

Edgar Filing: BIOENVISION INC - Form 10-Q

BIOENVISION INC  
Form 10-Q  
November 14, 2005

FORM 10-Q

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

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

For the quarterly period ended  
September 30, 2005  
Commission File # 0-24875

BIOENVISION, INC.  
(Exact name of 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

As of November 1, 2005, there were 40,760,763 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

PART I FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

## Edgar Filing: BIOENVISION INC - Form 10-Q

Consolidated Balance Sheets (Unaudited) -  
As of September 30, 2005 and June 30, 2005

Consolidated Statements of Operations (Unaudited) -  
For the periods ended September 30, 2005 and 2004

Consolidated Statements of Stockholders Equity (Unaudited) -  
For the periods ended September 30, 2005 and June 30, 2005

Consolidated Statements of Cash Flows (Unaudited) -  
For the periods ended September 30, 2005 and 2004

Notes to Consolidated Financial Statements (Unaudited)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 4. Controls and Procedures

### PART II OTHER INFORMATION

Item 1. Legal Proceedings

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Item 3. Defaults Upon Senior Securities

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

Item 5. Other Information

Item 6. Exhibits

### SIGNATURES

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

September 30,  
2005  
-----

#### ASSETS

##### Current assets

Cash and cash equivalents	\$12,208,760
Restricted cash	290,000
Short-term securities	48,209,088
Accounts receivable, less allowances of \$869,220 and \$869,220, respectively	1,403,542
Inventory	361,741
Other current assets	781,060

Edgar Filing: BIOENVISION INC - Form 10-Q

	-----
Total current assets	63,254,191
Property and equipment, net	290,068
Intangible assets, net	8,155,836
Goodwill	1,540,162
Security deposits	208,475
Deferred costs	3,599,006
	-----
Total assets	\$77,047,738
	=====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities	
Accounts payable	\$1,755,461
Accrued expenses	5,266,932
Accrued dividends payable	57,329
Deferred revenue	498,607
	-----
Total current liabilities	7,578,329
Deferred revenue	7,312,945
	-----
Total liabilities	14,891,274
Commitments and contingencies	-
Stockholders' equity	
Convertible preferred stock - \$0.001 par value; 20,000,000 shares authorized;	
2,250,000 shares issued and outstanding on each of September 30, 2005 and June 30, 2005 (liquidation preference \$6,750,000)	2,250
Common stock - par value \$0.001; 70,000,000 shares authorized;	
40,760,763 and 40,558,948 shares issued and outstanding at September 30, 2005 and June 30, 2005, respectively	40,761
Additional paid-in capital	129,282,618
Deferred compensation	-
Accumulated deficit	(67,220,665)
Accumulated other comprehensive income	51,500
	-----
Stockholders' equity	62,156,464
	-----
Total liabilities and stockholders' equity	\$77,047,738
	=====

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

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

Edgar Filing: BIOENVISION INC - Form 10-Q

	Three months ended September 30,	
	2005	2004
	-----	-----
		(Restated) Note I
Revenue		
Licensing and royalty revenue	\$400,130	\$36,000
Product sales	194,996	194,996
Research and development contract revenue	75,092	72,000
	-----	-----
Total revenue	670,218	1,080,000
Costs and expenses		
Cost of products sold, including royalty expense of \$201,000 for the three months ending September 30, 2005	328,291	328,291
Research and development	2,430,918	2,130,000
Selling, general and administrative, (includes stock based compensation expense of \$482,000 and \$391,000 for the three months ending September 30, 2005 and 2004, respectively)	2,887,462	1,750,000
Depreciation and amortization	224,283	330,000
	-----	-----
Total costs and expenses	5,870,954	4,230,000
Loss from operations	(5,200,736)	(3,140,000)
Interest and finance charges	(66,761)	50,000
Interest income	462,905	50,000
	-----	-----
Net loss	(4,804,592)	(3,090,000)
Cumulative preferred stock dividend	(85,068)	(120,000)
	-----	-----
Net loss available to common stockholders	\$ (4,889,660)	\$ (3,210,000)
	=====	=====
Basic and diluted net loss per share of common stock	\$ (0.12)	\$
	=====	
Weighted average shares used in computing basic and diluted net loss per share	40,572,626	28,510,000
	=====	=====

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

Edgar Filing: BIOENVISION INC - Form 10-Q

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
(unaudited)

	Convertible		Common Stock		Additional	Deferred
	Preferred Stock				Paid In	Compen-
	Shares	\$	Shares	\$	Capital	sation
	-----	-	-----	-	-----	-----
Balance at July 1, 2004 (Restated - Note I)	3,341,666	\$ 3,342	28,316,163	\$ 28,316	\$ 68,517,702	\$(223,990)
Net loss for the period (Restated - Note I)						
Cumulative preferred stock dividend for the period						
Currency translation adjustment						
Deferred compensation						78,344
Preferred stock converted to common stock	(1,091,666)	(1,092)	2,183,332	2,183	(1,092)	
Income related to repricing of options					(314,950)	
Warrants issued in connection with services				-	524,928	
Shares issued in connection with services			62,500	63	496,188	
Options exercised to common stock			685,833	686	707,638	
Warrants exercised to common stock			1,811,120	1,811	3,277,151	
Shares issued in connection with public offering, net of related expenses			7,500,000	7,500	55,739,152	
Balance at June 30, 2005	2,250,000	\$ 2,250	40,558,948	\$ 40,559	\$128,946,717	\$(145,646)
Net loss for the period						
Cumulative preferred stock dividend						

Edgar Filing: BIOENVISION INC - Form 10-Q

Currency translation adjustment					
Employee stock-based compensation				458,565	
Deferred compensation				(136,457)	145,646
Options exercised	191,196		191	(191)	
Warrants issued in connection with services				13,995	
Warrants exercised	10,619		11	(11)	
Balance at September 30, 2005	2,250,000	\$ 2,250	40,760,763	\$ 40,761	\$129,282,618 \$ -
	=====	=====	=====	=====	=====

