

Edgar Filing: BIOENVISION INC - Form 10QSB

BIOENVISION INC  
Form 10QSB  
November 14, 2003

FORM 10-QSB

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

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

For the quarterly period ended September 30, 2003  
Commission File # 0-24875

BIOENVISION, INC.

(Exact name of small business issuer as specified in its charter)

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

509 Madison Avenue Suite 404 New York, N.Y. 10022

-----  
(Address of principal executive offices)

(Issuer's Telephone Number) (212) 750-6700  
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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 12 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   
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As of October 25, 2003, there were 18,252,771 shares of the issuer's common stock, par value \$.001 per share (the "Common Stock") outstanding.

Traditional Small Business Disclosure Format (Check One): YES [ ] No

C O N T E N T S

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Condensed Consolidated Statements of Operations

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

Item 4. Controls and Procedures

Part II - Other Information

### Bioenvision, Inc. and Subsidiaries CONDENSED CONSOLIDATED BALANCE SHEETS

		September 2003 ----- (unaudite
ASSETS		
Current assets		
Cash and cash equivalents		\$7,013,
Restricted cash		290,
Deferred costs		22,
Accounts receivable		25,
Other Assets		303, -----
Total current assets		7,655,
Property and equipment, net		45,
Intangible assets, net		15,465,
Goodwill		3,902,
Security deposits		79,
Other long term assets		45,
Deferred costs		219, -----
Total assets		\$ 27,412, =====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable		\$ 150,
Accrued expenses		1,083,
Accrued dividends payable		1,232,
Deferred revenue		113, -----
Total current liabilities		2,581,
Deferred revenue-long term		1,095,
Deferred tax liability		6,183,

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Total liabilities	9,860,
-----	
Stockholders' equity	
Preferred stock - \$0.001 par value; 5,920,000 shares authorized and 5,464,150 and 5,916,966 shares issued and outstanding at September 30, 2003 and June 30, 2003 respectively (liquidation preference \$16,392,450)	5,
Common stock - par value \$0.01; 50,000,000 shares authorized and 18,202,771 and 17,122,739 shares issued and outstanding at September 30, 2003 and June 30, 2003, respectively	18,
Additional paid-in capital	48,850,
Accumulated deficit	(31,474,
Accumulated other comprehensive income	152,
	-----
Stockholders' equity	17,552,
	-----
Total liabilities and stockholders' equity	\$ 27,412,
	=====

The accompanying notes are an integral part of these statements.

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Thre S
	-----
	2003
	-----
	(unaudited)
Licensing and royalty revenue	\$ 54,041
Research and development contract revenue	775,000
	-----
Total Revenue	829,041
Costs and expenses	
Research and development	803,900
Selling, general and administrative (including stock based compensation of \$1,284,646 and \$97,500 for the three months ended September 30, 2003 and 2002, respectively).	2,438,088
Depreciation and amortization	339,621
	-----
Total costs and expenses	3,581,609
	-----
Loss from operations	(2,752,568)

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Interest income (expense)	
Interest and finance charges	-
Interest income	19,037
	-----
Net loss before income tax benefit	(2,733,531)
Income tax benefit	134,226
	-----
Net loss	(2,599,305)
	-----
Cumulative preferred stock dividend	(223,710)
	-----
Net loss available to common stockholders	\$ (2,823,015)
	=====
Basic and diluted net loss per share of common stock	\$ (0.16)
Weighted average shares used in computing basic and diluted net loss per share	17,188,295

The accompanying notes are an integral part of these statements.

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

	T
	-----
	2003
	-----
	(unaudited)
Cash flows from operating activities	
Net loss	\$ (2,599,305)
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	339,620
Financing charges - noncash	

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Deferred tax benefit	(134,22)
Compensation costs - shares and warrants issued to nonemployees	569,76
Compensation costs -re-pricing of options	714,88
Changes in assets and liabilities	
Deferred costs	5,80
Deferred revenue	(29,04)
Accounts payable	(260,50)
Other current assets	(197,58)
Other long term assets	81,69
Accounts Receivable	
Accrued dividends payable	
Other accrued expenses and liabilities	352,97
	-----
Net cash used in operating activities	(1,155,90)
	-----
Cash flows from investing activities	
Purchase of intangible assets	(22,33)
Capital expenditures	
Restricted cash	
Net cash used in investing activities	(22,33)
	-----
Cash flows from financing activities	
Proceeds from issuance of common stock	262,50
Net decrease in cash and equivalents	(915,74)
Cash and equivalents, beginning of period	7,929,68
	-----
Cash and equivalents, end of period	\$ 7,013,94
	=====

The accompanying notes are an integral part of these statements.

