

Edgar Filing: BIOENVISION INC - Form 10QSB

BIOENVISION INC
Form 10QSB
June 29, 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 March 31, 2005
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 _____ No X

As of June 27 , 2005, there were 40,558,948 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

Condensed Consolidated Balance Sheets (Unaudited) -
As of March 31, 2005 and June 30, 2004- as restated

Condensed Consolidated Statements of Operations (Unaudited) -

Edgar Filing: BIOENVISION INC - Form 10QSB

For the period ended March 31, 2005 and June 2004- as restated

Condensed Consolidated Statements of Stockholders Equity (Unaudited) -
For the period ended March 31, 2005 and June 2004- as restated

Condensed Consolidated Statements of Cash Flows (Unaudited) -
For the period ended March 31, 2005 and June 2004- as restated

Notes to Condensed Consolidated Financial Statements (Unaudited) - as restated

Item 2. Management's Discussion and Analysis of Financial Condition or Plan of Operation

Item 3. Controls and Procedures

Part II - Other Information

Bioenvision, Inc. and Subsidiaries CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

	March 31, 2005 -----
ASSETS	
Current assets	
Cash and cash equivalents	\$70,334,939
Restricted cash	290,000
Deferred costs	231,171
Accounts receivable	2,204,662
Inventory	433,335
Other current assets	582,415 -----
Total current assets	74,076,522
Property and equipment, net	262,207
Intangible assets, net	13,799,903
Goodwill	1,540,162
Security deposits	211,796
Deferred costs	3,483,419 -----
Total assets	\$93,374,009 =====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities	
Accounts payable	\$3,014,427
Accrued expenses	1,712,585
Accrued dividends payable	55,479
Deferred revenue	498,607

Edgar Filing: BIOENVISION INC - Form 10QSB

Total current liabilities	5,281,098
Deferred revenue	7,562,251

Total liabilities	12,843,349
Commitments and contingencies	-
Stockholders' equity	
Convertible Preferred stock - \$0.001 par value; 20,000,000 shares authorized; 2,250,000 and 3,341,666 shares issued and outstanding at March 31, 2005 and June 30, 2004 (liquidation preference \$6,750,000 and \$10,024,998, respectively)	2,250
Common stock - par value \$0.001; 70,000,000 shares authorized; 40,448,948 and 28,316,163 shares issued and outstanding at March 31, 2005 and June 30, 2004, respectively	40,449
Additional paid-in capital	128,684,678
Deferred compensation	(158,280)
Accumulated deficit	(48,155,869)
Accumulated other comprehensive income	117,432

Stockholders' equity	80,530,660

Total liabilities and stockholders' equity	\$93,374,009
	=====

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

Bioenvision, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three months ended March 31,	
	2005	2004
	-----	-----
Revenue		
Licensing and royalty revenue	\$430,411	\$76,452
Product sales	149,364	-
Research and development contract revenue	819,194	770,042
	-----	-----

(Restated -
Note I)

Edgar Filing: BIOENVISION INC - Form 10QSB

Total revenue	1,398,969	846,494
Costs and expenses		
Cost of products sold	99,061	-
Research and development	2,136,849	994,307
Selling, general and administrative (includes stock based compensation income (expense) of \$713,116 and \$(2,526,943) for the three months ended March 31, 2005 and 2004, respectively, and \$(687,290) and \$(3,625,535) for the nine months ended March 31, 2005 and 2004, respectively)	2,074,430	3,721,937
Depreciation and amortization	346,504	343,456
	-----	-----
Total costs and expenses	4,656,844	5,059,700
	-----	-----
Loss from operations	(3,257,875)	(4,213,206)
Interest income	185,465	14,576
	-----	-----
Net loss before income tax benefit	(3,072,410)	(4,198,630)
Income tax benefit	-	506,087
	-----	-----
Net loss	(3,072,410)	(3,692,543)
Cumulative preferred stock dividend	(83,219)	(175,704)
	-----	-----
Net loss available to common stockholders	\$ (3,155,629)	\$ (3,868,247)
	=====	=====
Basic and diluted net loss per share of common stock	\$ (0.08)	\$ (0.19)
	=====	=====
Weighted average shares used in computing basic and diluted net loss per share	37,602,163	19,912,396
	=====	=====

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

-2-

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

Edgar Filing: BIOENVISION INC - Form 10QSB

	Convertible		Common Stock		Addi- tional		Ac
	Preferred Stock		Common Stock		Paid In	Deferred	
	Shares	\$	Shares	\$	Capital	Compensation	
	-----	-	-----	-	-----	-----	
Balance at July 1, 2003 (Restated - Note I)	5,916,966	\$5,917	17,122,739	\$17,123	\$47,304,449	\$ -	\$(2
Net loss for the period (Restated - Note I)							(1
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 employee			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	2,509,883		
	-----	-----	-----	-----	-----	-----	-----
Balance at June 30, 2004 (Restated - Note I)	3,341,666	\$3,342	28,316,163	\$28,316	\$68,517,702	\$(223,990)	\$(3
Net loss for the period							(1
Cumulative preferred stock dividend for the period							
Currency translation adjustment							

