BIOENVISION INC
Form 10QSB
February 14, 2005

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 December 31, 2004
Commission File # 0-24875

BIOENVISION, INC.
(Exact name of small business issuer as specified in its charter)

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

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 February 11, 2005, there were 40,432,173 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

ASSETS	December 31, 2004 (unaudited)	June 30, 2004 (audited
Current assets		
Cash and cash equivalents	$17,476,072	$18,875,6
Restricted cash	290,000	290,0
Deferred costs	241,824	241,8
Accounts receivable	1,285,983	2,627,7
Inventory-finished goods	62,890	
Other current assets	503,346	253,3
Total current assets	19,860,115	22,288,5
Property and equipment, net	71,308	47,8
Intangible assets, net	13,987,547	14,563,6
Goodwill	3,902,705	3,902,7
Security deposits	211,796	79,1
Deferred costs-long term	3,530,559	3,651,4
Total assets	$41,564,030	$44,533,3
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$414,449	$1,495,8
Accrued expenses	2,028,924	1,322,5
Accrued dividends payable	75,058	90,1
Deferred revenue	551,828	551,8
Total current liabilities	3,070,259	3,460,4

Deferred revenue-long term	7,633,682	7,909,5
Deferred tax liability-non-current	5,505,486	5,780,7
Total liabilities	16,209,427	17,150,8
Stockholders' equity		
Preferred stock - $0.001 par value; 20,000,000 shares authorized; 2,250,000 and 3,341,666 shares issued and outstanding at December 31, 2004 and June 30, 2004 (liquidation preference $6,750,000 and $10,024,998, respectively)	2,250	3,3
Common stock - par value $0.001; 70,000,000 shares authorized; 32,490,791 and 28,316,163 shares issued and outstanding at December 31, 2004 and June 30, 2004, respectively	32,491	28,3
Additional paid-in capital	73,494,899	68,517,7
Deferred compensation	(179,865)	(223,9
Accumulated deficit	(48,143,183)	(41,082,3
Accumulated other comprehensive income	148,011	139,5
Stockholders' equity	25,354,603	27,382,5
Total liabilities and stockholders' equity	$41,564,030	$44,533,3

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 e December 3	
	2004	2003	2004	
	(unaudited)	(unaudited)	(unaudited)	(
Licensing and royalty revenue	$340,254	$82,495	$703,436	
Products sales	215,131	-	215,131	
Research and development contract revenue	620,538		1,342,684	
Total revenue	1,175,923	82,495	2,261,251	
Costs and expenses				
Cost of products sold	130,356	-	130,356	
Research and development	1,710,750	746,921	3,849,647	
Selling, general and administrative	3,054,239	919,342	4,810,952	

(includes stock based compensation expense(income) of $1,009,308 and $(186,054) for the three months ended December 31, 2004 and 2003, respectively, and $1,400,406 and $1,098,591 for the six months ended December 31, 2004 and 2003, respectively)				
Depreciation and amortization	341,987	340,248	681,693	
Total costs and expenses	5,237,332	2,006,511	9,472,648	
Loss from operations	(4,061,409)	(1,924,016)	(7,211,397)	(
Interest income (expense)				
Interest income	56,578	15,852	112,014	
Net loss before income tax benefit	(4,004,831)	(1,908,162)	(7,099,383)	(
Income tax benefit	141,087	134,351	275,313	
Net loss	(3,863,744)	(1,773,811)	(6,824,070)	(
Cumulative preferred stock dividend	(110,375)	(188,557)	(236,716)	
Net loss available to common stockholders	$(3,974,119)	$(1,962,368)	$(7,060,786)	$(
Basic and diluted net loss per share of common stock	$(0.13)	$(0.11)	$(0.24)	
Weighted average shares used in computing basic and diluted net loss per share	29,728,769	18,439,234	29,122,609	1

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

Bioenvision, Inc. and Subsidiaries
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