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

September 30, 2003

(Unaudited)

#### NOTE A - Description of Business

Bioenvision, Inc. ("Bioenvision" or the "Company") is an emerging biopharmaceutical company whose primary business focus is the acquisition, development and distribution of drugs to treat cancer. The Company has a broad range of products and technologies under development, but its two lead drugs are Clofarabine and Modrenal(R). Modrenal(R) is approved for marketing in the U.K. for advanced breast cancer. The Company's plan is to bring Modrenal(R) into the

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U.S. to perform further clinical trials and to access the U.S. market. Most of the Company's other drugs are now in clinical trials in various stages of development.

### NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments (consisting only of normal recurring accruals) necessary to present fairly the consolidated financial position as of September 30, 2003 and the consolidated results of operations for the three months ended September 30, 2003 and 2002, and cash flows for the three months ended September 30, 2003 and 2002.

The condensed consolidated balance sheet at June 30, 2003 has been derived from the audited financial statements at that date, but does not include all the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. For further information, refer to the audited consolidated financial statements and footnotes thereto included in the Form 10-KSB filed by the Company for the year ended June 30, 2003.

The condensed consolidated results of operations for the three months ended September 30, 2003 and 2002 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

### NOTE C - Stock Based Compensation

At September 30, 2003, the Company has stock based compensation plans which are described more fully in the Company's annual report on Form 10-K for the year ended June 30, 2003. As permitted by SFAS No. 123, "Accounting for Stock Based Compensation", the Company accounts for stock based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB" Opinion No. 25 "Accounting for Stock Issued to Employees".) Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. Under APB 25, no stock based employee compensation cost is reflected in reported net loss, as all options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant. For the quarter ended September 30, 2003, the Company recognized stock based employee compensation costs of \$714,883 as a result of the March 31, 2003 re-pricing of 380,000 options granted to an employee pursuant to the terms of his employment contract.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force 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 00-27. Under EITF No. 96-18, where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument. The Company expects to continue applying the provisions of APB 25 for equity issuances to employees.

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The following table illustrates the effect on net loss and loss per share as if the fair value based method had been applied to all outstanding and unvested awards in each period.

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	Quarter Ended September
	-----
Net loss available to common stockholders, as reported	\$ (2,823,015)
	-----
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards; net of related tax effects	(986,100)
	-----
Pro forma net loss	\$ (3,094,232)
Loss per share	
Basic and diluted - as reported	\$ (0.16)
Basic and diluted - pro forma	\$ (0.18)

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

	Quarter Ended September 30, 2003
	-----
Expected life (years)	4.00
Risk free interest rate	3.00%
Expected volatility	80%
Expected dividend yield	0.00

NOTE D - Net Loss Per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options and warrants to purchase 15,574,543 and 5,234,544 shares of common stock have not been included in the calculation of net loss per share for the quarters ended September 30, 2003 and 2002, respectively, as their effect would have been anti-dilutive.

NOTE E - License And Co-Development Agreements

Clofarabine

The Company has a license from Southern Research Institute ("SRI"), Birmingham, Alabama, to develop and market purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. The lead compound of these purine-based nucleosides is known as Clofarabine. The Company plans to develop Clofarabine initially for the treatment of leukemia and lymphoma and to study 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

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Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

To facilitate the development of Clofarabine, the Company entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX") in March 2001. Under the terms of the co-development agreement, ILEX is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia). The Company also granted Ilex an option to purchase \$1 million of Common Stock after completion of the pivotal Phase II clinical trial, and ILEX has an additional option to purchase \$2 million of Common

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Stock after the filing of a new drug application in the United States for the use of Clofarabine in the treatment of lymphocytic leukemia. The exercise price per share for each option is determined by a formula based around the date of exercise. Under the co-development agreement, ILEX also pays royalties to Southern Research Institute based on certain milestones. Also, the Company is obligated to pay milestones and royalties to Southern Research Institute in respect to Clofarabine sales outside the United State and Canada. On September 12, 2003, ILEX paid the Company \$775,000 in respect of Research and Development costs incurred by the Company for European drug development through August 31, 2003.