Edgar Filing: BIOENVISION INC - Form 10QSB

Deferred compensation						65,710	
Warrants issued in connection with services					509,686		
Options issued in connection with services						46,369	
Preferred stock converted to common stock	(1,091,666)	(1,092)	2,183,332	2,183		(1,092)	
Shares issued in connection with public offering net of related expenses			7,500,000	7,500		55,642,500	
Shares issued from warrant conversion			1,598,411	1,598		3,277,365	
Cash exercise of options to shares			575,833	576		626,898	
Cashless exercise of options to shares (non-employees)			212,709	213		(213)	
Shares issued in connection with services			62,500	63		496,188	
Expenses (income) related to repricing of options						(430,725)	
Balance at March 31, 2005	2,250,000	\$2,250	40,448,948	\$40,449	\$128,684,678	\$ (158,280)	\$ (4

The accompanying notes are an integral part of this financial statement.

-3-

Bioenvision, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

		Nine mo Mar
		----- 2005 -----
Cash flows from operating activities		
Net loss		\$ (10,171,793)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization		1,028,197
Deferred tax benefit		-
Stock based compensation		687,290
Changes in net deferred revenue and expenses		(221,863)

Edgar Filing: BIOENVISION INC - Form 10QSB

Changes in assets and liabilities	
Accounts payable	1,496,396
Inventory	(433,335)
Other current assets	(329,104)
Security deposits	(132,686)
Accounts receivable	423,111
Accrued expenses	390,003

Net cash used in operating activities	(7,263,784)
Cash flows from investing activities	
Purchase of intangible assets	(241,998)
Capital expenditures	(236,793)

Net cash used in investing activities	(478,791)
Cash flows from financing activities	
Proceeds from issuance of common stock, net of related expenses	55,650,000
Proceeds from exercise of options, warrants and other convertible securities	3,906,436
Dividends paid	(354,597)

Net cash provided by financing activities	59,201,839
Net increase in cash and cash equivalents	51,459,264
Cash and cash equivalents, beginning of period	18,875,675

Cash and cash equivalents, end of period	\$70,334,939
	=====

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

-4-

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

March 31, 2005

(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. On December 29, 2004, the FDA 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. 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 certain cancer

Edgar Filing: BIOENVISION INC - Form 10QSB

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 pediatric acute myelogenous leukemia, or AML, with the European Medicines Evaluation Agency, or EMEA.

The Company is currently selling its second product, Modrenal(R), in the United Kingdom. Modrenal(R) 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(R), the Company is developing Velostan, initially for the treatment of bladder cancer, and Virostat, initially 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 to be important in understanding our operating results and financial condition.

Revenue Recognition

In accordance with SEC Staff Accounting Bulletin No. 104, upfront nonrefundable fees associated with research and development collaboration agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the estimated research and development period using the straight-line method. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis using the straight-line method. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved. Continuation of certain contracts and grants are dependent upon the Company and/or its co-development partners' achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project.

Upfront nonrefundable fees associated with licensing arrangements are recorded as deferred revenue and recognized over the licensing arrangement using the straight line method, which approximates the life of the patent.

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 risk of loss is passed to the customer, the sales price is fixed and determinable, and collectibility is reasonably assured.

The Company follows the guidance of Emerging Issues Task Force ("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 the Company to assess whether it acts as a principal in the transaction or as an agent acting on behalf of others. The Company records revenue transactions gross in its statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

In May 2003, the 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 because the Company had already followed a revenue recognition model consistent with EITF 00-21.

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 March 31, 2005 and June 30, 2004.

Inventory

Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. The Company periodically reviews inventories and items considered outdated or obsolete are reduced to their estimated net realizable value. Inventories consisted of \$125,211 of raw material, \$218,160 of work-in-progress, and \$89,964 of finished goods at March 31, 2005.

Accounting for Stock-Based Compensation

At March 31, 2005, 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 Statement of Financial Accounting Standards ("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 Opinion No. 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 nine months ended March 31, 2005 and 2004 because there is no incremental tax effect related to the additional expense incurred.

Three months ended
March 31,

Nin

Edgar Filing: BIOENVISION INC - Form 10QSB

	2005 ----	2004 ---- (As restated)	2005 ----
Net loss available to common stockholders, as reported	\$ (3,155,629)	\$ (3,868,247)	\$ (10,491)
Add: Stock-based employee compensation expense (income) included in reported net loss	(628,508)	1,962,337	(365)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,268,146) -----	(194,060) -----	(1,859) -----
Pro forma net loss	\$ (5,052,283)	\$ (2,099,970)	\$ (12,716)
Loss per share			
Basic and diluted - as reported	\$ (0.08)	\$ (0.19)	\$ (0.19)
Basic and diluted - pro forma	\$ (0.13)	\$ (0.11)	\$ (0.11)

The weighted-average assumptions used for the three and nine months ended March 31, 2005 were: risk-free interest rate of 3.40% and 3.36%, respectively; expected dividend yield of 0.0%, expected life of 3.95 and 3.88 years,

-6-

respectively; and expected volatility of 80% for both periods. The weighted-average assumptions used for the three and nine months ended March 31, 2004 were: risk-free interest rate of 2.19% and 2.21%, respectively; expected dividend yield of 0.0%, expected life of 3.5 years and expected volatility of 80% for both periods.