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

- 3 -

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

	Three mo Septe 2005 -----
Cash flows from operating activities	
Net loss	\$ (4,804,592)
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	224,283
Stock based compensation	481,748
Changes in net deferred revenue and expenses	(66,861)
Changes in assets and liabilities	
Accounts payable	167,241
Inventory	(91,406)
Other current assets	(443,113)
Accrued interest on investments	(287,498)
Accounts receivable	363,380
Accrued expenses	715,786
	-----
Net cash used in operating activities	(3,741,032)
Cash flows from investing activities	
Purchase of intangible assets	(103,586)
Capital expenditures	(35,576)
Purchase of short-term securities	(15,174,642)

Edgar Filing: BIOENVISION INC - Form 10-Q

	-----
Net cash used in investing activities	(15,313,804)
Cash flows from financing activities	
Proceeds from exercise of options, warrants and other convertible securities	-
Dividends paid	(84,144)
	-----
Net cash (used in) provided by financing activities	(84,144)
Effect of exchange rates on cash	(59,793)
	-----
Net decrease in cash and cash equivalents	(19,198,773)
Cash and cash equivalents, beginning of period	31,407,533
	-----
Cash and cash equivalents, end of period	\$12,208,760
	=====

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

- 4 -

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 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 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 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.

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 pipeline. In addition to clofarabine and Modrenal(R), we are performing

## Edgar Filing: BIOENVISION INC - Form 10-Q

initial development work on Virostat for the treatment of Hepatitis C and Velostan, initially for the treatment of bladder cancer.

### Significant Accounting Policies

#### Revenue Recognition

In accordance with SEC Staff Accounting Bulletin No. 104 "Revenue Recognition", or SAB 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. 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.

Royalty revenue from product licensees is recorded as earned.

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.

Research & development contract revenue represent payments due from our co-development partner relating to the reimbursement of 50% for certain of our ongoing research costs in the development of clofarabine outside the United States. Currently, the Company has billed but not recorded approximately \$1,825,000 of revenues relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of clofarabine outside the United States. When the Company has determined that the criteria relating to revenue recognition has been met, the Company will record the revenue. At September 30, 2005, the Company continues to hold a provision for bad debts of \$869,000 relating to the outstanding receivables due from the co-development partner.

The Company follows the guidance of Emerging Issues Task Force 99-19, or EITF, "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.

- 5 -

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

Note A - Description of Business and Summary of Significant Accounting Policies  
- continued

Research and development



## Edgar Filing: BIOENVISION INC - Form 10-Q

Research and development costs are charged to expense as incurred. Research and development costs include the cost of clofarabine sold prior to product approval through our named patient program.

### Accounting for Stock-Based Compensation

On July 1, 2005, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123 (R)"), requiring the Company to recognize expense related to the fair value of stock-based compensation. The modified prospective transition method was used as allowed under SFAS No. 123 (R). Under this method, the stock-based compensation expense includes: (a) compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of July 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, "Accounting for Stock-Based Compensation"; and (b) compensation expense for all stock-based compensation awards granted subsequent to July 1, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123 (R). Prior to the adoption of SFAS 123 (R), the Company had accounted for stock based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees", as permitted by SFAS No. 123, "Accounting for Stock Based Compensation." 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.

Upon adoption of SFAS 123 (R), beginning July 1, 2005, the Company reversed the unrecognized deferred compensation costs, associated with options granted to certain employees, of approximately \$136,000 with a corresponding reduction to the Company's Additional paid-in capital (see Note E). The Company also no longer re-measures the intrinsic value of the 380,000 re-priced options granted to an officer of the Company (see Note E). The Company recognized expense of approximately \$12,000 for the options during the three months ended September 30, 2005 based on the fair value, as determined in accordance with SFAS 123 (R), of the modified award that remains unvested.

Beginning July 1, 2005, the Company is recognizing compensation costs for stock option awards to employees based on their grant-date fair value. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The weighted average fair value per share for the 10,000 stock options granted to employees during the three months ended September 30, 2005 was \$4.64. Values were estimated using a zero dividend yield, expected volatility of 80%, and a risk free interest rate range of 3.99% to 4.07%. The expected term of 3.5 years was utilized based on historical exercise of employees.

As required by SFAS 123 (R), management made an estimate of expected forfeitures for all unvested awards and is recognizing compensation costs only for those equity awards expected to vest. The impact on previously reported pro forma disclosures under SFAS No. 123 where forfeitures were recognized as incurred is not material. As of September 30, 2005, the total compensation cost related to unvested equity awards granted to employees but not yet recognized is approximately \$3.2 million. This cost will be amortized on a straight-line basis over the remaining weighted average vesting period of 1.1 years.

## Edgar Filing: BIOENVISION INC - Form 10-Q

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note A - Description of Business and Summary of Significant Accounting Policies  
- continued

A summary of the Company's stock option activity for options issued to employees and related information follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
	-----	-----	----	-----
Balance - June 30, 2005	4,156,000	\$3.18		
Granted during 2006	10,000	8.04		
Exercised during 2006	225,000	1.25		\$189,000
Forfeited during 2006	5,000	8.80		
	-----	-----		
Balance - September 30, 2005	3,936,000	\$3.30	5.31	\$7,993,000
	-----	-----		
Exercisable - September 30, 2005	2,497,000	\$2.21	3.49	\$3,484,000

A summary of the Company's nonvested options at September 30, 2005 and changes during the three months ended September 30, 2005 is presented below:

	Non-vested Number of Shares	Weighted Average Fair Value at Grant Date
	-----	-----
Balance - June 30, 2005	1,434,000	\$3.13
Granted during 2006	10,000	4.64
Exercised during 2006	-	-
Vested during 2006	-	-
Forfeited during 2006	5,000	5.03
	-----	-----
Balance - September 30, 2005	1,439,000	\$3.13
	-----	-----

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 for the three months ended September 30, 2004.