			Additional	Deferred	
	Preferred Stock	Common Stock	Paid In	Compen-	A

	Shares	$	Shares	$	Capital	sation
Balance at June 30, 2003	5,916,966	$5,917	17,122,739	$17,123	$47,304,449	$ -
Net loss for the period						
Cumulative preferred stock dividend for the period						
Currency translation adjustment						
Deferred compensation						(223,990)
Shares issued in connection with private placement			2,602,898	2,603	16,265,495	
Costs related to March private placement financing					(1,301,035)	
Preferred stock converted to common stock	(2,575,300)	(2,575)	5,150,000	5,150	(2,575)	
Expense related to repricing of options					2,381,066	
Cashless exercise of options to shares			2,122,682	2,122	(2,122)	
Warrants issued in connection with services				-	671,601	
Shares issued to consultants for services			14,510	15	305,972	
Shares issued to employees			20,000	20	28,380	
Options issued in connection with services					93,987	
Options issued to employees					262,601	
Shares issued from warrant conversions			1,283,334	1,283	2,509,882	
Balance at June 30, 2004	3,341,666	3,342	28,316,163	28,316	68,517,702	(223,990)
Net loss for the period						
Cumulative preferred stock dividend for the period						
Currency translation adjustment						
Deferred compensation						44,125
Warrants issued in connection						

with services					617,054	
Options issued to consultants					23,610	
Preferred stock converted to common stock	(1,091,666)	(1,092)	2,183,332	2,183	(1,092)	
Shares issued from warrant conversions			1,577,969	1,578	3,253,671	
Cash exercise of options to shares			308,946	309	368,441	
Cashless exercise of options to shares			41,881	42	(42)	
Shares issued in connection with services			62,500	63	496,188	
Expenses related to repricing of options					219,367	
Balance at December 31, 2004	2,250,000	$2,250	32,490,791	$32,491	$73,494,899	$(179,865)

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,	
	2004	2003
	(unaudited)	(unaudited)
Cash flows from operating activities		
Net loss	$(6,824,070)	$(4,373,118
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	681,693	679,869
Deferred tax benefit	(275,313)	(268,577
Shares and warrants issued to non-employees	1,136,914	444,683
Stock based compensation expense	263,492	653,908
Changes in assets and liabilities		
Deferred costs	120,912	(1,724,156
Deferred revenue	(275,916)	3,413,464
Accounts payable	(1,081,417)	(260,500
Inventory-finished goods	(62,890)	

Other current assets	(250,035)	(136,627
Other assets	(132,685)	94,141
Accounts receivable	1,341,790	-
Accrued expenses	706,339	282,148
Net cash used in operating activities	(4,651,186)	(1,194,765
Cash flows from investing activities		
Purchase of intangible assets	(93,992)	(27,882
Capital expenditures	(35,039)	-
Net cash used in investing activities	(129,031)	(27,882
Cash flows from financing activities		
Proceeds from issuance of common stock	-	262,500
Proceeds from exercise of options, warrants and other convertible securities	3,624,000	-
Dividends paid	(251,799)	-
Net cash provided by financing activities	3,372,201	262,500
Effect of exchange rate on cash	8,413	-
Net decrease in cash and cash equivalents	(1,399,603)	(960,147
Cash and cash equivalents, beginning of period	18,875,675	7,929,686
Cash and cash equivalents, end of period	$17,476,072	$6,969,539
Supplemental cash flow information		
Cash paid during the period for income taxes	$32,975	$24,891

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

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

December 31, 2004

(Unaudited)

NOTE A - Description of Business and Significant Accounting Policies

Description of Business

Bioenvision, Inc. is a product-focused biopharmaceutical company with two

approved cancer therapeutics. The FDA recently approved its lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL in patients who have received two or more prior regimens. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, the Company's co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for all cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is selling clofarabine under the brand name Clolar in the U.S. In Europe, the Company has filed for approval of clofarabine in pediatric ALL and acute myelogenous leukemia, or AML, with the European Medicines Evaluation Agency, or EMEA.