During 2005, the Company corrected an error on the pro-forma stock based compensation disclosures required under SFAS 123 determined under fair value based method in the table above. The Company failed to add back to net loss the stock based compensation recorded by the Company in connection with the repricing of an officer's options and deduct the fair value of the award calculated under SFAS 123. This has decreased such amounts previously reported in the proforma net loss for the three month and nine month periods ended March 31, 2004 by \$1,909,000 and \$2,475,000, respectively.

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 upon their fair values. As amended by the SEC on April 14, 2005, this standard is effective for the quarter beginning July 1, 2005 and includes two transition methods. Upon adoption, we will be required to use either the modified retrospective transition method or the modified prospective transition method. Under the modified retrospective transition method, the previously reported amounts are restated for all periods presented to reflect the SFAS 123 amounts in the income statement. Under the modified prospective transition 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. We are currently evaluating the impact of this standard and

Edgar Filing: BIOENVISION INC - Form 10QSB

its transitional alternatives.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and 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 11,572,415 and 13,145,020 shares of common stock have not been included in the calculation of net loss per share for the three months and nine months ended March 31, 2005 and 2004, respectively, as their effect would have been anti-dilutive.

Comprehensive Loss

Total comprehensive loss for the three months ended March 31, 2005 and 2004 was \$ (3,186,208) and \$(3,868,247), respectively. Total comprehensive loss for the nine months ended March 31, 2005 and 2004 was \$(10,513,894) and \$(8,362,721).

Recent Accounting Pronouncements

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.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs". SFAS 151 amends Accounting Research Bulletin ("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.

-7-

The adoption of SFAS 151 is not expected to have a material impact on the results of operations or financial position of the company.

NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited condensed consolidated

Edgar Filing: BIOENVISION INC - Form 10QSB

financial statements contain all the adjustments consisting of normal accrued adjustments necessary to present fairly the consolidated financial position of the Company as of March 31, 2005, the consolidated results of operations for the three months and nine months ended March 31, 2005 and 2004, the Condensed Consolidated Statements of Stockholders Equity for the nine months ended March 31, 2005, and cash flows for the nine months ended March 31, 2005 and 2004. Certain reclassifications of balances previously reported have been made to conform to the current presentation.

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 nine months ended March 31, 2005 and 2004 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 for certain 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

Edgar Filing: BIOENVISION INC - Form 10QSB

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. 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 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 Genzyme and received an additional \$3.5 million in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application for clofarabine with FDA, the Company received an additional (i) \$2 million in April 2004 and (ii) \$2 million in September

-8-

2004. 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 March 31, 2005 and 2004, the Company recognized revenues of approximately \$110,000, and \$22,000, respectively, in connection with the milestone payments received to date. For the nine months ended March 31, 2005 and 2004, the Company recognized revenues of approximately \$329,000, and \$51,000, 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 Genzyme. 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 \$11,000 for the three months ended March 31, 2005 and 2004, respectively, and (ii) \$165,000 and \$26,000 for the nine months ended March 31, 2005 and 2004, 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 ("GMP"). 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, currently through September 2022. The Company recognized revenues of approximately \$15,000 and \$29,000 in connection with the upfront payment from Dechra for the three months ended March 31, 2005 and 2004, respectively. The Company recognized revenues of approximately \$72,000 and \$87,000 in connection with the upfront payment from Dechra for the nine months ended March 31, 2005 and 2004, respectively.

Edgar Filing: BIOENVISION INC - Form 10QSB

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 \$3,000 and \$6,000 for the three months ended March 31, 2005 and 2004, respectively. Research and Development costs related to this agreement include approximately \$14,000 and \$18,000 for the nine months ended March 31, 2005 and 2004, 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.

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 the Company's requirements for clofarabine-active pharmaceutical ingredient ("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, as amended and restated on December 31, 2004, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply Clinical Trials Monitor and GMP supplier qualifications of the API. 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 the Company'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

-9-

upon expiration of the last patent related to Modrenal(R) or the completion of the last royalty set forth in the agreement. Cumulatively, through March 31, 2005, we have recognized revenue and costs related to this agreement of approximately \$198,000 and \$40,000 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

Edgar Filing: BIOENVISION INC - Form 10QSB

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 (Micellar Improved Drug Delivery Solution) 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 March 31, 2005, 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- Intangible Assets

	3/31/2005	6/30/2004
Patents & Trademarks	\$ 17,999,099	\$ 17,757,101
Accumulated Amortization	(4,199,196)	(3,193,441)
	\$ 13,799,903 \$ 14,563,660	

Amortization of patents and trademarks amounted to \$1,006,000 and \$1,009,000 for the nine months ended March 31, 2005 and 2004, respectively. Intangible assets are recorded at cost and amortized over periods generally ranging from 10-20 years. Amortization for each of the next five fiscal years is expected to amount to approximately \$1,343,000 annually.