	Three months ended September 30, 2004 ---- (As restated)
Net loss available to common stockholders, as reported	\$ (3,220,892)
Add: Stock-based employee compensation expense	

## Edgar Filing: BIOENVISION INC - Form 10-Q

(income) as reported		(175,845)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards		
		(283,423)
		-----
Pro forma net loss	\$	(3,680,160)
Loss per share		
Basic and diluted - as reported	\$	(0.11)
Basic and diluted - pro forma	\$	(0.13)

- 7 -

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

#### Note A - Description of Business and Summary of Significant Accounting Policies - continued

The weighted-average assumptions used for the three months ended September 30, 2004 were risk-free interest rate of 2.41%, expected dividend yield of 0.0%, expected life of 3.89 years and expected volatility of 80%. 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. In calculating the fair value using the Black-Scholes option-pricing model, the Company unintentionally used the vesting term of the awards instead of the expected term. The correction has decreased such amounts previously reported in the proforma net loss for the three months ended September 30, 2004 by approximately \$40,000.

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.

#### Income taxes

The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes", or SFAS 109. Under SFAS 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse.

We have not generated any taxable income, subject to federal taxes, to date and, therefore, have not paid any federal income taxes since inception. We record a valuation allowance to reduce deferred income tax assets to an amount that is more likely than not to be realized. Assessment of the realization of deferred income tax assets requires that estimates and assumptions be made as to the taxable income of future periods. Our deferred tax assets are reduced to zero, as management believes that it is more likely than not that the deferred tax assets will not be realized. Projection of future period earnings is inherently difficult as it involves consideration of numerous factors such as our overall strategies and estimates of new product development and acceptance, product lifecycles, selling prices and volumes, responses by competitors, manufacturing costs and assumptions as to operating expenses and other industry specific and

## Edgar Filing: BIOENVISION INC - Form 10-Q

macro and micro economic factors.

### 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 11,234,314 and 12,983,535 shares of common stock have not been included in the calculation of net loss per share for the three months ended September 30, 2005 and 2004, respectively, as their effect would have been anti-dilutive.

### Comprehensive Loss

Total comprehensive loss for the three months ended September 30, 2005 and 2004 was \$4,939,000 and \$3,087,000, respectively.

### Foreign currency translation

The reporting currency of the Company is the US dollar. The functional currency of Bioenvision Limited, the Company's wholly-owned subsidiary, organized under the laws of the United Kingdom with offices in Edinburgh, Scotland, is the Pound Sterling. We translate assets and liabilities to their U.S. dollar equivalents at rates in effect at the balance sheet date and record translation adjustments in accumulated other comprehensive income (loss). We translate statement of income accounts at average rates for the period. For the three months ended September 30, 2005, foreign currency transaction gains and losses included in selling, general and administrative expense were \$1,000 and \$9,000, respectively.

### Cash and cash equivalents and Short-term securities

The Company considers all highly liquid financial instruments with a maturity of three months or less when purchased to be cash equivalents. All funds invested in a Certificate of Deposit with maturities greater than three months and less than one year are classified as short-term securities determined by management to be available-for-sale securities.

- 8 -

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

### Note A - Description of Business and Summary of Significant Accounting Policies - continued

#### Deferred costs

Deferred costs represent payments to Southern Research Institute, or SRI, and to Stegram Pharmaceutical Ltd, which directly relate to milestone payments received in connection with the Genzyme Co-Development Agreement and the Dechra Sub-License Agreement, respectively. The amortization of these costs have been presented in research and development on the statement of operations.

#### Credit Risk

Our accounts receivable are primarily due from wholesale distributors and our co-development partners. One customer comprises approximately 52% of revenues earned for the three months ended September 30, 2005. At September 30, 2005, the Company continues to hold a provision for bad debts of \$869,000 relating to the

## Edgar Filing: BIOENVISION INC - Form 10-Q

outstanding receivables due from the customer. Another customer comprises approximately 29% of revenues earned for the three months ended September 30, 2005.

### Inventory

Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. We only capitalize inventory that is produced for commercial sale. The Company periodically reviews inventories and items considered outdated or obsolete are reduced to their estimated net realizable value. Inventories consisted of \$117,000 and \$0 of raw materials, \$6,000 and \$171,000 of work-in-progress, and \$239,000 and \$107,000 of finished goods at September 30, 2005 and June 30, 2005, respectively.

### Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Property and equipment are depreciated on a straight-line basis over their estimated useful lives, which range from 3 to 7 years.

Asset Description	Estimated Useful Life	September 30, 2005	June 30, 2005
Computer equipment and software	3 to 5 years	337,000	305,000
Furniture and fixtures	7 years	51,000	49,000
		388,000	354,000
Less: accumulated depreciation		(97,000)	(74,000)
Net property and equipment		\$ 291,000	\$ 280,000

The Company recorded depreciation expense for the three months ended September 30, 2005 and 2004 of approximately \$24,000 and \$5,000 respectively.

### Fair Value of Financial Instruments

The Company has estimated the fair value of financial instruments using available market information and other valuation methodologies in accordance with SFAS No. 107, "Disclosures About Fair Value of Financial Instruments." Management of the Company believes that the fair value of financial instruments, consisting of cash, cash equivalents, short term securities, accounts receivable, accounts payable and accrued liabilities, approximates their carrying value due to the immediate or short-term maturity associated with these instruments.

