, 2004, respectively.

Depreciation and amortization expense for the three months ended March 31, 2004 and 2003 were $343,000 and $339,000, respectively, representing an increase of $5,000. Depreciation and amortization expense for the nine months ended March 31, 2004 and 2003 were $1,023,000 and $1,006,000, respectively, representing an increase of $17,000. The increase is primarily due to the amortization of certain intangible assets we acquired.

Liquidity and Capital Resources

We anticipate that we may continue to incur significant operating losses for the foreseeable future. There can be no assurance as to whether or when we will generate material revenues or achieve profitable operations. We are actively seeking strategic alliances in order to develop and market our range of products.

We consummated a private placement transaction on March 22, 2004, pursuant to which we raised $12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of $7.50 per share. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional $3.5 million in the second closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of $7.50 per share.

We received an initial payment from Dechra of $1,250,000 on May 13, 2003 upon execution of our sub-license agreement with Dechra. This agreement expires upon expiration of the last patent related to modrenal or the completion of the last royalty obligation as set forth therein.

We received a milestone payment from ILEX of $3.5 million on December 30, 2003, upon executing an amendment to the co-development agreement. This payment related to the achievement of a milestone; namely, completion of pivotal phase II trials. Pursuant to the Company's co-development agreement with SRI,

the Company immediately paid $1.75 million of such milestone payment to SRI.

On March 31, 2004, we had cash and cash equivalents of $17,558,813 and working capital of $17,197,041, which management believes will be sufficient to continue currently planned operations over the next twelve months. Although we do not currently intend to raise any additional funds for the next twelve months, we cannot ensure additional funds will not be raised during such period because of the significant scale-up of our operating activities, including Clofarabine development and the launch of Modrenal.

Further, a key element of our business strategy is to continue to develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. We are not presently considering any such transactions, and we do not presently expect to acquire any significant assets over the coming twelve month period, but if any such opportunity arises and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.



Future commitments of the Company for the twelve-month period April 1st through March 31 are as follows:

| | | Payments Due: | |
|---|---|---|---|
| | Total | 2005 | 2006 |
| Employee Contracts | 2,436,186 | 1,218,093 | 1,218,093 |
| Occupancy Lease | 248,605 | 164,972 | 83,633 |
| Total | 2,684,791 | 1,383,065 | 1,301,726 |

In management's opinion, cash flows from operations and borrowing capacity combined with cash on hand will provide adequate flexibility for funding the Company's working capital obligations for the next twelve months. However, there can be no assurance that suitable debt or equity financing will be available for the Company. The Company has a commitment under its operating lease with the New York office. The Company leases 3,229 square feet under a lease that expires on September 30, 2005. The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision Limited.

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. In the event of a voluntary or involuntary liquidation or dissolution of the Company, before any distribution of assets shall be made to the holders of the Company's securities which are junior to the preferred stock (such as the common stock), holders of the preferred stock shall be paid out of the assets of the Company legally available for distribution to the Company's stockholders an amount per share equal to the initial original issue price ($3.00) subject to certain adjustments plus all accrued but unpaid dividends on such preferred stock.

Subsequent Events

In April 2004, ILEX paid the Company the $2,000,000, which it agreed to pay upon the filing of the NDA. ILEX filed the NDA with FDA in March 2004.

In April 2004, the Company entered into a Clinical Development Agreement with Covance Inc. pursuant to which Covance has agreed to perform certain drug development activities in connection with the Company's BIV-121 sponsor lead clinical trial in Europe.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report on Form 10-QSB. Based on this evaluation, our principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the requisite time periods.

In connection with its review of the Company's consolidated financial statements for and as of the three month period ended March 31, 2004, Grant Thornton LLP ("Grant Thornton"), the Company's independent accountants, advised the Audit Committee and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness, including, inadequate staffing and supervision leading to the untimely identification and resolution of certain accounting matters; failure to perform timely reviews, substantiation and evaluation of certain general ledger account balances; lack of procedures or expertise needed to prepare all required disclosures; and evidence that employees lack the qualifications and training to fulfill their assigned functions. Grant Thornton indicated that they considered these deficiencies to be reportable conditions as that term is defined under standards established by the American Institute of Certified Public Accountants. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes our internal control from reducing to an appropriately low level the risk that material misstatements in our financial statements will not be prevented or detected on a timely basis. The Company considered these matters in connection with the quarter end closing of accounts and preparation of related quarterly financial statements at and as of March 31, 2004 and determined that no prior period financial statements were materially affected by such matters.

In response to the observations made by Grant Thornton, the Company will proceed more expeditiously with its existing plan to enhance the Company's internal controls and procedures, which it believes addresses each of the matters raised by Grant Thornton.