NOTE E - 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 fair value 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 remeasured the intrinsic value of these options at the end of each reporting period based on changes in the stock price. For the three months ended March 31, 2005 and 2004 the Company recognized stock based employee compensation income (expense) of approximately \$650,000 and \$(1,944,000), respectively, as a result of the March 31, 2003 re-pricing. For the nine months ended March 31, 2005 and 2004 the Company recognized stock based employee compensation income (expense) of approximately \$431,000 and \$(2,598,000), respectively.

For the three months ended March 31, 2005 and 2004, the Company recorded compensation expense of approximately \$22,000 and \$18,000, respectively, as a result of options granted to certain employees. For the nine months ended March 31, 2005 and 2004, the Company recorded compensation expense of approximately \$66,000 and \$18,000, 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

Edgar Filing: BIOENVISION INC - Form 10QSB

share which vest ratably on the first and second anniversaries of the grant date. The Company recognized approximately \$12,000 and \$9,000 as a consulting expense for the three months ended March 31, 2005 and 2004 relating to said options. The Company recognized approximately \$35,000 and \$9,000 as a

-10-

consulting expense for the nine months ended March 31, 2005 and 2004 relating to said options.

On January 6, 2005, the Company granted 7,500 options to a board member for serving as a member of the Board of Directors, at an exercise price of \$8.17 per share which 1,875 vest immediately on the grant date and the remaining 5,625 vest ratably on the first, second and third anniversaries of the grant date. The Company recognized approximately \$11,000 as a consulting expense for the three and nine months ended March 31, 2005.

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 recognized approximately \$243,000 as a consulting expense for the nine months ended March 31, 2005.

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 recognized approximately \$44,000 as consulting income and approximately \$125,000 as consulting expense for the nine months ended March 31, 2005, 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 recognized approximately \$57,000 as consulting expense for the three months ended March 31, 2005 and approximately \$142,000 as a consulting expense for the nine months ended March 31, 2005 relating to said warrants.

For the three and nine months ended March 31, 2005, the Company granted 651,000 and 774,000 options to certain employees at exercise prices ranging from \$5.44 to \$8.87 per share, respectively. No expense was recognized for the three and nine months ended March 31, 2005 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 approximately \$497,000 as compensation expense for the three and nine months ended March 31, 2005.

During the three months ended March 31, 2005, certain warrant holders of the Company exercised their warrants to acquire 20,442 shares of the Company's common stock. The Company received proceeds of approximately \$24,000 during the three months ended March 31, 2005 from the exercise of such warrants. During the nine months ended March 31, 2005, certain warrant holders of the Company exercised their warrants to acquire 1,598,411 shares of the Company's common stock. The Company received proceeds of approximately \$3,279,000 during the nine months ended March 31, 2005 from the exercise of such warrants.

Edgar Filing: BIOENVISION INC - Form 10QSB

During the three month period ended March 31, 2005, certain holders of options to purchase an aggregate of 437,715 shares of the Company's common stock were exercised. The Company received proceeds of approximately \$259,000 during the three months ended March 31, 2005 from the exercise of such options. During the nine month period ended March 31, 2005, certain holders of options to purchase an aggregate of 788,542 shares of the Company's common stock were exercised. The Company received proceeds of approximately \$627,000 during the nine months ended March 31, 2005 from the exercise of such options.

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 \$55.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

NOTE F-Quarterly Tax Accounting Policy

Income taxes have been provided for using the liability method in accordance with SFAS No. 109, "Accounting for Income Taxes." The provision for income taxes reflects management's estimate of the effective tax rate expected to be applicable for the full fiscal year. This estimate is re-evaluated by management each quarter based on the Company's estimated tax expense for the year. The Company also pays capital stock tax to certain state and local jurisdictions. The Company evaluates the amount due on a quarterly basis.

NOTE G - Related Party Transactions

-11-

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 260,290 shares of common stock for \$6.25 per share for the March and May 2004 financings.

NOTE H - Litigation

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 I - Restatement

In May of 2005, the Company identified an error with respect to the accounting for income taxes in connection with the Pathagon acquisition completed on February 1, 2002. The Company had originally concluded that the realization of

Edgar Filing: BIOENVISION INC - Form 10QSB

the deferred tax asset related to the net operating losses and other deductible temporary differences existing at the acquisition date, and generated after the acquisition date, did not meet the "more likely than not" criteria and, as a result, a valuation allowance was established on the deferred tax assets of the Company. The Company's restated accounting treatment determined that the deferred tax liability recorded in connection with the Pathagon acquisition creates taxable income as the taxable temporary differences reverse. Consequently, the ability to realize the deferred tax assets is "more likely than not" and a valuation allowance is not required against the deferred tax assets, to the extent the deferred tax liability offsets the deferred tax assets. This restated accounting treatment resulted in the recognition of our deferred tax assets to the extent of our deferred tax liabilities. The deferred tax asset, in excess of the deferred tax liability, is not "more likely than not" to be realized, and therefore, a full valuation allowance has been established against the net deferred tax asset.