### Modrenal (R)

The Company holds an exclusive license, until the expiration of existing and new patents related to modrenal, to market modrenal in major international territories, and an agreement with a United Kingdom company to co-develop modrenal for other therapeutic indications. Management believes that modrenal currently is manufactured by third-party contractors in accordance with good manufacturing practices. The Company has no plans to establish its own manufacturing facility for modrenal, but will continue to use third-party contractors.

Anti-Estrogen Prostate. The Company has received Institutional Review Board approval from the Massachusetts General Hospital for a Phase II study of trilostane for the treatment of androgen independent prostate cancer. The study will be conducted by The Dana Faber Cancer Institute and currently is intended to commence in November 2003.

### Operational Developments

In April 2003, the Company entered into an exclusive license agreement with CLL-Pharma ("CLL"), pursuant to which CLL has agreed to perform certain development works and studies to create a new formulation of modrenal in the form of a soft gel capsule. CLL intends to use its proprietary MIDDS -patented technology to perform this service on behalf of the Company. This new formulation, once in hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell modrenal throughout Europe. The Company paid and capitalized \$175,000 related to development costs over an eighteen month period.

In May 2003, the Company entered into a sub-license agreement with Dechra Pharmaceuticals plc ("Dechra"), pursuant to which Dechra has been granted a sub-license for all of Bioenvision's rights and entitlements to market and distribute modrenal in the United States and Canada solely in connection with animal health applications. Subject to certain circumstances, this agreement

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expires upon expiration of the last patent related to modrenal or the completion of the last royalty set forth in the agreement. The Company received a payment of \$1.25 million upon execution of this agreement and may receive up to an additional \$3.75 million upon the achievement by Dechra of certain milestones set forth in the agreement.

In May 2003, the Company entered into a master services agreement with Penn-Pharmaceutical Services Limited ("Penn"), pursuant to which Penn has agreed to label, package and distribute clofarabine on behalf of and at the Company's request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three month prior written notice.

In June 2003, the Company entered into a supply agreement with Ferro-Pfanstiehl Laboratories ("Ferro"), pursuant to which Ferro has agreed to manufacture and supply 100% of Bioenvisions global requirements for Clofarabine-API. Subject to

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certain circumstances, this agreement will expire on the fifth anniversary date of the first regulatory approval of Clofarabine drug product.

In June 2003, the Company entered into a development agreement with Ferro, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply CTM and GMP supplier qualifications of the API-Clofarabine. Subject to certain circumstances, this agreement expires upon the completion of the development program. The development agreement is milestone based and payments are to be paid upon completion of each milestone. If Ferro has not completed the development agreement by December 2007, the development agreement will automatically terminate without further action by either party. The Company paid and capitalized \$50,000 related to development costs.

In May 2003, the Company entered into a master services agreement with Penn-Pharmaceutical Services Limited ("Penn"), pursuant to which Penn has agreed to label, package and distribute clofarabine on behalf of and at the Company's request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three month prior written notice.

In August 2003, the Company entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, the Company succeeded to Stegram the United Kingdom marketing rights to modrenal.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from clofarabine in Japan and Southeast Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

In September 2003, the Company entered into a letter agreement with ILEX pursuant to which the Company will collaborate with ILEX to co-develop an oral formulation for clofarabine; the rights and related costs of which will be

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shared equally.

