BIOENVISION INC
Form 10QSB/A
April 02, 2004

FORM 10-QSB/A2

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 December 31, 2003
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 March 23, 2004, there were 22,934,616 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

| | December 31, 2003 (unaudited) |
|---|---|
| ASSETS | |
| Current assets | |
| Cash and cash equivalents | $6,969,539 |
| Restricted cash | 290,000 |
| Deferred costs | 1,758,499 |
| Accounts receivable | 25,000 |
| Other assets | 242,603 |
| Total current assets | 9,285,641 |
| Property and equipment, net | 41,593 |
| Intangible assets, net | 15,135,084 |
| Goodwill | 3,902,705 |
| Security deposits | 79,111 |
| Other long term assets | 32,728 |
| Deferred costs | 213,321 |
| Total assets | $28,690,183 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| Current liabilities | |
| Accounts payable | $150,892 |
| Accrued expenses | 1,012,870 |
| Accrued dividends payable | 1,421,413 |

| | |
|---|---|
| Deferred revenue | 3,585,181 |
| Total current liabilities | 6,170,356 |
| Deferred revenue-long term | 1,066,604 |
| Deferred tax liability | 6,049,125 |
| Total liabilities | 13,286,085 |
| Stockholders' equity | |
| Preferred stock - $0.001 par value; 5,920,000 shares authorized and 5,440,000 and 5,916,966 shares issued and outstanding at December 31, 2003 and June 30, 2003, respectively (liquidation preference $16,320,000) | 5,440 |
| Common stock - par value $0.001; 50,000,000 shares authorized and 19,091,535 and 17,122,739 shares issued and outstanding at December 31, 2003 and June 30, 2003, respectively | 19,092 |
| Additional paid-in capital | 48,664,049 |
| Accumulated deficit | (33,436,828) |
| Accumulated other comprehensive income | 152,346 |
| Stockholders' equity | 15,404,099 |
| Total liabilities and stockholders' equity | $28,690,183 |

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

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

| | Three months ended December 31, | | Six months December |
|---|---|---|---|
| | 2003 | 2002 | 2003 |
| | (unaudited) | (unaudited) | (unaudited) |
| Licensing and royalty revenue | $82,495 | $209,091 | $136,536 |
| Research and development contract revenue | - | - | 775,000 |
| Total revenue | 82,495 | 209,091 | 911,536 |
| Costs and expenses | | | |

| | | | | |
|---|---|---|---|---|
| Research and development | 746,921 | 322,481 | 1,550,821 | |
| Selling, general and administrative (includes stock based compensation income(expense) of $186,055 and $(325,000) for the three months ended December 31, 2003 and 2002, respectively, and $(1,098,592) and $(422,500) for the six months ended December 31, 2003 and 2002, respectively) | 919,342 | 548,231 | 3,357,430 | |
| Depreciation and amortization | 340,248 | 334,683 | 679,869 | |
| Total costs and expenses | 2,006,511 | 1,205,395 | 5,588,120 | |
| Loss from operations | (1,924,016) | (996,304) | (4,676,584) | ( |
| Interest income (expense) | | | | |
| Interest and finance charges | - | - | - | |
| Interest income | 15,852 | 40,768 | 34,889 | |
| Net loss before income tax benefit | (1,908,162) | (955,536) | (4,641,695) | ( |
| Income tax benefit | 134,351 | 152,100 | 268,577 | |
| Net loss | (1,773,811) | (803,436) | (4,373,118) | ( |
| Cumulative preferred stock dividend | (188,557) | (221,279) | (412,267) | |
| Net loss available to common stockholders | $(1,962,368) | $(1,024,715) | $(4,785,385) | $( |
| Basic and diluted net loss per share of common stock | $(0.11) | $(0.06) | $(0.27) | |
| Weighted average shares used in computing basic and diluted net loss per share | 18,439,234 | 16,887,786 | 17,850,814 | 1 |

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



Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

| | Six months ended December 31, | |
|---|---|---|
| | 2003 | 2002 |
| | (unaudited) | (unaudited) |
| Cash flows from operating activities | | |
| Net loss | $(4,373,118) | $(2,715,796) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 679,869 | 667,021 |
| Deferred tax benefit | (268,577) | (304,200) |
| Compensation costs - shares and warrants issued to nonemployees | 444,683 | 422,500 |
| Compensation costs - re-pricing of options | 653,908 | - |
| Changes in assets and liabilities | | |
| Deferred costs | (1,724,156) | 184,091 |
| Deferred revenue | 3,413,464 | (368,181) |
| Accounts payable | (260,500) | 58,218 |
| Other current assets | (136,627) | (56,767) |
| Other long term assets | 94,141 | (79,111) |
| Other accrued expenses and liabilities | 282,148 | (664,497) |
| Net cash used in operating activities | (1,194,765) | (2,856,722) |
| Cash flows from investing activities | | |
| Purchase of intangible assets | (27,882) | (67,787) |
| Capital expenditures | - | (48,860) |
| Restricted cash | - | (290,000) |
| Net cash used in investing activities | (27,882) | (406,647) |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock | 262,500 | - |
| Net decrease in cash and equivalents | (960,147) | (3,263,369) |
| Cash and equivalents, beginning of period | 7,929,686 | 12,882,521 |
| Cash and equivalents, end of period | $6,969,539 | $9,619,152 |
| Supplemental disclosure of cash flow information | | |
| Cash paid during the period for Interest paid | $ - | $ - |
| Supplemental disclosure of non cash investing and financing activities | | |