## Edgar Filing: BIOENVISION INC - Form 10-Q

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

Note A - Description of Business and Summary of Significant Accounting Policies  
- continued

#### Goodwill and Other Intangible Assets

Goodwill represents the excess of costs over the fair value of identifiable net assets of Pathagon. Intangible assets include patents and licensing rights acquired in connection with the acquisition of Pathagon. The Company accounts for these assets in accordance with SFAS No. 142, Goodwill and Other Intangible Assets. Goodwill is not amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 144, Accounting for Impairment or Disposal of Long-Lived Assets.

For goodwill, each year and whenever impairment indicators are present, we will calculate the implied fair value of each goodwill amount and record an impairment loss for the excess of book value over the implied fair value, if any.

#### Impairment of Long-Lived Assets

The Company adopted the provisions of SFAS No. 144 on July 1, 2003. In accordance with SFAS No. 144, long-lived assets, such as property and equipment and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset (see Note D).

#### Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 153 "Exchange of Nonmonetary 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 Nonmonetary 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 nonmonetary 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 was effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 did not have a material impact on the results of operations or financial position of the

## Edgar Filing: BIOENVISION INC - Form 10-Q

company.

### NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited 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 September 30, 2005, the consolidated results of operations for the three months ended September 30, 2005 and 2004, the consolidated statements of stockholders equity for the three months ended September 30, 2005, and cash flows for the three months ended September 30, 2005 and 2004. Certain reclassifications of balances previously reported have been made to conform to the current presentation.

The consolidated balance sheet at June 30, 2005 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, 2005.

The consolidated results of operations for the three months ended September 30, 2005 and 2004 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

- 10 -

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

### 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.

## Edgar Filing: BIOENVISION INC - Form 10-Q

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 performs its development obligations in accordance with that agreement. The Company is 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, is paying 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 the 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 service period, through March 2021. For each of the three months ended September 30, 2005 and 2004, the Company recognized revenues of approximately \$110,000, 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 \$55,000 for each of the three months ended September 30, 2005 and 2004.

### 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").

- 11 -

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

NOTE C - License and Co-Development Agreements -continued



## Edgar Filing: BIOENVISION INC - Form 10-Q

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 \$28,000 in connection with the upfront payment from Dechra for the three months ended September 30, 2005 and 2004, 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 \$3,000 and \$6,000 for the three months ended September 30, 2005 and 2004, respectively.

### NOTE D- Intangible Assets

	September 30, 2005 ----	June 30, 2005 ----
Patents & Trademarks	\$9,618,000	\$9,514,000
Accumulated Amortization	(1,462,000)	(1,261,000)
	-----	
	\$8,156,000	\$8,253,000
	=====	

Amortization of patents and trademarks amounted to \$201,000 and \$334,000 for the three months ended September 30, 2005 and 2004, respectively. Intangible assets are recorded at cost and amortized over periods generally ranging from 5-20 years. Amortization for each of the next five fiscal years is expected to amount to approximately \$800,000 annually.

At June 30, 2005, we recognized an impairment of approximately \$5,276,000 relating to the methylene blue intangible acquired in connection with the Pathagon acquisition. Due to the loss of an intellectual property patent suit which occurred during the Company's fourth quarter of 2005, relating to the international use of virostat in fresh frozen plasma, we re-evaluated the intangible asset relating to Virostat at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, relating solely and exclusively to approved uses of Virostat, were less than the carrying value of our long-lived asset. As a result, we recognized a non-cash impairment loss of \$5,276,000, equal to the difference between the estimated future cash flows for approved uses of Virostat, discounted at an appropriate rate, and the carrying amount of the asset. Making the determinations of impairment and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows of the assets. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective.

### NOTE E - Stockholders' Transactions

#### Stock Options

The Board of Directors adopted, and the stockholders approved the 2003 Stock Incentive Plan at the Annual Meeting held in January of 2004. The plan was

## Edgar Filing: BIOENVISION INC - Form 10-Q

adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 4,500,000 shares reserved for grants of options under the plan and at September 30, 2005, options to purchase 2,966,500 shares of common stock had been issued. The Company's policy is to issue new shares for option exercises. Stock options vest pursuant to individual stock option

- 12 -

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

#### NOTE E - Stockholders' Transactions -continued

agreements. No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Board of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors or until expiration of the plan on November 17, 2013.

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 through June 30, 2005. As a result of the adoption of SFAS 123 (R) on July 1, 2005, the Company no longer re-measures the intrinsic value of the 380,000 re-priced options. The Company determined the fair value of the modified award in accordance with SFAS 123, the guidance then in effect, and has recognized expense relating to the portion of the options that were unvested on July 1, 2005. For the three months ended September 30, 2005 and 2004, the Company recognized stock based employee compensation (expense) income of approximately \$(12,000) and \$198,000, respectively, related to these options.

For the three months ended September 30, 2004, the Company recorded compensation expense of approximately \$22,000 as a result of 505,000 options granted to certain employees at an exercise price below the grant date trading price. Upon adoption of SFAS 123 (R), beginning July 1, 2005, the Company reversed the unrecognized deferred compensation costs of approximately \$136,000, associated with these options, with a corresponding reduction to the Company's additional paid-in capital and is recognizing the fair value estimated in accordance with the original provisions of SFAS No. 123 for the unvested 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 \$2,000 as consulting expense for the three

## Edgar Filing: BIOENVISION INC - Form 10-Q

months ended September 30, 2005.

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 approximately \$12,000 as consulting expense for both the three months ended September 30, 2005 and 2004 relating to said options.

During the three month period ended September 30, 2005, certain non-employee holders of options exercised pursuant to the cashless exercise feature available to such option holders and the Company issued approximately 191,196 shares of its common stock in connection therewith.

### Warrants

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 \$218,000 as consulting expense for the three months ended September 30, 2004.

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 \$155,000 as consulting expense for the three months ended September 30, 2004, relating to said warrants.