### Deferred revenue

As of September 30, 2003, the Company had fully amortized the deferred revenue related to the contract with ILEX. The Company had been amortizing the deferred revenue, and recognizing revenues ratably, on a straight-line basis concurrent with certain development activities described in the contract, through December 2002. As of September 30, 2003, the Company reported deferred revenue of \$1,209,280 related to the payment received by the Company of \$1.25 million from Dechra upon execution of the agreement with Dechra. The Company is recognizing the initial payment to revenues on a straight-line basis over the term of the license agreement through May 2014.

### Deferred Costs

Deferred costs represent amounts that became due and payable upon the Company's execution of co-development and sub-licensing agreements. Since the revenue related to these agreements is to be realized over the life of the agreement, the Company has deferred the related costs. The Company amortizes such costs ratably, on a straight-line basis. As of September 30, 2003, the Company has deferred costs of \$241,856.

### NOTE F - Equity Transactions

In June 2002, the Company granted options to David Luci to purchase 380,000 shares of common stock at an exercise price of \$1.95 per share, which equaled the stock price on the date of grant. Of this amount 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003, the Company entered into an Employment Agreement with Mr. Luci, pursuant to which, among other things, the exercise price for all of the 380,000 options were changed to \$0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of \$.735 per share which vest immediately. As a result of the repricing of all of the 380,000 options, the Company will remeasure the intrinsic value of these options at the end of each reporting period and will record a charge for compensation expense to the extent the vested portion of the options are in the money. Compensation expense recognized as a result of this re-pricing amounted to \$714,883 for the quarter ended September 30, 2003.

On December 31, 2002 the Company issued 200,000 options to purchase 200,000 shares of common stock to a consultant to the Company. The options have an exercise price of \$2.00 and vest ratably over a three-year period on each anniversary date. Compensation expense of \$56,666 was recorded as consulting fees for the three months ended September 30, 2003.

During the three months ended March 31, 2003, the Company also issued 20,000 options to another employee to purchase 20,000 shares of common stock at an exercise price of \$1.42 per share. Of this amount, 10,000 options vest on January 9, 2004 and the remaining 10,000 options will vest on January 9, 2005.

In September, 2003 certain preferred stockholders converted an aggregate of 452,516 preferred shares into 905,032 shares of the Company's common stock.

### NOTE G - Related Party Transactions

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

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issuance of these shares was capitalized as deferred financing costs and was amortized over a twelve-month period.

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

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

### NOTE H - New Accounting Pronouncements

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

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (SFAS 150). The objective of SFAS No. 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. Adoption of SFAS 150 did not have a material impact on the results of operations or financial position of the Company.

In November 2002, the EITF reached a consensus on issue No. 00-21 "Accounting for Revenue Arrangements with Multiple Deliverables." This issue provides guidance on when and how to separate elements of an arrangement that may involve the delivery or performance of multiple products, services and rights to use assets into separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The transition provision allows either prospective application or a cumulative effect adjustment upon adoption. The effect of the adoption of this statement is immaterial to the Company.

### NOTE I - Litigation

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint

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alleges a breach of contract by the Company and demands judgment against the Company for \$112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary judgment and RLB filed its response on October 27, 2003. On November 12, 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. No assurance can be given that RLB will not appeal the court's decision, but management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations.

### NOTE J- Subsequent Events

In October 2003, the Company, through its wholly-owned subsidiary, Bioenvision Limited, entered into an Employment Agreement with Mr. Hugh S. Griffith, pursuant to which Mr. Griffith continues to serve in his capacity as Commercial Director (Europe) of the Company. Under this contract, the term is six months, with automatic six-month extensions thereafter unless either party provides written notice to the contrary. The employment agreement provides for an initial base salary of (pound)120,000 per annum, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to employees of the Company or its subsidiaries. In addition, Mr. Griffith received options to purchase 300,000 shares of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.45, which vest in equal installments on the first, second and third anniversary of the date of the agreement.

In October 2003, the Company, through its wholly-owned subsidiary, Bioenvision Limited, entered into an Employment Agreement with Mr. Ian Abercrombie, pursuant to which Mr. Abercrombie continues to serve in his capacity as Sales

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Manager (Europe) of the Company. Under this contract, the term is six months, with automatic six-month extensions thereafter unless either party provides written notice to the contrary. The employment agreement provides for an initial base salary of (pound)75,000 per annum, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to employees of the Company or its subsidiaries. In addition, Mr. Abercrombie received options to purchase 50,000 shares of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.29 which vest in equal installments on the first and second anniversary of the date of the agreement.

