BIOENVISION INC
Form 10QSB
November 15, 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 September 30, 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.

345 Park Avenue, 41st Floor, New York, NY 10154
(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 November 12, 2004, there were 28,797,169 shares of the issuer's common stock, par value $.001 per share (the "Common Stock") outstanding.

Transitional 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

	September 30, 2004
ASSETS	(unaudited)
Current assets	
Cash and cash equivalents	$17,662,989
Restricted cash	290,000
Deferred costs	241,824
Accounts receivable	860,284
Other assets	393,769
Total current assets	19,448,866
Property and equipment, net	44,881
Intangible assets, net	14,271,299
Goodwill	3,902,705
Security deposits	79,111
Deferred costs-long term	3,591,015
Total assets	$41,337,877
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities	
Accounts payable	$1,541,214
Accrued expenses	869,572
Accrued dividends payable	90,341
Deferred revenue	551,828
Total current liabilities	3,052,955
Deferred revenue-long term	7,771,640
Deferred tax liability-non-current	5,646,573
Total liabilities	16,471,168

Stockholders' equity	
Preferred stock - $0.001 par value; 20,000,000 shares authorized; 3,341,666 shares issued and outstanding at September 30, 2004 and June 30, 2004 (liquidation preference $10,024,998)	3,342
Common stock - par value $0.001; 70,000,000 shares authorized; 28,597,172 and 28,316,163 shares issued and outstanding at September 30, 2004 and June 30, 2004, respectively.	28,597
Additional paid-in capital	69,066,456
Deferred compensation	(201,927)
Accumulated deficit	(44,169,063)
Accumulated other comprehensive income	139,304
Stockholders' equity	24,866,709
Total liabilities and stockholders' equity	$41,337,877

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

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months end September 30,
	2004
	(unaudited)
Licensing and royalty revenue	$363,182
Research and development contract revenue	722,146
Total revenue	1,085,328
Costs and expenses	
Research and development	2,138,897
Selling, general and administrative (includes stock based compensation expense of $391,098 and $1,284,646 for the three months ended September 30, 2004 and 2003, respectively)	1,756,713
Depreciation and amortization	339,706
Total costs and expenses	4,235,316

Loss from operations	(3,149,988)	
Interest income (expense)		
Interest income	55,437	
Net loss before income tax benefit	(3,094,551)	
Income tax benefit	134,226	
Net loss	(2,960,325)	
Cumulative preferred stock dividend	(126,341)	
Net loss available to common stockholders	$(3,086,666)	$
Basic and diluted net loss per share of common stock	$(0.11)	
Weighted average shares used in computing basic and diluted net loss per share	28,516,450	

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

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Three mo Septe
	2004
	(unaudited)
Cash flows from operating activities	
Net loss	$(2,960,325)
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	339,706
Deferred tax benefit	(134,226)
Shares and warrants issued to non-employees	566,943
Compensation costs - re-pricing of options	(197,908)
Compensation costs-options issued to employees	22,063
Changes in assets and liabilities	

Deferred costs	60,456
Deferred revenue	(137,958)
Accounts payable	45,349
Other current assets	(140,459)
Other long term assets	-
Accounts receivable	1,767,489
Other accrued expenses and liabilities	(453,012)
Net cash used in operating activities	(1,221,882)
Cash flows from investing activities	
Purchase of intangible assets	(42,115)
Capital expenditures	(2,254)
Net cash used in investing activities	(44,368)
Cash flows from financing activities	
Proceeds from issuance of common stock	-
Proceeds from exercise of options, warrants and other convertible securities	180,000
Cash dividends paid	(126,141)
Net cash provided by financing activities	53,859
Effect of exchange rate on cash	(294)
Net decrease in cash and cash equivalents	(1,212,685)
Cash and cash equivalents, beginning of period	18,875,675
Cash and cash equivalents, end of period	$17,662,989
Supplemental cash flow information	
Income taxes	$32,975

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

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

September 30, 2004

(Unaudited)

NOTE A - Description of Business

Bioenvision, Inc. (the "Company") is an emerging biopharmaceutical company that

develops and markets drugs to treat cancer. The Company's two lead drugs are clofarabine and Modrenal(R), although the Company has several other products and technologies under development. As of November 8, 2004, the Company employs eleven full-time and four part-time employees based in New York, New York and Edinburgh, Scotland.