On August 9, 2004, the Company issued two warrants to a consultant pursuant to which said consultant has the right to purchase 45,000 shares of the Company's common stock at a price of \$6.10 per share. The Company recognized approximately \$9,000 and

- 13 -

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

### NOTE E - Stockholders' Transactions -continued

\$181,000 as consulting expense for the three months ended September 30, 2005 and 2004, respectively, relating to said warrants.

During the three months ended September 30, 2005, certain warrant holders of the Company exercised their warrants to acquire 10,619 shares of the Company's common stock. The Company received proceeds of approximately \$76,000 from the exercise of such warrants.

### Common Stock

On December 3, 2004, the Company 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 period ended June 30, 2005.

## Edgar Filing: BIOENVISION INC - Form 10-Q

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. 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 - Geographic Information

We define geographical regions as countries in which we operate. Our corporate headquarters in the United States collects licensing, royalties and research & development contract revenue from our arrangements with external customers and our co-development partners. Our wholly owned subsidiary, Bioenvision Limited, located in the United Kingdom manages our product sales (including the named patient program).

The following table reconciles our revenues by geographic region to the consolidated total:

Region	Three Months Ended	
	September 30	
	2005	2004
United States	\$400,000	\$1,075,000
United Kingdom	270,000	10,000
	-----	-----
	\$670,000	\$1,085,000
	-----	-----

### 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 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.

# Edgar Filing: BIOENVISION INC - Form 10-Q

Consequently, the

- 14 -

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

### NOTE I- Restatements -continued

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. For the 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 months ended September 30, 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 months ended September 30, 2004.

	Three months ended September 30, 2004	
	As Reported	As Restated
-----		
Consolidated Statements of Operations:		
Income tax benefit	\$ 134,226	\$ -
Net loss	(2,960,325)	(3,094,551)
Net loss available to common stockholders	(3,086,666)	(3,220,892)
Basic and diluted net loss per share	\$ (0.11)	\$ (0.11)

Edgar Filing: BIOENVISION INC - Form 10-Q

of common stock

- 15 -

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE I- Restatement-continued

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.

	As of and for the three months ended September 30, 2004	
	(as reported)	(as restated)
Goodwill	3,902,705	1,540,162
Total assets	41,337,877	38,975,334
Deferred tax liability	5,646,573	-
Total liabilities	16,471,168	10,824,595
Accumulated deficit	(44,169,063)	(40,885,033)
Shareholder's equity	24,866,709	28,150,739
Revenue	1,085,328	1,085,328
Loss before income tax benefit	(3,094,551)	(3,094,551)
Income tax benefit	134,226	-
	-----	-----
Net loss	(2,960,325)	(3,094,551)
Net loss available to common shareholders	(3,086,666)	(3,220,892)
Net loss available to common shareholders per basic and dilutive share	\$ (0.11)	\$ (0.11)

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 A for further discussion.

- 16 -

## Edgar Filing: BIOENVISION INC - Form 10-Q

### BIOENVISION, INC. AND SUBSIDIARIES

#### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Except for historical information contained herein, this quarterly report on Form 10-Q 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 and "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 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. In December 2004, the Food and Drug Administration, or FDA, approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. 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 E.U. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for certain cancer indications and currently controls U.S. development of clofarabine in these indications. Genzyme is marketing clofarabine under the brand name Clolar(R) in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL with the European Medicines Evaluation Agency, or EMeA. If approved, we anticipate commencing sales in Europe during the first half of calendar 2006 through a dedicated European sales force. We are selling our second product, Modrenal(R), in the U.K., 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.

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. Further, we intend to penetrate all of the other markets within the E.U. upon establishing traction in the E.U.'s major markets.

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. Currently, we are considering all options available to us for the marketing and distribution of clofarabine in our primary markets,

## Edgar Filing: BIOENVISION INC - Form 10-Q

including, without limitation, doing so directly and internally with our own sales force, doing so through one or more distributors or wholesalers or disposing of the marketing and distribution rights to a third party.

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 early stage of our operations. 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 in Europe and successfully develop certain of our other product candidates.

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 Virostat for the treatment of Hepatitis C and Velostan. 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 Virostat, the Company has commenced a phase II clinical trial in patients with hepatitis C viral infection and with Velostan the Company has been developing a process for the separation of optical isomers of the compound and we are conducting additional pre-clinical testing. 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.

- 17 -

In May 2003, we entered into a License and Sub-License Agreement with Dechra Pharmaceuticals, plc, or 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 U.S. 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.

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;
- 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



## Edgar Filing: BIOENVISION INC - Form 10-Q

- 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 or any risks associated with our business and/or products. 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 September 30, 2005 and 2004 of approximately \$670,000 and \$1,085,000, respectively, representing a decrease of approximately \$415,000. This was primarily due to a decrease in research and development contract revenue as the Company did not record approximately \$685,000 of revenues relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of clofarabine outside the United States because it determined that the criteria for recognizing such contract revenues had not been met. When the Company has determined that the criteria relating to revenue recognition has been met, the Company will record the revenue. This decrease is offset by an increase in product sales of Modrenal(R). The increase in product sales of Modrenal(R) is due to the fact that we received marketing authorization from the Medicines and Healthcare Products Regulatory Agency for Modrenal(R) in September of 2004 and we are now marketing, Modrenal(R) in the U.K., through our own sales specialists, for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.

The cost of products sold for the three months ended September 30, 2005 was approximately \$328,000. 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 September 30, 2005 and 2004 were approximately \$2,431,000 and \$2,139,000, respectively, representing an increase of approximately \$292,000.