### BIOENVISION, INC. AND SUBSIDIARIES

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

The information set forth in this Quarterly Report on Form 10-QSB including, without limitation, that contained in this Item 2, Management's Discussion and Analysis or Plan of Operation, contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results may differ materially from those projected in the forward-looking statements as a result of certain risks and uncertainties set forth in this report. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the

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underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this report.

The following discussion and analysis of significant factors effecting the Company's operating results, liquidity and capital resources and should be read in conjunction with the accompanying financial statements and related notes.

### Overview

We are an emerging biopharmaceutical company with a primary business focus on the acquisition, development and distribution of drugs to treat cancer. We have acquired development and marketing rights to a portfolio of six platform technologies developed over the past 15 years from which a range of products have been derived and additional products may be developed in the future. Although we have commenced marketing one of our lead products, Modrenal(R), and intend to continue to develop Clofarabine, and our existing platform technologies and commercializing products derived from such technologies, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. Once a product or technology has been launched into the market for a particular disease indication, we plan to work with numerous collaborators, both pharmaceutical and clinical, in the oncology community to extend the permitted uses of the product to other indications. In order to market our products effectively, we intend to develop marketing alliances with strategic partners and may co-promote and/or co-market in certain territories.

We plan to continue to use a major portion of the proceeds of the May 2002 private placement to initiate clinical trials of Clofarabine in Europe. The emphasis will be on the use of Clofarabine in the treatment of refractory acute leukemia in children and adults. The drug has received orphan drug designation in Europe.

We plan to identify licensing partners for OLIGON(R) and to continue developing new aspects of the technology. We also plan to continue development of methylene blue and other products in our pipeline.

With respect to our gene therapy technology, we have completed laboratory research which confirms proof of principal of our gene therapy technology and has added to the pre-clinical data which will be important for any subsequent regulatory submission. This laboratory research was required to allow the Company and the research departments of the relevant universities assisting with this technology to file patents for which the Company has licensing rights. We now plan to perform additional clinical trials with the two lead products related to this technology.

### Clofarabine

Based on third party studies conducted to date, we believe that Clofarabine is effective in the treatment of leukemia and lymphoma. To expedite the commercialization Clofarabine, we have entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX") under which Phase II clinical trials of Clofarabine are currently being conducted. The combination of the Phase II trials in acute leukemia at M.D. Anderson Cancer Center and other leading cancer centers in the U.S. and Europe and the encouraging results from the Phase I, early Phase II studies and current Phase II studies lead us to be enthusiastic for the prospects of Clofarabine reaching the market, possibly as soon as the third quarter of calendar year 2004. The United States Food and Drug Administration recently indicated that it would review clofarabine for the treatment of

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### BIOENVISION, INC. AND SUBSIDIARIES

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

refractory or relapsed ALL in children more quickly than normal after having granted "fast track" status to clofarabine. "Fast track" status means that the FDA will start reviewing clinical trial data even before the entire New Drug Application ("NDA") is complete. The FDA could complete its review within six months rather than the normal 12 month review period.

We believe the set of clinical data from the current Phase II clinical trials could serve as the basis for a marketing application, which we believe could be filed as early as April 2004. Management believes that the "fast track" designation may also result in our more expeditiously gaining marketing approval for clofarabine for the treatment of refractory or relapsed ALL.

Further, Southern Research Institute, which granted us the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the clofarabine 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 us and by Southern Research Institute from the technology, recently granted us an irrevocable, exclusive option to make, use and sell products derived from the clofarabine technology in Japan and Southeast Asia. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in Japan and Southeast Asia.

In January 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. The drug has also been granted orphan drug status in the United States.

Extensive preclinical and mechanistic studies have provided much of the rationale for the rapidly advancing Clofarabine clinical development program. Published data and information presented at recent scientific meetings suggest that Clofarabine has broader anti-cancer activity, and may be more potent than other currently marketed purine analogues such as Fludara(R) (fludarabine) and Leustatin(R) (cladribine).