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

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

December 31, 2003

(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 breast cancer. The Company's plan is to bring Modrenal(R) into the United States to perform further clinical trials and to access the U.S. market. Most of the Company's other drugs are now in clinical trials in various stages of development.

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 December 31, 2003 and the consolidated results of operations for the three months and six months ended December 31, 2003 and 2002, and cash flows for the six months ended December 31, 2003 and 2002.

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 six months ended December 31, 2003 and 2002 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 December 31, 2003, 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, as all 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 six months ended December 31, 2003, the Company recognized stock based employee compensation income (expense) of $61,000 and $(654,000), 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.

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 December 31, | | |
|---|---|---|---|
| | 2003 | 2002 | |
| Net loss available to common stockholders, as reported | $(1,962,368) | $(1,024,714) | $ |
| Deduct: Total stock based employee compensation expense determined under fair value based method for all awards; net of related tax effects | $ (244,992) | $(793,594) | $ |
| Pro forma net loss | (2,207,360) | (1,818,308) | |
| Loss per share | | | |
| Basic and diluted - as reported | $ (0.11) | $ (0.06) | $ |
| Basic and diluted - pro forma | $ (0.12) | $ (0.11) | $ |

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

| | Three months ended December 31, | | Six months en December 3 |
|---|---|---|---|
| | 2003 | 2002 | 2003 |
| 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 14,269,543 and 6,234,544 shares of common stock have not been included in the calculation of net loss per share for the three months and six months ended December 31, 2003 and 2002, 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 $775,000 in respect of Research and Development costs incurred by the Company for European drug development through August 31, 2003.

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 concurrent with certain development activities described in the contract, through December 2002. The Company recognized revenues of approximately $490,000 and $800,000_in connection with the up-front payment of ILEX agreement for the years ended June 30, 2003 and 2002, respectively.

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.

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.

Modrenal(R)

The Company holds an exclusive license, until the expiration of existing and new patents related to modrenal, to market modrenal in major international territories, and an agreement with a United Kingdom company to co-develop modrenal for other therapeutic indications. Management believes that modrenal 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, 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 trilostane 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 February 2004.

Operational Developments

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. The related costs paid to SRI were also deferred and are being amortized over the same service period.

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 approximately $12,000 for the year ended June 30, 2003 in connection with this sublicense agreement with Dechra. As of June 30, 2003, deferred revenues include approximately $1,238,000 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, the Company 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. The Company paid and capitalized $175,000 related to development costs over an eighteen month period.

NOTE F - Equity Transactions

In June 2002, the Company granted options to David Luci 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 Mr. Luci, 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 six months ended December 31, 2003, the Company recognized stock based compensation income (expense) of $61,000 and $(654,000).

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.

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 six months ended December 31, 2003, certain holders of 476,666 shares of the Company's preferred stock converted such shares into 953,332 shares of the Company's common stock. In addition, during the three and six months ended December 31, 2003, certain holders of the Company's warrants converted an aggregate of 175,000 warrants into 175,000 shares of the Company's common stock. The Company received an aggregate $262,500, as payment for the

conversion price with respect to the foregoing conversions. During the three and six month periods ended December 31, 2003, certain holders of options to purchase an aggregate of 1,080,000 shares of the Company's common stock were exercised pursuant to the cashless exercise feature available to such option holders and the Company issued 790,464 shares of its common stock in accordance therewith.

NOTE G - Related Party Transactions

On November 16, 2001, we entered into an engagement letter with SCO Capital, pursuant to which SCO would act as our financial advisor. In connection with the engagement letter, we issued a warrant to purchase 100,000 shares of common stock at an exercise price of $1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The issuance of these shares was capitalized as deferred financing costs and was amortized over a twelve-month period.

In connection with securing a credit facility with SCO Capital, we issued warrants to purchase 1,500,000 shares of our common stock at an exercise price of $1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The credit facility with SCO Capital was terminated in May 2002 at which time the Company received a payoff letter evidencing such termination.

On February 5, 2002, we completed the acquisition of Pathagon Inc. Affiliates of SCO Capital owned 82% of Pathagon prior to the acquisition. In connection therewith, on February 1, 2002, we issued 7,000,000 shares of common stock to the former stockholders of Pathagon Inc.