Our research and development costs include costs associated with the six projects shown in the table below, four of which the Company currently devotes time and resources:

- 18 -

Product	Three months ended September 30,		Change from prior year
-----	2005	2004	-----
(in thousands)			
Clofarabine	\$2,138	\$1,880	\$258

## Edgar Filing: BIOENVISION INC - Form 10-Q

Modrenal	\$236	\$251	\$(15)
Virostat	\$57	\$0	\$57
Velostan	\$0	\$8	\$(8)
OLIGON	-	-	-
Gene Therapy	-	-	-

Clofarabine research and development costs for the three months ended September 30, 2005 and 2004 were approximately \$2,138,000 and \$1,880,000, respectively, representing an increase of approximately \$258,000. 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 September 30, 2005 and 2004 were approximately \$236,000 and \$251,000, respectively, representing a decrease of \$15,000. These costs did not increase in the three-month period ended September 30, 2005 because the Company had not yet expanded its clinical development program for this compound as it continued to review the development strategy with its regulatory advisors.

Virostat research and development costs for the three months ended September 30, 2005 and 2004 were approximately \$57,000 and \$0, respectively, representing an increase of \$57,000. The increase primarily reflects the costs associated with the ongoing, multi-center investigator sponsored Phase II clinical trial being conducted in Egypt and Southern Europe.

Velostan research and development costs for the three months ended September, 2005 and 2004 were approximately \$0 and \$8,000, respectively, representing a decrease of \$8,000. These costs did not increase because the Company is actively working on the manufacturing process with its regulatory advisors to develop a raceamic form of the compound for use in the Company's clinical development program. No assurance can be given the Company will be able to create the L-form velostan required for the clinical development program or, if it can, the timing of such development.

There were no research and development costs associated with Gene Therapy or OLIGON for the three months ended September 30, 2005 and 2004 due to the Company's focus on clofarabine during this period. We anticipate that revenues derived from our two lead drugs, clofarabine and Modrenal(R) will permit us to further develop these products.

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 \$16,453,000; (ii) Modrenal(R) research and development costs have been approximately \$6,605,000; (iii) Velostan research and development costs have been approximately \$380,000; (iv) Virostat research and development costs have been approximately \$246,000; (v) OLIGON research and development costs have been approximately \$25,000; and (vi) Gene Therapy research and development costs have been approximately \$451,000.

Selling, general and administrative expenses for the three months ended September 30, 2005 and 2004 were approximately \$2,887,000 and \$1,757,000,

## Edgar Filing: BIOENVISION INC - Form 10-Q

respectively, representing an increase of \$1,130,000. Of this amount \$882,000 is related to an increase in payroll and other compensation expenses due to an increase in headcount in both the New York and Edinburgh offices and stock-based compensation due to the Company adopting SFAS 123(R), on July 1, 2005, an increase in sales and marketing costs of \$250,000 related to the Company's deployment of a sales and marketing force in the UK in early 2005, and an increase in rent expense of \$104,000 due to the Company moving offices in both New York and Edinburgh.

Depreciation and amortization expense for the three months ended September 30, 2005 and 2004 were approximately \$224,000 and \$340,000, respectively, representing a decrease of \$116,000. The decrease is due to the Company recording an impairment charge of \$5,276,000 at June 30, 2005, which decreased the cost basis of our methylene blue intangibles.

- 19 -

### 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.

At September 30, 2005, we had cash and cash equivalents and short-term securities of approximately \$60,708,000 and working capital of \$55,676,000. 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.

For the three months ended September 30, 2005 and 2004, net cash used in operating activities was approximately \$3,741,000 and \$1,222,000, respectively, representing an increase of approximately \$2,519,000. This increase is primarily due to increased costs associated with (i) our expanded research and development activity, (ii) selling general and administrative expenses, including an increased headcount, sales and marketing costs and increased rent expense and (iii) cash paid for insurance premiums. For the three months ended September 30, 2005 and 2004, net cash used in investing activities was approximately \$15,314,000 and \$44,000, respectively, representing an increase of approximately \$15,270,000. This increase is primarily due to our purchase of short term securities with proceeds from our February 2005 secondary offering in the amount of approximately \$15,175,000. For the three months ended September 30, 2005 and 2004, net cash (used in) or provided by financing activities was approximately \$(84,000) and \$54,000 representing an increase of \$138,000. This increase is primarily due to the fact that we did not receive any proceeds this quarter from the exercise of options, warrants, or other convertible securities where we had received \$180,000 for the three months ended September 30, 2004 for such matters. This is partially offset by a decrease in dividends paid to our Series A preferred shareholders which resulted from the conversion of a majority of these shares that were outstanding for the quarter ended September 30, 2004.

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

## Edgar Filing: BIOENVISION INC - Form 10-Q

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 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 has the following commitments as of September 30, 2005:

	Total	Payments Due in				
		2006	2007	2008	2009	2010
Occupancy Lease	1,514,721	397,780	326,401	316,216	316,216	158,108
Contractual obligations	433,270	213,786	219,484	0	0	0
<b>Total</b>	<b>1,947,991</b>	<b>611,566</b>	<b>545,885</b>	<b>316,216</b>	<b>316,216</b>	<b>158,108</b>

- 20 -

### Off-balance sheet arrangements

We have no off-balance sheet arrangements.

### Restatement

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

## Edgar Filing: BIOENVISION INC - Form 10-Q

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 was 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 was 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 timely requested a hearing, the Company's securities would 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 stayed the delisting pending the hearing and a determination by the Nasdaq Listing Qualifications Panel. On June 29, 2005, the Nasdaq Listings Qualifications Panel approved Bioenvision's request for continued listing on the Nasdaq National Market and the fifth character "E" was removed from Bioenvision's trading symbol on the opening of trading on Friday, July 1, 2005.

### Recent Accounting Pronouncements

On July 1, 2005, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123 (R)"), requiring the Company to recognize expense related to the fair value of stock-based compensation. The modified prospective transition method was used as allowed under SFAS No. 123 (R). Under this method, the stock-based compensation expense includes: (a) compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of July 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, "Accounting for Stock-Based Compensation"; and (b) compensation expense for all stock-based compensation awards granted subsequent to July 1, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123 (R). Prior to the adoption of SFAS 123 (R), the Company had accounted for stock based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees", as permitted by SFAS No. 123, "Accounting for Stock Based Compensation." 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.