Preliminary results from ongoing clinical studies indicate that Clofarabine may be an effective treatment for acute leukemias in adult and pediatric patients that have become resistant, or refractory, to prior treatment. According to researchers at the MD Anderson Cancer Center, interim Phase II study results showed that 45% of adults with acute myelogenous leukemia (AML) achieved a complete remission (CR) rate, and acute lymphocytic leukemia (ALL) patients achieved a 20% CR rate when treated with Clofarabine as a single agent. Data from a separate Phase I dose-escalation study demonstrated a 25% CR rate, and an overall response rate of 40%, in children with acute leukemias who were refractory to previous therapy. Trials in adult and pediatric acute leukemias are currently ongoing in the U.S. and are planned to commence in Europe later this year. Complete remission, in this context, means complete clearance of all leukemic cells from the blood and normalization of the blood count, sustained for a period of more than 4 weeks. In this context, a response, or partial response, has largely the same meaning, except that the bone marrow may still contain more than 5% but less than 25% blast cells (leukemic cells).

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### Modrenal (R)

We launched Modrenal(R), in May 2003 in the United Kingdom, where we obtained regulatory approval for its use in the treatment of post-menopausal breast cancer. In August 2003, pursuant to an amendment to our co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), we obtained the right to market Modrenal(R) in the United Kingdom and have succeeded to Stegram's existing revenue streams from UK sales.

Our management believes that Modrenal(R) works by a unique action as compared with other commercially available drugs to treat post-menopausal breast cancer. We believe that Modrenal(R) alters the way in which the female hormone, estrogen, binds to the hormone receptor on the cell in a previously unrecognized fashion. In particular, it changes the manner in which the hormone acts on a newly identified second estrogen receptor, ER beta (ER(beta)). Modrenal(R) is the first drug to be commercially available in a new class of agents that specifically target ER(beta). We intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer. This would target patients that have hormone-sensitive cancers and have become resistant, or refractory, to prior hormone treatments, such as Tamoxifen(R) or aromatase inhibitors. We believe that the potential market for Modrenal(R), based upon the sales of currently available drugs for hormonal therapy for breast cancers, is in excess of \$1.8 billion of sales per annum worldwide. The results of extensive clinical trails to date with Modrenal(R) illustrate that it is at least as effective in second line or third line treatment of advanced breast cancer as the currently available hormonal treatments, such as the SERM's and aromatase inhibitors, and more effective than these agents in certain specific patient types, such as those who have become Tamoxifen(R) refractory. Furthermore, our management currently intends to price Modrenal(R) in such a manner as to make treatment with Modrenal(R)

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### BIOENVISION, INC. AND SUBSIDIARIES

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

compare very favorably, on a price basis, with the cost of treatment with the existing drugs used for second line or third line therapy. We believe that this should result in cost benefits for physicians, patients and health-care systems.

#### Company Status

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this emerging stage. Our management believes that we have the opportunity to become a leading oncology-focused pharmaceutical company in the next five years if we successfully bring our two lead drugs to market. We anticipate that revenues derived from the two lead drugs will permit us to further develop the twelve other products and potential products currently in our development portfolio. We currently plan to have as many as twelve products at market by the end of 2006. We have commenced marketing one of our lead products, Modrenal(R), and we intend to continue developing our existing platform technologies with a primary business focus on drugs to treat cancer, and commercializing products derived from such technologies. A key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. As a result of the

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acquisition of Pathagon Inc. in February 2002, we have several anti-infective technologies. These include the OLIGON(R) technology, an advanced biomaterial that has been approved for certain indications by the FDA in the U.S., and is being sold by a product co-development partner, and the use of thiazine dyes, such as methylene blue, which are used for in vitro and in vivos inactivation of pathogens (viruses, bacteria and fungus) in biological fluids. It is not the Company's strategy to sell devices or to expand into the anti-infective market per se, but the technology obtained in the Pathagon acquisition has specific application for support of the cancer patient and oncology treatment. We have had discussions with potential product co-development partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans. In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. In May 2003, we entered into a Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed the marketing and development rights to modrestane, solely with respect to animal health applications, in the United States and Canada, to Dechra. We received \$1.25 million in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try and exploit these types of opportunities as they arise.