The Company's primary business strategy relates to its two lead drugs, clofarabine and Modrenal(R). With clofarabine, the Company's strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory authorities to market and distribute clofarabine in Europe for the treatment of pediatric and adult acute leukemias (ALL and AML). The Company anticipates launching clofarabine in Europe in mid-2005, subject to its obtaining from the European regulatory authorities the first approval for clofarabine which is expected to be for pediatric ALL and AML. The Company will continue clinical trials in other indications with the intention of aggressively seeking label extensions after clofarabine's first approval, including its Pivotal Phase II trial of clofarabine in adults with Acute Myeloid Leukemia (AML) which commenced in August 2004 and is ongoing. Following this strategy, throughout the world, approximately two-thirds of the cancer patients dosed with clofarabine to date fall outside of the pediatric acute leukemias.

Clofarabine is a small molecule and a purine nucleoside analogue, which the Company believes is effective in the treatment of leukemias, based upon its own clinical studies and studies conducted by others on the Company's behalf. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I clinical trials performed to date.

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. The Company launched Modrenal(R) in May 2003 in the United Kingdom, where it received regulatory approval for its use in the treatment of post-menopausal breast cancer. In the second quarter of calendar year 2005, the Company intends to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such territory. The Company anticipates receiving approval in each such territory during calendar 2005, but such approval is subject to the appropriate regulatory decisions.

With Modrenal(R), the Company's strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to market and distribute Modrenal(R) in the major European markets. The Company anticipates receiving mutual recognition from major European Community member states by Q3 of calendar 2005. The Company intends to further U.S. development of Modrenal(R) in prostate and breast cancer indications, subject to the ongoing results of its clinical trials it is currently conducting in the U.S. and Europe.

The Company's secondary business strategy is to continue to develop its portfolio of ancillary products and technologies. The Company anticipates that revenues derived from clofarabine and Modrenal(R) and milestone payments and royalties from the ancillary products will permit it to further develop its portfolio of ancillary products and technologies.

NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments necessary to present fairly the consolidated financial position of the Company as of September 30, 2004 and the consolidated results of operations and cash flows for the three months ended September 30, 2004 and 2003.

The condensed consolidated balance sheet at June 30, 2004 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, 2004.

The condensed consolidated results of operations for the three months ended September 30, 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 September 30, 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, 2004. 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 ended September 30, 2004, the Company recognized stock based employee compensation income of $197,908, 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 the three months ended September 30, 2004, the Company recorded compensation expense of $22,063, as a result of options granted to certain employees.

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 September 30	
	2004	2003
Net loss available to common stockholders, as reported	$(3,086,666)	$(2,823,015)

Add: Stock based employee compensation recognized under fair value based method for all awards	(175,845)	714,883
Deduct: Total stock based employee compensation recognized under fair value based method for all awards; net of related tax effects	(243,317)	(986,100)
Pro forma net loss	$(3,505,828)	$(3,094,232)
Loss per share		
Basic and diluted - as reported	$ (0.11)	$ (0.16)
Basic and diluted - pro forma	$ (0.12)	$ (0.22)

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

	Three months ended September 30	
	2004	2003
Expected life (years)	4	4
Risk free interest rate	3.35%	3.00%
Expected volatility	80.00%	80.00%
Expected dividend yield	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 12,983,535 and 15,574,543 shares of common stock have not been included in the calculation of net loss per share for the three months ended September 30, 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, lymphoma and certain solid tumor cancers. The lead compound of these purine-based nucleosides is known as clofarabine. Under the terms of the agreement with SRI, the Company was granted the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by the Company and by SRI from the technology. Initially, the Company is developing clofarabine for the treatment of leukemia and lymphoma and studying its potential role in treatment of 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 for the development of clofarabine in cancer indications. Under the terms of the co-development agreement, ILEX is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia), in each case, for the development of clofarabine in cancer indications. ILEX is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada in cancer indications. The Company retains the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia) and retains the right to handle these matters in the U.S. and Canada in all non-cancer indications. The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. Under the co-development agreement, ILEX will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay ILEX a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. In turn, ILEX, which would have U.S. and Canadian distribution rights in cancer indications, would pay the Company a royalty on sales in the U.S. and Canada. In addition, the Company received $7.5 million in milestone payments from ILEX throughout the U.S. drug development program. Under the terms of the co-development agreement, ILEX also pays royalties to Southern Research Institute based on certain milestones. The Company also is obligated to pay certain milestones and royalties to Southern Research Institute with respect to clofarabine.