The Company is currently selling its second product, Modrenal, in the United Kingdom. Modrenal is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and the Company has initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

In addition to clofarabine and Modrenal, the Company is developing Velostan, initially for the treatment of bladder cancer and Virostat for the treatment of Hepatitis C.

Significant Accounting Policies

In addition to the accounting policies reported in Note 1 to the consolidated financial statements -- "Organization and significant accounting policies" in the Company's annual report on Form 10-KSB for the year ended June 30, 2004, we deem the following recent accounting policies important in understanding our operating results and financial condition.

Revenue Recognition

The Company currently sells its products to wholesale distributors and directly to hospitals, clinics, and retail pharmacies. Revenue from product sales is recognized when the product is shipped from our distributor to the customer, the sales price is fixed and determinable, and collectibility is reasonably assured.

We follow the guidance of EITF 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent" in the presentation of revenues and direct costs of revenues. This guidance requires us to assess whether we act as a principal in the transaction or as an agent acting on behalf of others. We record revenue transactions gross in our statements of operations if we are deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

Credit Risk

Our accounts receivable are primarily due from wholesale distributors and our co-development partners. Based on our evaluation of the collectibility of these accounts receivable, we believe the exposure to credit risk is minimal and, as such, we feel that no allowance for doubtful accounts is necessary at December 31, 2004.

Inventory

Inventories consist of finished goods and are stated at the lower of cost or market. The Company periodically reviews inventories and estimates reserves for excess based on inventory levels on hand.

Accounting for Stock-Based Compensation

At December 31, 2004, the Company has stock based compensation plans which are

described more fully in the Company's annual report on Form 10-KSB for the year ended June 30, 2004. As permitted by SFAS No. 123,

"Accounting for Stock Based Compensation," and amended by SFAS 148, 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.

The following table summarizes the pro forma effect of stock-based compensation as if the fair value method of accounting for stock options had been applied in measuring compensation cost. No tax benefits were attributed to the stock-based employee compensation expense during the three and six months ended December 31, 2004 and 2003 because we maintained a valuation allowance on substantially all of our net deferred tax assets.

	Three months ended December 31,		S
	2004	2003	2004
Net loss available to common stockholders, as reported	$(3,974,119)	$(1,962,368)	$(7,060
Add: Stock-based employee compensation expense (income) included in reported net loss	439,337	(60,975)	263
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(307,774)	(108,421)	(591
Pro forma net loss	$(3,842,556)	$(2,131,764)	$(7,388
Loss per share			
Basic and diluted - as reported	$ (0.13)	$ (0.11)	$ (0.24
Basic and diluted - pro forma	$ (0.13)	$ (0.12)	$ (0.25

The weighted-average assumptions used for the three and six months ended December 31, 2004, and 2003 were: risk-free interest rate of 3.14% and 2.63%, respectively; expected dividend yield of 0.0%, expected life of 3.5 years and expected volatility of 80% for both periods.

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.

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 4,196,555 and 7,207,809 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, 2004 and 2003, respectively, as their effect would have been anti-dilutive.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123R, "Share-Based Payment," requiring all share-based payments to employees, including grants of employee stock options, to be recognized as compensation expense in the consolidated financial statements based on their fair values. This standard is effective for periods beginning after June 15, 2005 and includes two transition methods. Upon adoption, we will be required to use either the modified prospective or the modified retrospective transition method. Under the modified prospective method, awards that are granted, modified, or settled after the date of adoption should be measured and accounted for in accordance with SFAS 123R. Unvested equity-classified awards that were granted prior to the effective

date should continue to be accounted for in accordance with SFAS 123 except that amounts must be recognized in the income statement. Under the modified retrospective approach, the previously-reported amounts are restated (either to the beginning of the year of adoption or for all periods presented) to reflect the SFAS 123 amounts in the income statement. We are currently evaluating the impact of this standard and its transitional alternatives.