The Company restated its previously reported financial statements and all interim periods as of and for the years ended June 30, 2004 and 2003, to record additional benefit relating to the recognition of deferred tax assets as indicated in the first paragraph of this note. In years ended June 30, 2004, June 30, 2003, and June 30, 2002, the Company previously recorded the reduction to the deferred tax liability and a corresponding tax benefit of \$537,000, \$537,000 and \$253,000, respectively. In the restated financial statements for years ended June 30, 2004 and June 30, 2003, the Company recorded deferred tax assets, with a corresponding additional deferred tax benefit of \$923,000 and \$1,580,000, respectively, offsetting the deferred tax liability resulting from the Pathagon acquisition. Additionally, as of the acquisition date on February 1, 2002, a deferred tax asset was recorded for \$2,363,000 with a corresponding reduction to goodwill. This represented the deferred tax assets that existed at the date of acquisition and for which the previously recorded valuation allowance was eliminated.

As a result of the above, the Company previously restated its consolidated financial statements as of June 30, 2004 in its Form 10-KSB/A. The following is a summary of the effects of the income tax accounting corrections on the Company's consolidated financial statements for the three and nine months ended March 31, 2004, and for the three months ended September 30, 2004 and December 31, 2004.

For the three and six months ended September 30, 2004 and December 31, 2004, the Company had recorded a deferred tax liability for \$5,647,000 and \$5,505,000, respectively. Due to the correction of an error, the Company has now reported no net deferred tax asset or deferred tax liability for the three, six and nine months ended September 30, 2004, December 31, 2004 and March 31, 2005.

	Three months ended March 31, 2004			Nin
	As Reported	As Restated		As R
Consolidated Statements of Operations:				
Income tax benefit	\$ 134,351	\$ 506,087	\$	4

Edgar Filing: BIOENVISION INC - Form 10QSB

Net loss	(4,064,277)	(3,692,543)	(8,43
Net loss available to common stockholders	(4,239,982)	(3,868,247)	(9,02
Basic and diluted net loss per share of common stock	\$ (0.21)	\$ (0.19)	\$

The restatement has no effect on total cash flows from operating, investing, or financing activities as shown in the Consolidated Statement of Cash Flows. However, the restatement did affect the individual components of net loss and deferred tax benefit within the net cash from operating activities.

2005	First Quarter (as reported)	First Quarter (as restated)	Second Quarter (as reported)	Second Quarter (as restated)
Goodwill	3,902,705	1,540,162	3,902,705	1,540,162
Total assets	41,337,877	38,975,334	41,564,030	39,201,486
Deferred tax liability	5,646,573	-	5,505,486	-
Total liabilities	16,471,168	10,824,595	16,209,427	10,703,941
Accumulated deficit	(44,169,063)	(40,885,033)	(48,143,183)	(45,000,233)
Shareholder's equity	24,866,709	28,150,739	25,354,603	28,497,544
Revenue	1,085,328	1,085,328	1,175,923	1,175,923
Loss before income tax benefit	(3,094,551)	(3,094,551)	(4,004,831)	(4,004,831)
Income tax benefit	134,226	-	141,087	-
Net loss	(2,960,325)	(3,094,551)	(3,863,744)	(4,004,831)
Net loss available to common shareholders	(3,086,666)	(3,220,892)	(3,974,119)	(4,115,200)
Net loss available to common shareholders per basic and dilutive share	\$ (0.11)	\$ (0.11)	\$ (0.13)	\$ (0.13)

Edgar Filing: BIOENVISION INC - Form 10QSB

The quarterly net loss per common share amounts are rounded to the nearest cent. Annual net loss per common share may vary depending on the effect of such rounding.

Additionally, the Company restated the pro-forma stock based compensation disclosures required under SFAS 123 determined under fair value based method due to the correction of an error noted during February 2005. Refer to Note 1 for further discussion.

-13-

BIOENVISION, INC. AND SUBSIDIARIES

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

Except for historical information contained herein, this quarterly report on Form 10-QSB contains forward-looking statements within the meaning of the Section 21E of the Securities and Exchange Act of 1934, as amended, which involve certain risks and uncertainties. Forward-looking statements are included with respect to, among other things, the Company's current business plan an "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. On December 29, 2004, the FDA 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 certain 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. The Company anticipates an opinion from the EMEA in Q3 calendar 2005.

We are selling our second product, Modrenal(R), in the United Kingdom, through our sales force of eight sales specialists. Modrenal(R) 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.

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

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.