The Company received a nonrefundable upfront payment of $1.35 million when it entered into the co-development agreement with ILEX and received an additional $3.5 million in December 2003 when it converted ILEX's option to market clofarabine in the U.S. into a sublicense. The Company received an additional (i) $2 million in April 2004 upon ILEX's filing the New Drug Application for clofarabine with FDA and (ii) $2 million from ILEX in September 2004 in connection with the achievement of the NDA filing. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related service period, through March 2021. For the three months ended September 30, 2004 and 2003, the Company recognized revenues of approximately $110,000, and $0, respectively, in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with ILEX. The Company 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 research and development costs including approximately $55,000 and $0 for the three months ended September 30, 2004 and 2003, respectively, related to such charges.

Modrenal(R)

The Company holds an exclusive license, until the expiration of existing and new patents related to Modrenal(R), to market Modrenal(R) 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.

The Company received a nonrefundable upfront payment of $1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, through May 2014. The Company recognized revenues of approximately $28,000 and $29,000 in connection with the upfront payment from Dechra for the three months ended September 30, 2004 and 2003, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made to Stegram and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with the Dechra agreement. Research and Development costs include approximately $5,700 and $5,800 for the three months ended September 30, 2004 and 2003, respectively.

Anti-Estrogen Prostate. We received Institutional Review Board approval from the Dana Faber Cancer Institute for a Phase II study of trilostane for the treatment of androgen independent prostate cancer. The study is being conducted by The Dana Faber Cancer Institute and commenced in July 2004.

Operational Developments

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.

In May 2003, we entered into a sub-license agreement with Dechra, pursuant to which Dechra has been granted a sub-license for all of Bioenvision's rights and

entitlements to market and distribute Modrenal(R) 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(R) or the completion of the last royalty set forth in the agreement. Through September 30, 2004, we have recognized revenue and costs related to this agreement of approximately $155,000 and $31,000 respectively. 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.

In May 2003, we 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 our behalf and at our 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 month 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(R). 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(R) throughout Europe. Through September 30, 2004, the Company paid an advance of $175,000 related to development services provided by CLL over an eighteen month period, which advance was initially 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 ended September 30, 2004 and 2003, the Company recognized stock based income (expense) of approximately $198,000 and $(715,000), respectively, due the re-pricing of said options.

The Company recorded compensation expense of $22,063 for the three months ended September 30, 2004 as a result of 505,000 options issued to certain employees on January 20, 2004.

On January 20, 2004, the Company granted 25,000 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. The Company recognized $11,805 as a consulting expense for the three months ended September 30, 2004 relating to said options.

On June 22, 2004, the Company entered into a consulting agreement pursuant to which the consultant will provide certain investor relations services on behalf of the Company. In connection therewith, the Company issued a warrant to said consultant pursuant to which he has the right to purchase 50,000 shares of the Company's common stock at a price of $8.25 per share upon the completion of certain milestones, as set forth in such agreement. The Company recorded $218,430 as consulting expense for the three months ended September 30, 2004 relating to said warrants.

On August 4, 2004, the Company issued a warrant to a consultant pursuant to which said consultant has the right to purchase 40,000 shares of the Company's common stock at a price of $7.22 per share upon satisfaction of certain milestones included in the warrant. The Company recorded $155,396 as consulting expense for the three months ended September 30, 2004 relating to said warrants.

On August 9, 2004, the Company issued two warrants to a consultant pursuant to which said consultant has the right to purchase 45,000 shares of the Company's common stock at a price of $6.10 per share. The Company recorded $181,313 as consulting expense for the three months ended September 30, 2004 relating to said warrants.

During the three months ended September 30, 2004, certain warrant holders of the Company exercised their warrants to acquire 214,277shares of the Company's common stock. The Company received proceeds of approximately $117,500 during the three months ended September 30, 2004 from the exercise of warrants.