Changes in Internal Controls

We enhanced our internal control procedures in March 2004 by adding Ms. Ying Peng, CPA, as a full-time dedicated accountant with more than seven years work experience to the staff in our principal executive offices in New York, New York. Ms. Peng works directly for our outsourced accounting firm which assists us in the preparation and finalization of our accounts on an ongoing basis. Ms. Peng's responsibilities include preparation of the Company's financial statements on a quarterly and annual basis and preparation of budget-to-actual analyses on a quarterly basis. Our management intends to expand her

responsibilities on our behalf to include preparation of monthly financial statements and monthly and annual budget-to-actual analyses. We believe the addition of Ms. Peng as a dedicated resource will further enhance the Company's internal control over financial reporting in the near term, which management will continue to monitor on a regular basis. In addition, we intend to streamline the responsibilities of our principal financial officer to permit him to focus more of his time and effort, as needed, on the accounting and financial reporting needs of the Company.

BIOENVISION, INC. AND SUBSIDIARIES

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleged a breach of contract by the Company and demanded judgment against the Company for $112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary judgment and RLB filed its response on October 27, 2003. In December 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. In March 2004, the complaint and two counterclaims asserted by the Company were dismissed with prejudice.

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Item 2. Changes in Securities and Use of Proceeds

We consummated a private placement transaction on March 22, 2004, pursuant to which we raised $12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of $7.50 per share to 28 investors. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional $3.5 million in the second closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of $7.50 per share to 6 investors.

The Company issued the common stock and warrants to the investors in reliance on the exemptions from registration under the Securities Act of 1933, as amended, (the "Securities Act") contained in Section 4(2) of the Securities Act and Regulation D promulgated thereunder. The Company believes the issuance of the common stock and warrants qualifies as a transaction by an issuer not involving a public offering within the meaning of Section 4(2) of Securities Act and meets the requirements of a safe harbor from registration contained in Regulation D, based on the manner of offering to "accredited investors" (as defined in Rule 501 of Regulation D) without general solicitation) and the

investors' financial status, investment experience and investment intent, as represented to the Company.

Item 3. Defaults upon Senior Securities

None

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

(a) The Company held its annual meeting of stockholders on January 14, 2004.

(b) and (c) At the annual meeting of stockholders on January 14, 2004 considered and approved:

1. A proposal to amend our certificate of incorporation to (i) increase the authorized number of shares of our common stock from 50,000,000 to 70,000,000 and (ii) increase the authorized number of share of our preferred stock from 10,000,000 to 20,000,000 ("Proposal 1");



2. A proposal to approve the adoption of our 2003 Stock Incentive Plan ("Proposal 2"); and

3. A proposal to elect five directors (identified in the table below) to serve until the next annual meeting of stockholders or until such directors' successors are elected and shall have been duly qualified ("Proposal 3").

The following table sets forth the number of votes in favor, the number of votes opposed, and the number of abstentions (or votes withheld in the case of the election of directors) with respect to each of the foregoing proposals.

| Proposal | Votes in Favor | Votes Opposed | Abstentions (Withheld) |
|---|---|---|---|
| Proposal 1 | 16,787,238 | 137,698 | 12,125 |
| Proposal 2 | 16,703,993 | 144,218 | 89,350 |
| Proposal 3 | | | |
| Christopher B. Wood | 22,637,210 | | 3,770 |
| Thomas Scott Nelson | 22,637,210 | | 3,770 |
| Jeffrey B. Davis | 22,637,210 | | 3,770 |
| Steven A. Elms | 22,637,210 | | 3,770 |
| Andrew N. Schiff | 22,637,210 | | 3,770 |

Item 5. Other information

There is no other information to report that is material to the Company's financial condition not previously reported.

Item 6. Exhibits and Reports on Form 8-K

A) Exhibits

31.1 Certification of Christopher B. Wood, Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of David P. Luci, Director of Finance, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification of Christopher B. Wood , Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of David P. Luci, Director of Finance, pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.

(B) Reports on Form 8-K:

During the fiscal quarter ended March 31, 2004, the Company filed the following Current Report on Form 8-K:

1. Current Report on Form 8-K, dated March 22, 2004, as filed with the Commission on March 25, 2004, reporting under Item 9 "Regulation FD Disclosure" the Company's issuance of a press release regarding the closing of its private placement on March 22, 2004.



SIGNATURES

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

Date: May 17, 2004 By: /s/ Christopher B. Wood M.D.
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Christopher B. Wood M.D.
Chairman and Chief Executive Officer
Principal Executive Officer)

Date: May 17, 2004 By: /s/ David P. Luci
---
David P. Luci
Director of Finance and General Counsel
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit No.

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