In December 2004, the FASB issued SFAS 153 "Exchange of Non-monetary assets". This statement was a result of a joint effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. One such difference was the exception from fair value measurement in APB Opinion No. 29, Accounting for Non-Monetary Transactions, for non-monetary exchanges of similar productive assets. SFAS 153 replaces this exception with a general exception from fair value measurement for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. This statement is effective for non-monetary assets exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 will not have a material effect on the company's financial position or result of operations.

In November 2004, the FASB issued SFAS No. 151 (SFAS 151), "Inventory Costs". SFAS 151 amends ARB No. 43, Chapter 4. This statement clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS 151 is the result of a broader effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. This statement is

effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 will not have a material impact on the results of operations or financial position of the company.

In May 2003, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations, but could affect the timing or pattern of revenue recognition for future collaborative research and/or license agreements.

NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments consisting of normal accrued adjustments necessary to present fairly the consolidated financial position of the Company as of December 31, 2004, the consolidated results of operations for the three months and six months ended December 31, 2004 and 2003, the Condensed Consolidated Statements of Stockholders Equity (Deficit) for the six months ended December 31, 2004, and cash flows for the six months ended December 31, 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 and six months ended December 31, 2004 and 2003 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

NOTE C - 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, in March 2001, the Company entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX"), our sub-licensor until it was acquired by Genzyme Corporation ("Genzyme") on December 21, 2004, for the development of clofarabine in cancer indications. Under the terms of the co-development agreement, Genzyme 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. Genzyme 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, Genzyme will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay Genzyme a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. In turn, Genzyme, 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, Genzyme 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 December 31, 2004 and 2003, the Company recognized revenues of approximately $110,000, and $28,000, respectively, in connection with the milestone payments received to date. For the six months ended December 31, 2004 and 2003, the Company recognized revenues of approximately $219,000, and $28,000, 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 (i) $55,000 and $14,000 for the three months ended December 31, 2004 and 2003, respectively, and (ii) $110,000 and $14,000 for the six months ended December 31, 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 December 31, 2004 and 2003, respectively. The Company recognized revenues of approximately $57,000 and $58,000 in connection with the upfront payment from Dechra for the six months ended December 31, 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 related to this agreement include approximately $6,000 and $6,000 for the three months ended December 31, 2004 and 2003, respectively. Research and Development costs related to this agreement include approximately $11,000 and $12,000 for the six months ended December 31, 2004 and 2003, respectively.

Operational Developments

The Company submitted a Marketing Authorization Application, or MAA, the European equivalent of a U.S. new drug application, or NDA, with the EMEA in July 2004 for European approval of clofarabine in relapsed or refractory pediatric acute leukemia. The company expects an opinion from the EMEA in mid-2005.

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 certain of Bioenvision's 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. Cumulatively, through December 31, 2004, we have recognized revenue and costs related to this agreement of approximately $183,000 and $37,000 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 December 31, 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 D - 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 vested 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 December 31, 2004 and 2003 the Company recognized stock based employee compensation expense (income) of $417,275 and $(60,975), respectively, as a result of the March 31, 2003 re-pricing. For the six months ended December 31, 2004 and 2003 the Company recognized stock based employee compensation expense of $219,367 and $653,908, respectively, as a result of the March 31, 2003 re-pricing.

For the three months ended December 31, 2004 and 2003, the Company recorded compensation expense of $22,062 and $0, respectively, as a result of options

granted to certain employees. For the six months ended December 31, 2004 and 2003, the Company recorded compensation expense of $44,125 and $0, respectively, as a result of options granted to certain employees.

On January 20, 2004, the Company granted 25,000 options to a board member 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 and $23,610 as a consulting expense for the three months and six months ended December 31, 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 $30,419 and $248,849 as consulting expense for the three months and six months ended December 31, 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 $13,706 and $169,101 as consulting expense for the three months and six months ended December 31, 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 $17,792 and $199,105 as consulting expense for the three months and six months ended December 31, 2004 relating to said warrants.