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. In addition to clofarabine and Modrenal(r), we are performing initial development work on Velostan, initially for the treatment of bladder cancer, and Virostat for the treatment of Hepatitis C. The work to date on these compounds has been limited because of the need to concentrate on clofarabine and Modrenal(r) but management believe these compounds have potential value. With Velostan the Company has been developing a process for the separation of optical isomers of the compound, and with Virostat the Company has commenced a phase II clinical trial in patients with hepatitis C viral infection. 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. The Company also owns rights to OLIGON(r) technology and we have had discussions with potential product licensing 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.

-14-

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:

- o satisfy our future capital requirements for the implementation of our business plan;

Edgar Filing: BIOENVISION INC - Form 10QSB

- o commercialize our existing products;
- o complete development of products presently in our pipeline and obtain necessary regulatory approvals for use;
- o implement and successfully execute our business and marketing strategy to commercialize products;
- o establish and maintain our client base;
- o continue to develop new products and upgrade our existing products;
- o continue to establish and maintain relationships with manufacturers for our products;
- o respond to industry and competitive developments; and
- o 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 March 31, 2005 and 2004 of approximately \$1,399,000 and \$846,000, respectively, representing an increase of approximately \$553,000. This amount was primarily due to an increase in license and royalty revenue due to increased milestone payments and royalties received from certain of our co-development partners, in the amount of \$354,000.

For the nine months ended March 31, 2005 and 2004, the Company recorded revenues of \$3,660,000 and \$1,758,000, representing an increase of approximately \$1,902,000. This increase primarily was due to an increase in license and royalty revenue from milestone payments and royalties received from certain of our co-development partners in the amount of approximately \$799,000 and an increase in research and development contract revenue due to increased sales in the Named Patient Program and increased clofarabine research and development expenses for which we receive 50% reimbursement from our co-development partner, in the amount of approximately \$739,000.

The cost of products sold for the three and nine months ended March 31, 2005 were approximately \$99,000 and \$229,000, respectively. The cost of products sold reflects the direct costs associated with our sales of Modrenal(R).

Research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$2,137,000 and \$994,000, respectively, representing an increase of approximately \$1,143,000. Research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$5,986,000 and \$2,545,000, respectively, representing an increase of approximately \$3,441,000.

-15-

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 March 31, 2005 and

Edgar Filing: BIOENVISION INC - Form 10QSB

2004 were approximately \$1,668,000 and \$962,000, respectively, representing an increase of approximately \$706,000. Clofarabine research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$4,661,000 and \$1,612,000, respectively, representing an increase of approximately \$3,049,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials of clofarabine being conducted in Europe.

Modrenal(R) research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$447,000 and \$(13,000), respectively, representing an increase of \$460,000. Modrenal(R) research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$1,267,000 and \$744,000, respectively, representing an increase of \$523,000. The increase primarily reflects costs associated with ongoing clinical trials.

Velostan research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$15,000 and \$39,000, respectively, representing a decrease of \$24,000. Velostan research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$32,000 and \$152,000, respectively, representing a decrease of \$120,000. The decrease primarily reflects the Company's primary focus on clofarabine and Modrenal(R) during these periods.

Virostat research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$7,000 and \$0, respectively, representing an increase of \$7,000. Virostat research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$13,000 and \$31,000, respectively, representing a decrease of \$18,000. The decrease primarily reflects the Company's primary focus on clofarabine and Modrenal(R) during these periods.

OLIGON research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$0 and \$6,000, respectively, representing a decrease of \$6,000. OLIGON research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$13,000 and \$6,000, respectively, representing an increase of \$7,000. 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 nine months ended March 31, 2005 and 2004 due to the Company's focus on clofarabine and Modrenal(R) during these periods.

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 each of our projects is as follows: (i) clofarabine research and development costs have been approximately \$10,279,000; (ii) Modrenal(R) research and development costs have been approximately \$5,664,000; (iii) Velostan research and development costs have been approximately \$333,000; (iv) Virostat research and development costs have been approximately \$71,000; (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 March 31, 2005 and 2004 were approximately \$2,074,000 and \$3,722,000, respectively, representing a decrease of \$1,648,000. Of this amount \$2,594,000 is related to a decrease in costs associated with the variable accounting treatment of options

Edgar Filing: BIOENVISION INC - Form 10QSB

issued to an officer of the Company, substantially offset by an increase in payroll due to the significant increase in headcount in both the New York and Edinburgh offices of \$387,000, an increase in sales and marketing costs of \$308,000 related to the Company's deployment of a sales and marketing force in the UK in early 2005, and an increase in royalty expense of \$205,000. Selling, general and administrative expenses for the nine months ended March 31, 2005 and 2004 were approximately \$6,885,000 and \$7,079,000, respectively, representing a decrease of \$194,000. Of this amount \$3,028,000 is related to a decrease in costs associated with the variable accounting treatment of options issued to an officer of the Company, substantially offset by an increase in payroll due to the significant increase in headcount in both the New York and Edinburgh offices of \$873,000, an increase in consulting fees due to the Company's expansion of regulatory and investor relations initiatives in the amount of \$1,192,000, an increase in sales and marketing costs of \$322,000 related to the Company's deployment of a sales and marketing force in the UK and an increase in royalty expense of \$205,000.