During the three month period ended September 30, 2004, certain holders of options to purchase an aggregate of 66,732 shares of the Company's common stock were exercised. The Company received proceeds of $62,500 during the three months ended September 30, 2004 from the exercise of options.

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. 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.

NOTE H - New Accounting Pronouncements

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. On November 12, 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.

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. Our two lead drugs are clofarabine and Modrenal(R), although we have several other products and technologies under development. As of November 8, 2004, we employ eleven full-time and four part-time employees based in New York, New York and Edinburgh, Scotland.

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 in Europe for the treatment of pediatric and adult acute leukemias (ALL and AML). We anticipate launching clofarabine in Europe in mid-2005, subject to our obtaining from the European regulatory authorities the first approval for clofarabine which is expected to be for pediatric ALL and AML. We will continue clinical trials in other indications with the intention of aggressively seeking label extensions after clofarabine's first approval, including our Pivotal Phase II trial of clofarabine in adults with Acute Myeloid Leukemia (AML) which commenced in August 2004 and is ongoing. Following this strategy, throughout the world, approximately two-thirds of the cancer patients dosed with clofarabine to date fall outside of the pediatric acute leukemias.

With Modrenal(R), our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to market and distribute Modrenal(R) in the major European markets. We anticipate receiving mutual recognition from major European Community member states by Q3 of calendar 2005. We intend to further U.S. development of Modrenal(R) in prostate and breast cancer indications, subject to the ongoing results of our clinical trials we are currently conducting in the U.S. and Europe.

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) and milestone payments and royalties from the ancillary products will permit us to further develop our portfolio of ancillary products and technologies.

Over the next 12 months, we intend to continue our internal growth strategy to provide the necessary regulatory, sales and marketing capabilities which will be required to pursue the expanded development programs for clofarabine and Modrenal(R) described above.

Clofarabine is a small molecule and a purine nucleoside analogue, which we believe is effective in the treatment of leukemias, based upon our own clinical studies and studies conducted by others on our behalf. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I clinical trials performed to date.

In July 2004, we filed for approval of clofarabine in Europe to treat children with pediatric acute leukemia (ALL and AML). Further, we are conducting a Pivotal Phase II clinical trial of clofarabine, as first line therapy for the treatment of adults with

Acute Myeloid Leukemia (AML). Also in Europe, at our direction, an Investigator Sponsored Trial of clofarabine as first-line therapy for adults with AML was completed ahead of schedule and an interim analysis indicates a 64% complete

response rate observed in this patient population.

In the U.S., ILEX Oncology, Inc., our sub-licensor of U.S. and Canadian cancer marketing rights, filed a New Drug Application ("NDA") in March 2004 for approval of clofarabine to treat children with acute leukemias (ALL or AML). The NDA was based upon results of two Pivotal Phase II clinical trials completed by ILEX prior to the NDA filing. In connection with the NDA, the United States Food and Drug Administration (the "FDA") has set a Prescription Drug User Fee Act ("PDUFA") response date at December 30, 2004. A PDUFA date is the is the date by which the FDA is expected to review and act upon an NDA submission. Clofarabine will be reviewed by the FDA Oncologic Drug Advisory Committee ("ODAC") on December 1, 2004.

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, upon grant of marketing authorization. The drug has also been granted orphan drug status and "fast track" treatment by the FDA. Further, in July 2004, the FDA granted six months of extended market exclusivity to clofarabine under the Best Pharmaceuticals for Children Act.

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 for cancer indications 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 second quarter of calendar 2005, 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 during calendar 2005, but such approval is subject to the appropriate regulatory decisions.

In the U.S., we filed an IND to conduct Modrenal(R) clinical trials for prostate cancer in February 2004 and commenced enrolling patients in this clinical trial in July 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.

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. Our management believes that we have the opportunity to become a leading oncology-focused pharmaceutical company in the next four years if we successfully bring clofarabine to market and if mutual recognition is granted for Modrenal(R) in the largest European commercial markets.

We anticipate that revenues derived from our two lead drugs, clofarabine and Modrenal(R) will permit us to further develop the other products currently in our product pipeline. We anticipate the launch of clofarabine in Europe by mid-2005 and further anticipate reaching profitability within 12 months following the marketing launch for clofarabine in Europe.