For the three and six months ended December 31, 2004, the Company granted 123,000 options to certain employees at exercise prices ranging from $7.87 to $8.87 per share which vest ratably on the first, second and third anniversaries of the grant date. No expense was recognized for the three and six months ended December 31, 2004 in connection with said grants as each option was granted at fair market value.

On December 3, 2004, we issued 62,500 shares of common stock to a consultant for services rendered. In connection with such issuance we recognized $496,250 as compensation expense for the three and six months ended December 31, 2004.

During the three months ended December 31, 2004, certain warrant holders of the Company exercised their warrants to acquire 1,363,692 shares of the Company's common stock. The Company received proceeds of approximately $3,137,749 during the three months ended December 31, 2004 from the exercise of such warrants. During the six months ended December 31, 2004, certain warrant holders of the Company exercised their warrants to acquire 1,577,969 shares of the Company's common stock. The Company received proceeds of approximately $3,255,249 during the six months ended December 31, 2004 from the exercise of such warrants.

During the three month period ended December 31, 2004, certain holders of options to purchase an aggregate of 284,095 shares of the Company's common stock were exercised. The Company received proceeds of $306,750 during the three months ended December 31, 2004 from the exercise of such options. During the six month period ended December 31, 2004, certain holders of options to purchase an aggregate of 350,827 shares of the Company's common stock were exercised. The Company received proceeds of $368,750 during the six months ended December 31, 2004 from the exercise of such options.

NOTE E - 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 F - 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.

Note G - Subsequent Events

On February 8, 2005, we completed a secondary public offering in which we sold we sold 7,500,000 common shares at $8.00 per share, with net proceeds to the Company of approximately $56.4 million, after deducting underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds for further development of our lead products, for sales and marketing expenses related to the commercial launch of our lead products, for working capital and other general corporate purposes.

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 "Management's 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 and Company Status

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. The FDA recently approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL in patients who have received two or more prior regimens. We believe clofarabine is the first new medicine initially approved in the United States for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for all cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is selling clofarabine under the brand name Clolar in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL and acute myelogenous leukemia, or AML, with the European Medicines Evaluation Agency, or EMEA. If approved, we anticipate commencing sales in Europe during the second half of calendar 2005 through a dedicated European sales force.

We are selling our second product, Modrenal, in the United Kingdom, through our sales force of eight sales specialists. Modrenal is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and we have initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden. In addition to clofarabine and Modrenal, we are developing Velostan, initially for the treatment of bladder cancer, and Virostat for the treatment of Hepatitis C.

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 described above.

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 in the largest European commercial markets.

We anticipate that revenues derived from our two lead drugs, clofarabine and Modrenal will permit us to further develop the other products currently in our product pipeline.

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

The Company recorded revenues for the three months ended December 31, 2004 and 2003 of approximately $1,176,000 and $82,000, respectively, representing an increase of $1,094,000. For the six months ended December 31, 2004 and 2003, the Company recorded revenues of $2,261,000 and $912,000, representing an increase of $1,349,000. Of the revenues recorded for the three months ended December 31, 2004, approximately $621,000 was recognized from Genzyme, pursuant to the Co-Development Agreement, approximately $215,000 was recognized from sales of Modrenal and approximately $112,000 was recognized from Name Patient Sales of clofarabine. Of the revenues recorded for the six months ended December 31, 2004, approximately $1,343,000 was recognized from Genzyme, pursuant to the Co-Development Agreement, approximately $344,000 was recognized from sales of Modrenal and approximately $122,000 was recognized from Name Patient Sales of clofarabine.

The cost of products sold for the three and six months ended December 31, 2004 and 2003 were approximately $130,000 and $0, respectively. The cost of products sold reflects the direct costs associated with our sales of Modrenal.