Depreciation and amortization expense for the three months ended March 31, 2005 and 2004 were approximately

-16-

\$347,000 and \$343,000, respectively, representing an increase of \$4,000. Depreciation and amortization expense for the nine months ended March 31, 2005 and 2004 were \$1,028,000 and \$1,023,000, respectively, representing an increase of \$5,000. 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.

On March 31, 2005, we had cash and cash equivalents of approximately \$70,335,000 and working capital of \$68,795,000. 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.

On February 8, 2005, we completed a secondary public offering in which we sold 7,500,000 common shares at \$8.00 per share, with net proceeds to the Company of approximately \$55.6 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.

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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 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. We 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.

The Company received a nonrefundable upfront payment of \$1.35 million when it entered into the co-development agreement with Genzyme and received an additional \$3.5 million in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application for clofarabine with FDA, the Company received an additional (i) \$2 million in April 2004 and (ii) \$2 million in September 2004. 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 March 31, 2005 and 2004, the Company recognized revenues of approximately \$110,000 and \$22,000, respectively, in connection with the milestone payments received to date. For the nine months ended March 31, 2005 and 2004, the Company recognized revenues of approximately \$329,000, and \$51,000, 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 Genzyme. 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 \$11,000 for the three months ended March 31, 2005 and 2004, respectively, and (ii) \$165,000 and \$26,000 for the nine months ended March 31, 2005 and 2004, respectively related to such charges.

-17-

The Company received a nonrefundable upfront payment of \$1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals ("Dechra") in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related royalty period, currently through September 2022. The Company recognized revenues of approximately \$15,000 and \$29,000 in connection with the upfront payment from Dechra for the three months ended March 31, 2005 and 2004, respectively. The Company recognized revenues of approximately \$72,000 and \$87,000 in connection with the upfront payment from Dechra for the nine months ended March 31, 2005 and 2004, respectively.

Edgar Filing: BIOENVISION INC - Form 10QSB

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 \$3,000 and \$6,000 for the three months ended March 31, 2005 and 2004, respectively. Research and Development costs related to this agreement include approximately \$14,000 and \$18,000 for the nine months ended March 31, 2005 and 2004, respectively.

The Company has the following commitments as of March 31, 2005:

	Payments Due in				
	Total	2005	2006	2007	Thereaf
Employee Contracts	893,369	274,770	618,599		
Occupancy Lease and Automobiles	1,899,102	184,134	598,027	326,401	790,5
Total	2,792,471	458,904	1,216,626	326,401	790,5

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 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.

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 upon their fair values. As amended by the SEC on April 14, 2005, this standard is effective for the quarter beginning July 1, 2005 and includes two transition methods. Upon adoption, we will be required to use either the modified retrospective transition method or the modified prospective transition method. Under the modified retrospective transition method, the previously reported amounts are restated for all periods presented to reflect the SFAS 123 amounts in the income statement. Under the modified prospective transition 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. 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 International Accounting Standards Board ("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

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs". SFAS 151 amends Accounting Research Bulletin ("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.

-18-

The adoption of SFAS 151 is not expected to have a material impact on the results of operations or financial position of the company.

Subsequent Events

On April 4, 2005, Bioenvision, Inc. notified Grant Thornton LLP ("GT") of GT's dismissal in connection with its decision to engage new auditors as its independent registered public accounting firm. On that date, Bioenvision appointed Deloitte & Touche LLP ("D&T") as its new independent registered public accounting firm for the fiscal year ending June 30, 2005. The decision to engage D&T was made by the Audit Committee of Bioenvision's Board of Directors on April 4, 2005. The appointment was effective as of such date.

On May 23, 2005, management and the audit committee of the Company concluded that financial statements included in its annual report on Form 10-KSB for the fiscal year ended June 30, 2004, should not be relied upon because of a requirement to correct the Company's tax accounting related to the acquisition of Pathagon, Inc. in February 2002 which was identified during the review process of the financial statements to be included in the Company's quarterly report on Form 10-QSB for the quarter ended March 31, 2005. Accordingly, the Company restated its financial statements included in its annual report on Form 10-KSB for the year ended June 30, 2004 (the "10-KSB/A"). The Company's 10-KSB/A was filed on June 29, 2005.

On May 24, 2005, the Company received a notice from the Nasdaq staff indicating that the Company is not in compliance with Nasdaq's requirements for the continued listing due to its failure to timely file its Form 10-QSB for the period ended March 31, 2005, as required under Marketplace Rule 4310(c)(14) and that therefore its common stock is subject to delisting from The Nasdaq Stock Market. The notice does not by itself result in immediate delisting of the common stock, although Nasdaq stated that unless the Company requests a hearing on Nasdaq's delisting notice, the Company's securities will be delisted from The Nasdaq Stock Market at the opening of business on June 2, 2005. The Company made a timely request for a hearing with the Nasdaq Listing Qualifications Panel to review the Nasdaq staff's determination which will stay the delisting pending the hearing and a determination by the Nasdaq Listing Qualifications Panel. The oral hearing is currently scheduled for June 30, 2005.