In December 2004, the FASB issued SFAS 153 "Exchange of Nonmonetary Assets". This statement was a result of a joint effort by the FASB and the International Accounting Standards Board, or 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 Nonmonetary 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 nonmonetary 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 was effective for non-monetary assets exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 did not have a material impact on the results of operations or financial position of the company.

## Edgar Filing: BIOENVISION INC - Form 10-Q

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs". SFAS 151 amends Accounting Research Bulletin, or 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 did not have a material impact on the results of operations or financial position of the company.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our excess cash is invested in certificates of deposit with various short-term maturities. We hold no derivative financial instruments and we do not currently engage in hedging activities. We do not have any outstanding debt. Accordingly, due to the maturity and credit quality of our investments, we are not subjected to any substantial risk arising from changes in interest rates, currency exchange

- 21 -

rates and commodity and equity prices. However the company does have some exposure to foreign currency rate fluctuations arising from maintaining an office for the Company's U.K. based, wholly owned subsidiary which transacts business in the local functional currency. Management periodically reviews such foreign currency risk and to date has not undertaken any foreign currency hedges through the use of forward exchange contracts or options and does not foresee doing so in the near future.

### 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-Q. 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.

#### Changes in Internal Controls

We made no changes in our internal controls over financial reporting during the quarter that materially affected or is reasonably likely to materially affect our internal control over financial reporting.

#### Description of Material Weaknesses in Internal Controls Over Financial Reporting

(a) Restatement of the Company's 10-KSB for the fiscal year ended June 30, 2004.

In connection with the preparation and filing of our 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

## Edgar Filing: BIOENVISION INC - Form 10-Q

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.

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 "Accounting for Income Taxes" with respect to purchase business combinations and failure to correct that error subsequently resulting from the lack of personnel knowledgeable 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.

As of June 30, 2005, we had 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 and therefore believe that this material weakness has been rectified. The remedial actions included:

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

- 22 -

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

(b) In connection with the filing of our annual report on Form 10-KSB, for the fiscal year ended June 30, 2005, under the direction of our principal executive officer and principal financial officer, we evaluated our disclosure controls and procedures and concluded that as of June 30, 2005, the following material weakness in internal control over financial reporting existed:

## Edgar Filing: BIOENVISION INC - Form 10-Q

- o we did not maintain effective controls relating to the timely identification, evaluation and accurate resolution of non-routine or complex accounting matters, specifically, (i) we did not timely identify and evaluate a change of circumstances that resulted in an impairment of our intangible assets relating to certain patents, (ii) we did not timely identify and accurately resolve an accounting issue related to contractual revenue recognition and (iii) we did not timely evaluate our accounts receivable for the need of a valuation allowance, each of which resulted in a material adjustment to our consolidated financial statements for the fiscal year ended June 30, 2005.

Management discussed this material weakness with the audit committee. In an effort to remediate the identified material weakness we continue to implement a number of changes to our internal controls over financial reporting, including, improved training and education for all relevant internal personnel, implementation of additional checklists, the more timely review of non-routine transactions, and the hiring of additional internal resources. We believe that the material weakness identified above had not yet been rectified as of September 30, 2005.

Notwithstanding the above mentioned weaknesses, we believe that the consolidated financial statements included in this report fairly present our consolidated financial position as of, and the consolidated results of operations for the period ended, September 30, 2005.

### 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. Each of the parties has moved for summary judgment dismissing all but one of the claims of the other parties. Those motions have not been decided by the Court.

##### 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.



# Edgar Filing: BIOENVISION INC - Form 10-Q

- 23 -

## ITEMS 6. EXHIBITS

Exhibit Number -----	Description -----
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1)
2.2	Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)
3.1	Certificate of Incorporation of Registrant. (2)
3.1(a)	Amendment to Certificate of Incorporation filed January 29, 1999. (3)
3.1(b)	Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)
3.1(c)	Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)
3.1(d)	Certificate of Designations, Preferences and Rights of series A Preferred Stock (6)
3.1(e)	Certificate of Amendment to the Certificate of Incorporation, filed January 14, 2004 (15)
3.2	Amended and Restated By-Laws of the Registrant. (13)
4.1	Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
4.2	Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
4.3	Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
4.4	Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
4.5	Form of Warrant (6)

## Edgar Filing: BIOENVISION INC - Form 10-Q

- 4.6 Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
  - 4.7 Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)
  - 4.8 Common Stock and Warrant Purchase Agreement, dated as of March 22, 2004, by and among Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
- 24 -
- 4.9 Registration Rights Agreement, dated March 22, 2004, by and between Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
  - 4.10 Form of Warrant (16)
  - 4.11 Bioenvision, Inc. 2003 Stock Incentive Plan (17)
  - 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc.
  - 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
  - 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc.
  - 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998. (3)
  - 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
  - 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
  - 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc
  - 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
  - 10.8 Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003 (14)
  - 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
  - 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
  - 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)

## Edgar Filing: BIOENVISION INC - Form 10-Q

- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.14 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
- 10.15 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.16 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 25 -
- 10.17 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.18 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.19 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.20 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.21 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
- 10.22 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
- 10.23 Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
- 10.24 Employment Agreement between Bioenvision Limited and Hugh Griffith, made effective as of October 23, 2002 (18)
- 10.25 Employment Agreement between Bioenvision Limited and Ian Abercrombie, made effective as of January 6, 2003 (18)
- 10.26 Amendment # 2 to the Co-Development Agreement between Bioenvision and ILEX Oncology, Inc. dated December 30, 2003.(21)
- 10.27 Amendment to the Co-Development Agreement between Bioenvision, Inc. and SRI, dated as of March 12, 2001.(21)