Research and development costs for the three months ended December 31, 2004 and 2003 were approximately $1,711,000 and $747,000, respectively, representing an increase of $964,000. Research and development costs for the six months ended December 31, 2004 and 2003 were approximately $3,850,000 and $1,551,000, respectively, representing an increase of $2,299,000.

Our research and development costs include costs associated with six projects, five of which the Company currently devotes time and resource. Clofarabine research and development costs for the three months ended December 31, 2004

and 2003 were approximately $1,113,000 and $213,000, respectively, representing an increase of approximately $900,000. Clofarabine research and development costs for the six months ended December 31, 2004 and 2003 were approximately $2,993,000 and $649,000, respectively, representing an increase of approximately $2,344,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials of clofarabine being conducted in Europe.

Modrenal research and development costs for the three months ended December 31, 2004 and 2003 were approximately $569,000 and $474,000, respectively, representing an increase of $95,000. Modrenal(R) research and development costs for the six months ended December 31, 2004 and 2003 were approximately $820,000 and $758,000, respectively, representing an increase of $62,000. The increase primarily reflects costs associated with ongoing clinical trials.

Velostan research and development costs for the three months ended December 31, 2004 and 2003 were approximately $9,000 and $49,000, respectively, representing a decrease of $40,000. Velostan research and development costs for the six months ended December 31, 2004 and 2003 were approximately $17,000 and $113,000, respectively, representing a decrease of $96,000. The decrease primarily reflects the Company's primary focus on clofarabine and Modrenal during these periods.

Virostat research and development costs for the three months ended December 31, 2004 and 2003 were approximately $6,000 and $11,000, respectively, representing a decrease of $5,000. Virostat research and development costs for the six months ended December 31, 2004 and 2003 were approximately $6,000 and $31,000, respectively, representing a decrease of $25,000. The decrease primarily

reflects the Company's primary focus on clofarabine and Modrenal during these periods.

OLIGON research and development costs for the three months ended December 31, 2004 and 2003 were approximately $13,000 and $0, respectively, representing an increase of $13,000. OLIGON research and development costs for the six months ended December 31, 2004 and 2003 were approximately $13,000 and $0, respectively, representing an increase of $13,000. The increase primarily reflects pre-development costs incurred in connection with continuing co-partnering discussions.

There were no research and development costs associated with Gene Therapy for the three and six months ended December 31, 2004 and 2003 due to the Company's focus on clofarabine and Modrenal during these periods.

The clinical trials and development strategy for the clofarabine and Modrenal projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) clofarabine research and development costs have been approximately $10,491,000; (ii) Modrenal(R) research and development costs have been approximately $5,467,000; (iii) Velostan research and development costs have been approximately $327,000; (iv) Virostat research and development costs have been approximately $64,000; (v) OLIGON research and development costs have been approximately $23,000; and (vi) Gene Therapy research and development costs have been approximately $451,000.

Selling, general and administrative expenses for the three months ended December 31, 2004 and 2003 were approximately $3,054,000 and $919,000, respectively, representing an increase of $2,135,000. Selling, general and administrative expenses for the six months ended December 31, 2004 and 2003 were approximately $4,811,000 and $3,357,000, respectively, representing an increase of $1,454,000. This increase primarily reflects an increase in costs associated with the expanded sales and marketing and administrative infrastructure and costs associated with the internal build out of the Company.

Depreciation and amortization expense for the three months ended December 31, 2004 and 2003 were $341,987 and $340,248, respectively, representing an increase of $1,739. Depreciation and amortization expense for the six months ended December 31, 2004 and 2003 were $681,693 and $679,869, respectively, representing an increase of $1,824. This increase primarily reflects the increase in our net asset base.