ITEM 3. CONTROLS AND PROCEDURES

Edgar Filing: BIOENVISION INC - Form 10QSB

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, except as set forth below, 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 registered public accounting firm at that time, 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

-19-

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 proceeded more expeditiously with its existing plan to enhance the Company's internal controls and procedures, which it believes addressed each of the matters raised by Grant Thornton.

Changes in Internal Controls

In May 2005, the Company appointed a Director of Financial Reporting who is involved with assisting the Controller 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 Director of Financial Reporting most recently served as a Supervising Senior Associate in the audit department of KPMG (New York office), an internationally recognized public accounting firm. In addition, in May 2005 the Company also added an Assistant Accountant to its UK office to assist with certain basic accounting and bookkeeping responsibilities. Our Assistant Accountant most recently served as an Intercompany Accountant with Quintiles, an international pharmaceutical company.

Unless otherwise disclosed, we made no other change in our internal control over

Edgar Filing: BIOENVISION INC - Form 10QSB

financial reporting during the quarter that materially affected or is reasonably likely to materially affect our internal control over financial reporting.

(a) Restatement.

In connection with the preparation and filing of this quarterly report on Form 10-QSB for the three-month period ended March 31, 2005, our internal corporate staff identified errors with respect to our tax accounting treatment associated with the acquisition of Pathagon, Inc. which was consummated in February 2002. Our initial accounting concluded that the realization of our deferred tax assets related to the net operating losses and other deductible temporary differences existing at the acquisition date, and generated after the acquisition date, did not meet the "more likely than not" criteria and, as a result, a valuation allowance was established on the deferred tax assets of the Company. The Company subsequently determined that the deferred tax liability recorded in connection with the Pathagon acquisition creates taxable income as the taxable temporary differences reverse and, therefore, a portion of the valuation allowance previously established on our deferred tax assets was not required.

Management reported its findings to the Audit Committee of the Board of Directors. After initial discussions with the Audit Committee, management reviewed these matters in further detail, and after completing its analysis on May 15, 2005, recommended to the Audit Committee that previously reported financial results be restated to reflect correction of these errors. The Audit Committee agreed with this recommendation. Pursuant to the recommendation of the Audit Committee, the Board of Directors determined at its meeting on May 15, 2005, that previously reported results be restated to correct the income tax treatment associated with the Pathagon acquisition.

(b) Evaluation of Disclosure Controls and Procedures

In connection with the restatement, under the direction of our Chief Executive Officer and Chief Financial Officer, we reevaluated our disclosure controls and procedures. We identified the following material weakness in our internal control over financial reporting with respect to accounting for income taxes associated with a purchase business combination:

- o a failure to ensure the correct application of SFAS 109 in respect to purchase business combinations and failure to correct that error subsequently resulting from the lack of personnel knowledge in the accounting for income taxes.

Solely as a result of this material weakness, we concluded that our disclosure controls and procedures were not effective as of March 31, 2005.

(c) Remediation of Material Weakness in Internal Control

-20-

As of the date of this filing (June 29, 2005), we have taken the following measures to remediate the material weakness in our internal control over financial reporting with respect to accounting for income taxes that existed as of March 31, 2005. The remedial actions include:

- o improving training, education and accounting reviews designed to ensure that all relevant personnel involved in income tax transactions understand and apply accounting in compliance with SFAS 109;
- o hiring additional internal resources, including a Director of Financial

Edgar Filing: BIOENVISION INC - Form 10QSB

Reporting, to perform internal control activities previously completed by outside consultants; and

- o engaging an outside tax consult to supplement our internal tax staff and enhance our internal controls over income tax accounting.

Additionally, we have tested our internal financial controls with respect to the corrected processes for evaluating and accounting for the deferred tax assets and liabilities in the preparation of its financial statements affected by the restatement to ensure compliance with SFAS 109.

-21-

BIOENVISION, INC. AND SUBSIDIARIES

PART II - OTHER INFORMATION

ITEM 1. Legal Proceedings

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. Unregistered Sales of Equity 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

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.

Edgar Filing: BIOENVISION INC - Form 10QSB

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 March 31, 2005, the Company filed the following Current Report on Form 8-K:

Current Report on Form 8-K, dated February 2, 2005 as filed with the Commission on February 3, 2005, reporting under Item 1.01 Entry into a Material Definitive Agreement, in connection with the Company entering into an underwriting agreement with J.P. Morgan Securities and UBS Securities as representatives of several underwriters listed on Schedule I thereto.

Current Report on Form 8-K, dated February 8, 2005 as filed with the Commission on February 8, 2005, reporting under Item 7.01 Regulation FD Disclosure, in connection with the Company's press release announcing the closing of its previously announced underwritten public offering of common stock.

-22-

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: June 29, 2005 By: /s/ Christopher B. Wood M.D.

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

Date: June 29, 2005 By: /s/ David P. Luci

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

EXHIBIT INDEX

Exhibit No.

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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 to Section 906 of the Sarbanes-Oxley Act of 2002.