We commenced marketing one of our lead products, Modrenal(R), in June 2003 and have commenced building out our internal infrastructure of sales and marketing professionals to sell Modrenal(R) and to conduct pre-marketing activities for clofarabine in Europe. Management believes it can create synergies through internal growth by developing a sales and marketing presence which will be in position to sell both lead drugs at lead European cancer centers across a broad range of cancer indications.

Further, 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. 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 U.S., 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 vivo 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 anti-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 License and Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which we sub-licensed the marketing and development rights to vetoryl(R) trilostane, solely with respect to animal health applications, in the United States and Canada, to Dechra. 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 and capitalize on 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 were 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 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(R), 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 September 30, 2004 and 2003 of approximately $1,085,000 and $830,000, respectively, representing an increase of $255,000. Of the revenues recorded for the three months ended September 30, 2004, approximately $830,000 was recognized from ILEX, pursuant to the Co-Development Agreement, and approximately $189,000 was recognized from Stegram Pharmaceuticals under the Stegram Co-Development Agreement.

Research and development costs for the three months ended September 30, 2004 and 2003 were approximately $2,139,000 and $804,000, respectively, representing an increase of $1,335,000.

Our research and development costs include costs associated with six projects, four of which, the Company devotes significant time and resource. Clofarabine research and development costs for the three months ended September 30, 2004 and 2003 were approximately $1,880,000 and $436,000, respectively, representing an increase of approximately $1,444,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials being conducted in Europe and costs associated with our filing a Common

Technical Document with EMEA for approval of clofarabine for the treatment of pediatric acute leukemias, which filing occurred in July 2004.

Modrenal(R) research and development costs for the three months ended September 30, 2004 and 2003 were approximately $250,000 and $283,000, respectively, representing a decrease of $33,000. The decrease primarily reflects our increased focus on clofarabine during this period, including the filing for approval of clofarabine in Europe which occurred in July 2004.

Gossypol research and development costs for the three months ended September 30, 2004 and 2003 were approximately $8,000 and $64,000, respectively, representing a decrease of $56,000. The decrease primarily reflects our increased focus on clofarabine during this period, including the filing for approval of clofarabine in Europe which occurred in July 2004.

The clinical trials and development strategy for the clofarabine and Modrenal(R) 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. Total costs to date for four of our projects is as follows: (i) clofarabine research and development costs have been approximately $7,500,000; (ii) Modrenal(R) research and development costs have been approximately $4,600,000; (iii) Gossypol research and development costs have been approximately $308,000; and (iv) Gene Therapy research and development costs have been approximately $450,000. 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(R), over the next two years.

Selling, general and administrative expenses for the three months ended September 30, 2004 and 2003 were approximately $1,756,000 and $2,438,000, respectively, representing a decrease of $681,000. The decrease primarily relates to stock based compensation recorded during the period resulting from the repricing of the options issued to an officer of the Company.

Depreciation and amortization expense for the three months ended September 30, 2004 and 2003 were $340,000 and $340,000, respectively.

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.

The Company received a nonrefundable upfront payment of $1.35 million when it entered into the co-development agreement with ILEX and received an additional $3.5 million in December 2003 when it converted ILEX's option to market clofarabine in the U.S. into a sublicense. The Company received an additional (i) $2 million in April 2004 upon ILEX's filing the New Drug Application for clofarabine with FDA and (ii) $2 million from ILEX in September 2004 in connection with ILEX having completed such NDA filing. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related royalty period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related service period, through March 2021. For the three months ended September 30, 2004, the Company recognized revenues of approximately $111,000 in connection with the milestone payments received to date.

Deferred costs included royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with ILEX. The Company 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 the ILEX agreement. Research and Development costs include approximately $55,000 for the three months ended September 30, 2004 related to such charges.

The Company received a nonrefundable upfront payment of $1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related royalty period, through May 2014. The Company recognized revenues of approximately $28,000 and $29,000 in connection with the upfront payment from Dechra for the three months ended September 30, 2004 and 2003, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made to Stegram and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with the Dechra agreement. Research and Development costs include approximately $5,700 and $5,800 for the three months ended September 30, 2004 and 2003, respectively.