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 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 royalty period, through March 2021. For the three months ended December 31, 2004 and 2003, the Company recognized revenues of approximately $110,000 and $28,000, respectively, in connection with the milestone payments received to date. For the six months ended December 31, 2004 and 2003, the Company recognized revenues of approximately $219,000, and $28,000, 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 (i) $55,000 and $14,000 for the three months ended December 31, 2004 and 2003, respectively, and (ii) $110,000 and $14,000 for the six months ended December 31, 2004 and 2003, respectively 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 December 31, 2004 and 2003, respectively. The Company recognized revenues of approximately $57,000 and $58,000 in connection with the upfront payment from Dechra for the six months ended December 31, 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 related to this agreement include approximately $6,000 and $6,000 for the three months ended December 31, 2004 and 2003, respectively. Research and Development costs related to this agreement include approximately $11,000 and $12,000 for the six months ended December 31, 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 February 8, 2005, we completed a secondary public offering in which we sold we sold 7,500,000 common shares at $8.00 per share, with net proceeds to the Company of approximately $56.4 million, after deducting underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds for further development

of our lead products, for sales and marketing expenses related to the commercial launch of our lead products, for working capital and other general corporate purposes. Prior to the offering, on December 31, 2004, we had cash and cash equivalents of approximately $17,476,000 and working capital of $16,790,000. Management believes the Company has sufficient cash and cash equivalents and working capital to continue currently planned operations over the next 12 months. 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.

The Company has the following commitments as of December 31, 2004:

	Payments Due in				
	Total	2005	2006	2007	Thereafter
Employee Contracts	$ 549,770	$ 387,270	$ 162,500	$ -	$ -
Occupancy Lease and Automobiles	2,018,059	303,091	598,027	326,401	790,540
Total	$2,567,829	$ 690,361	$ 760,527	$ 326,401	$ 790,540

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.

Subsequent Events

On February 8, 2005, we completed a secondary public offering in which we sold we sold 7,500,000 common shares at $8.00 per share, with net proceeds to the

Company of approximately $56.4 million, after deducting underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds for further development of our lead products, for sales and marketing expenses related to the commercial launch of our lead products, for working capital and other general corporate purposes.

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

In November 2004, the Company appointed a Controller who is involved with the administration of all accounting functions including Sarbanes-Oxley compliance, preparation of all monthly, quarterly and annual financial statements and further enhancements of the Company's internal controls. Our Controller most recently served as a Manager in the audit department of KPMG (New York office), an internationally recognized public accounting firm.

BIOENVISION, INC. AND SUBSIDIARIES

PART II - OTHER INFORMATION

ITEM 1. Legal Proceedings

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

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ITEM 2. Changes in securities and Use of Proceeds

None

ITEM 3. Defaults upon Senior Securities

None

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

(a) The Company held its annual meeting of stockholders on December 17, 2004.

(b) and (c) At the annual meeting of stockholders on December 17, 2004, our stockholders considered and approved:

1. A proposal to approve and adopt an amendment to our 2003 Stock Incentive Plan to increase the number of shares that may be granted under the plan from 3,000,000 to 4,500,000 ("Proposal 1"); and

2. A proposal to elect five directors (identified in the table below) to serve until the next annual meeting of stockholders or until such directors' successors are elected and shall have been duly qualified ("Proposal 2").

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

Proposal	Votes in Favor	Votes Opposed	Abstentions(withh
Proposal 1	19,735,996	1,161,592	98,230
Proposal 2			
Christopher B. Wood	28,854,073		2,142,165
Thomas Scott Nelson	28,869,234		2,128,379
Michael Kauffman	30,515,894		481,719

Steven A. Elms	30,475,659		521,954
Andrew N. Schiff	30,474,459		523,154

ITEM 5. Other information

None.

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:

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

Current Report on Form 8-K, dated November 17, 2004, as filed with the Commission on November 18, 2004, reporting under Item 1.01 Entry into a Material Definitive Agreement in connection with the adoption of the Company's Preferred Share Purchase Rights Plan.

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: February 14, 2005 By: /s/ Christopher B. Wood M.D.

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

Date: February 14, 2005 By: /s/ David P. Luci

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

EXHIBIT INDEX

Exhibit No.

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