Edgar Filing: BIOENVISION INC - Form 10-Q

- 10.28 Letter Agreement For Co-Development Of An Oral Clofarabine Formulation and First Amendment to Co-Development Agreement dated March 12, 2001 between Bioenvision, Inc. and ILEX .(21)
- 10.29 Joinder made by Bioenvision, Inc., dated February 26, 2004
- 10.30 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Sterling SNIFF, dated as of August 12, 2005
- 10.31 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Steroid SpA, dated as of August 12, 2005
- 14.1 Bioenvision Inc.'s Code of Business Conduct and Ethics (19)
- 16.1 Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
- 16.2 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
- 16.3 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
- 16.4 Letter from Grant Thornton LLP to the Securities and Exchange Commission , dated April 7, 2005 (20)

- 26 -

- 21.1 Subsidiaries of the registrant (4)
- 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 Accounting Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of 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 Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 
- (1) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 12, 1999.
- (2) Incorporated by reference and filed as an Exhibit to Registrant's Registration Statement on Form 10-12g filed with the SEC on September 3, 1998.
- (3) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.

## Edgar Filing: BIOENVISION INC - Form 10-Q

- (4) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.
- (5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2002.
- (6) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2002.
- (7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.
- (8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.
- (9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.
- (10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.
- (11) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 6, 2001.
- (12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.
- (13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.
- (14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.
- (15) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2004.

- 27 -

- (16) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2004.
- (17) Registrant's definitive proxy statement on Schedule 14-A, filed in connection with the annual meeting held on January 14, 2004.
- (18) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended September 30, 2003.
- (19) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the year ended June 30, 2004.
- (20) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on April 7, 2005.
- (21) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB, filed with the SEC on October 13, 2005.

- 28 -

Edgar Filing: BIOENVISION INC - Form 10-Q

SIGNATURES

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

Date: November 14, 2005      By: /s/ Christopher B. Wood M.D.  
-----  
Christopher B. Wood M.D.  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2005      By: /s/ David P. Luci  
-----  
David P. Luci  
Chief Financial Officer and General Counsel  
(Principal Financial and Accounting Officer)

- 29 -

Exhibit Index

Exhibit Number -----	Description -----
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1)
2.2	Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)
3.1	Certificate of Incorporation of Registrant. (2)
3.1(a)	Amendment to Certificate of Incorporation filed January 29, 1999. (3)
3.1(b)	Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)
3.1(c)	Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)
3.1(d)	Certificate of Designations, Preferences and Rights of series A Preferred Stock (6)
3.1(e)	Certificate of Amendment to the Certificate of Incorporation,

## Edgar Filing: BIOENVISION INC - Form 10-Q

filed January 14, 2004 (15)

- 3.2 Amended and Restated By-Laws of the Registrant. (13)
- 4.1 Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 4.2 Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 4.3 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 4.4 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 4.5 Form of Warrant (6)
- 4.6 Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
- 4.7 Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)
- 4.8 Common Stock and Warrant Purchase Agreement, dated as of March 22, 2004, by and among Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
- 4.9 Registration Rights Agreement, dated March 22, 2004, by and between  
  
Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
- 4.10 Form of Warrant (16)
- 4.11 Bioenvision, Inc. 2003 Stock Incentive Plan (17)
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc.
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc.
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd.

## Edgar Filing: BIOENVISION INC - Form 10-Q

and Bioenvision, Inc. dated July 15, 1998. (3)

- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
- 10.8 Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003 (14)
- 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.14 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
- 10.15 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.16 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.17 Inter-Institutional Agreement between Sloan-Kettering Institute  
  
for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.18 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.19 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)



## Edgar Filing: BIOENVISION INC - Form 10-Q

- 10.20 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.21 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
- 10.22 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
- 10.23 Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC(14)
- 10.24 Employment Agreement between Bioenvision Limited and Hugh Griffith, made effective as of October 23, 2002 (18)
- 10.25 Employment Agreement between Bioenvision Limited and Ian Abercrombie, made effective as of January 6, 2003 (18)
- 10.26 Amendment # 2 to the Co-Development Agreement between Bioenvision and ILEX Oncology, Inc. dated December 30, 2003.(21)
- 10.27 Amendment to the Co-Development Agreement between Bioenvision, Inc. and SRI, dated as of March 12, 2001.(21)
- 10.28 Letter Agreement For Co-Development Of An Oral Clofarabine Formulation and First Amendment to Co-Development Agreement dated March 12, 2001 between Bioenvision, Inc. and ILEX .(21)
- 10.29 Joinder made by Bioenvision, Inc., dated February 26, 2004
- 10.30 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Sterling SNIFF, dated as of August 12, 2005
- 10.31 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Steroid SpA, dated as of August 12, 2005
- 14.1 Bioenvision Inc.'s Code of Business Conduct and Ethics (19)
- 16.1 Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
- 16.2 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
- 16.3 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
- 16.4 Letter from Grant Thornton LLP to the Securities and Exchange Commission , dated April 7, 2005 (20)
- 21.1 Subsidiaries of the registrant (4)

## Edgar Filing: BIOENVISION INC - Form 10-Q

- 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 Accounting Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of 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 Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 
- (1) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 12, 1999.
  - (2) Incorporated by reference and filed as an Exhibit to Registrant's Registration Statement on Form 10-12g filed with the SEC on September 3, 1998.
  - (3) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.
  - (4) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.
  - (5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2002.
  - (6) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2002.
  - (7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.
  - (8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.
  - (9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.
  - (10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.
  - (11) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 6, 2001.
  - (12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.
  - (13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.
  - (14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.
  - (15) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2004.

Edgar Filing: BIOENVISION INC - Form 10-Q

(16) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC

on March 24, 2004.

(17) Registrant's definitive proxy statement on Schedule 14-A, filed in connection with the annual meeting held on January 14, 2004.

(18) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three- month period ended September 30, 2003.

(19) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the year ended June 30, 2004.

(20) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on April 7, 2005.

(21) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB, filed with the SEC on October 13, 2005.