On May 7, 2002 we authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock may be converted into shares of common stock at an initial conversion price of $1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A Convertible Preferred Stock also received, in respect of each share of Series A Convertible Preferred Stock purchased in a private placement which took place in May 2002, one warrant to purchase one share of our common stock at an initial exercise price of $2.00 subject to adjustment.

Through May 16, 2002 we have sold an aggregate of 5,916,666 shares of Series A Convertible Preferred Stock in the May 2002 private placement for $3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock, resulting in aggregate gross proceeds of approximately $17,750,000. A portion of the proceeds were used to repay in full the Jano Holdings and SCO Capital obligations upon which such facilities were terminated as well as to repay fees amounting to $1,610,000 related to the transaction.

On March 22, 2004, we 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. We recorded proceeds of $11,792,801 net of all legal, professional and financing fees incurred in connection with the offering. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations to our holders of Series A Convertible Preferred Stock which hold preemptive rights for equity offerings. We raised an additional $3.2 million (net of all legal, professional and financial services incurred) 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.

On September 30, 2004, we have cash and cash equivalents of approximately $17,663,000 and working capital of $16,396,000 which management believes will be

sufficient to continue currently planned operations over the next 12 months. We can not ensure additional funds will not be raised during the next twelve months because of the significant scale up of our operating activities, including clofarabine development, the potential launch of clofarabine, and the launch of Modrenal(R). However, if required or desirable, there can be no assurance that suitable debt or equity financing will be available for the Company. Further, although we do not currently plan to acquire or obtain licenses for new technologies, 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.

We anticipate that we may continue to incur significant operating losses for the foreseeable future. There can be no assurance as to whether or where we will generate material revenues or achieve profitable operations.

The Company has the following commitments as of September 30, 2004:

	Payments Due in				
	Total	2005	2006	2007	Thereafter
Employee Contracts	824,539	662,039	162,500	-	
Occupancy Lease and Automobiles	1,547,435	259,105	332,043	323,855	632,43
Total	2,371,974	921,144	494,543	323,855	632,43

The Company leased 3,229 square feet under a lease that expires on September 30, 2005. This lease was terminated on October 31, 2004.

Subsequent Events

On October 25, 2004, the Company filed a $90 million shelf registration statement with the Securities and Exchange Commission. The Company announced that, if consummated, the proceeds from the offering would be used for the marketing launch of clofarabine in Europe and expanding the Company's existing sales and marketing infrastructure to accommodate European sales of both clofarabine and Modrenal(R).

On October 20, 2004, the Company appointed Dr. Achim Mueller to serve as European Marketing Manager and appointed Mr. Robert Bradbury to serve as U.K. Sales Manager. Further, in November 2004, the Company commenced development of its sales infrastructure by appointing four U.K. sales representatives. The Company intends to hire additional sales representatives in the U.K. and in other European countries over the course of the next 12 months.

In October, 2004, the Company executed a Sublease Agreement pursuant to which we sublease 5,549 square feet of commercial space at 345 Park Avenue, 41st Floor, New York, NY 10154, which is the new location of the Company's principal executive offices. Subject to the terms and conditions of the Sublease Agreement, the lease expires on December 31, 2009.

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 a material weakness 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 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. Our accountant works directly for our outsourced accounting firm which assists us in the preparation and finalization of our accounts on an ongoing basis. Her 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 this 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 June 2004, we hired a new employee to serve as our Vice President, Corporate Compliance and Associate General Counsel. This new employee has five years of corporate law experience with a full-service internationally based law firm in

the office located in New York, New York. She has represented several public companies and is knowledgeable with respect to contract law, the requirements under the Sarbanes-Oxley Act and other areas of public disclosure. We intend to continue to streamline the responsibilities of our Chief Financial Officer and General Counsel to permit him to focus more of his time and effort, as needed, on the accounting and financial reporting needs of the Company.

Further, in July 2004, the Company adopted, and management implemented, a comprehensive set if internal accounting controls, which were approved by the audit committee.

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.

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.

Item 2. Changes in securities and Use of Proceeds

None

Item 3. Defaults upon Senior Securities

None

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

None

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, Chief Financial Officer, 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, Chief Financial Officer, 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: November 15, 2004 By: /s/ Christopher B. Wood M.D.

Christopher B. Wood M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2004 By: /s/ David P. Luci

David P. Luci
Chief Financial Officer and General Counsel
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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