NOTE H - New Accounting Pronouncements

In January 2003, the FASB issued interpretation No. 46, "Consolidation of Variable Interest Entities--An Interpretation of ARB No. 51" ("FIN 46"), which addresses consolidation of variable interest entities. FIN 46 expands the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disburse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and variable interest entities in which an enterprise obtains any interest after that date. It applies in the first fiscal year or interim period ending after December 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material impact on the results of operation or financial position of the Company.

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.

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 No. 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. The adoption of SFAS 150 is not expected to have a material impact on the results of operations or financial position of the Company.

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 alleges a breach of contract by the Company and demands 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. On November 12, 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. No assurance can be given that RLB will not appeal the court's decision, but management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations. The Company maintains its counter claim against RLB Capital, which it intends to pursue.

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. 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. Neither Tessman nor Tessman Technology has submitted an answer to the amended complaint to date, although Tessman and Tessman Technology have removed the action to the United States District Court for the Southern District of New York.

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 are an emerging biopharmaceutical company that develops and markets drugs to treat cancer. 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.

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. 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 reported revenues of $82,000 and $209,000 for the three month period ended December 31, 2003 and 2002, respectively. For the six months ended December 31, 2003 and 2002, the Company reported revenues of $137,000 and $418,000. Revenues reflect our agreement with our co-development partners and/or licenses in connection with our platform of drugs and technologies.

Research and development costs for the three months ended December 31, 2003 and 2002 were $747,000 and $322,000, respectively, an increase of $425,000. This increase is primarily attributable to increased royalty payments under certain development contracts. Research and development costs for the six months ended December 31, 2003 and 2002 were $1,551,000 and $842,000, respectively, an increase of $709,000. The increase reflects royalty payments under certain development contracts.

Selling, general and administrative expenses for the three months ended December 31, 2003 and 2002 were $919,000 and $548,000, respectively, an increase of $371,000. The increase is primarily attributable to the Company's increase in sales and marketing activity. Selling, general and administrative expenses (including stock based compensation of $1,099,000 and $423,000 for the six months ended December 31, 2003 and 2002 were $3,357,000 and $1,693,000, respectively, an increase





of $1,664,000. This increase is primarily attributable to the Company's increased sales and marketing activities since the May 2002 financing, the option re-pricing of 653,908, the Company's re-constituting its wholly-owned subsidiary, Bioenvision Limited, as a fully operational sales and marketing subsidiary, salaries of newly-added employees of approximately 65,000, rent at both Company's new principal executive offices in New York, New York and new rental facility for its sales and marketing subsidiary in Edinburgh, Scotland of approximately $20,000, travel expenses, insurance costs and other customary costs associated with our becoming an operating company.

Depreciation and amortization expense for the three month and six month period ended December 31, 2003 were $340,000 and $670,000 compared to the three month

and six month period ended December 31, 2002 of $335,000 and $667,000. The increase in amortization is related to the amortization of certain intangible assets acquired by the Company.

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 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 December 31, 2003, we have cash and cash equivalents of $6,969,539 and working capital of $3,115,285, 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.

The Company has the following commitments as of December 31, 2003:

| | | Payments Due in | | |
|---|---|---|---|---|
| | Total | 2004 | 2005 | 2006 |
| Employee Contracts | 199,800 | 199,800 | - | - |
| Occupancy Lease | 328,300 | 121,200 | 166,100 | 41,000 |
| Total | 528,100 | 321,000 | 166,100 | 41,000 |

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 3,299 square feet under a lease that expires on December 31, 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

On January 20, 2004, the Company appointed Dr. Michael Kauffman to the board of directors.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation of the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-QSB was made under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Accounting Officer. The Company's management, including its Chief Executive Officer and Chief Accounting Officer, does not expect that its disclosure controls and procedures will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with its policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Based upon the evaluation of disclosure controls and procedures, the Chief Executive Officer and Chief Accounting Officer of the Company have concluded that, subject to the limitations noted above, the Company's disclosure controls and procedures were effective to ensure that material information relating to the Company and the Company's consolidated subsidiaries would be made known to them by others within those entities to allow timely decisions regarding required disclosures.

Changes in Internal Controls

There was no significant change in our "internal control over financial

reporting" (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 alleges a breach of contract by the Company and demands 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. On November 12, 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. No assurance can be given that RLB will not appeal the court's decision, but management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations. The Company maintains its counter claim against RLB Capital, which it intends to pursue.



On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. 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. Neither Tessman nor Tessman Technology has submitted an answer to the amended complaint to date, although Tessman and Tessman Technology have removed the action to the United States District Court for the Southern District of New York.

Item 2. Changes in Securities

None

Item 3. Defaults upon Senior Securities

None

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

No matter has been submitted to a vote of security holders during the period covered by this report.

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

3.1 Certificate of Amendment of Certificate of Incorporation, filed January 14, 2004.

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: None.



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: April 1, 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: April 1, 2004 By: /s/ David P. Luci
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David P. Luci
Director of Finance and General Counsel
(Principal Financial and Accounting Officer)

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