You should consider the likelihood of our future success to be highly speculative in light of our limited operating history, as well as the limited resources, problems, expenses, risks and complications frequently encountered by similarly situated companies. To address these risks, we must, among other things:

- 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 commercialize products;
- o establish and maintain our client base;
- o continue to develop new products and upgrade our existing products;
- o respond to industry and competitive developments; and
- o attract, retain, and motivate qualified personnel.

We may not be successful in addressing these risks. If we were unable to do so, our business prospects, financial condition and results of operations would be materially adversely affected. The likelihood of our success must be considered in light of

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BIOENVISION, INC. AND SUBSIDIARIES

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

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### OPERATION - CONTINUED

the development cycles of new pharmaceutical products and technologies and the competitive and regulatory environment in which we operate.

### Results of Operations

We have acquired development and marketing rights to a portfolio of four platform technologies developed over the past fifteen years, from which a range of products have been derived and additional products may be developed in the future. Although we intend to commence marketing our lead product, Modrenal (TM), and to continue developing our existing platform technologies and commercializing products derived from such technologies, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. Once a product or technology has been launched into the market for a particular disease indication, we plan to work with numerous collaborators, both pharmaceutical and clinical, in the oncology community to extend the permitted uses of the product to other indications. In order to market our products effectively, we intend to develop marketing alliances with strategic partners and may co-promote and/or co-market in certain territories.

The Company reported revenues of \$829,041 and \$209,091 for the three-month period ended September 30, 2003 and 2002, respectively. The increase is primarily attributable to the payment received from our co-development partner, ILEX, of \$775,000, which represented a reimbursement of Research and Development costs incurred through August 31, 2003.

Research and development costs for the three-months ended September 30, 2003 and 2002 were \$ 803,900 and \$ 519,867, respectively, an increase of \$284,033. This increase is primarily attributable to the increase in drug development activities related to clorfarabine and modrenal European development in the three months ended September 30, 2003.

Selling ,general and administrative expenses (including stock based compensation of \$1,284,646 and \$97,500 for the three months ended September 30, 2003 and September 30, 2002, respectively) for the three-months ended September, 2003 and 2002 were \$2,438,088 and \$1,144,756 respectively, an increase of \$1,293,332. The increase is primarily attributable to the Company's increased sales and marketing activities since the May 2002 financing, the option re-pricing, the Company's re-constituting its wholly-owned subsidiary, Bioenvision, Ltd. as a fully operational sales and marketing subsidiary, salaries of newly-added employees, rent both at the Company's new principal executive offices in New York, New York and new rental facility for its sales and marketing subsidiary in Edinburgh, Scotland, travel expenses, insurance costs and other customary costs associated with our becoming an operating company.

Depreciation and amortization expense for the three-month period ended September 30, 2003 was \$339,621 compared to the three-month period ended September 30, 2002 of \$332,338. The increase in amortization is related to the amortization of certain intangible assets acquired by the Company in connection with its acquisition of Pathagon.

### Liquidity and Capital Resources

We anticipate that we may continue to incur significant operating losses for the foreseeable future. There can be no assurance as to whether or when we will generate material revenues or achieve profitable operations. We are actively seeking strategic alliances in order to develop and market our range of products.

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We received an initial payment from Dechra of \$1,250,000 on May 13, 2003 upon execution of our sub-license agreement with Dechra. This agreement expires upon expiration of the last patent related to modrenal or the completion of the last royalty obligation as set forth therein.

On September 30, 2003, we have cash and cash equivalents of \$7,013,946 and working capital of \$5,074,146 which management believes will be sufficient to continue currently planned operations over the next 12 months. Although we do not currently intend to raise any additional funds for the next 12 months, we can not ensure additional funds will not be raised during such period because of the significant scale up of our operating activities, including clofarabine development and the launch of modrenal.

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### BIOENVISION, INC. AND SUBSIDIARIES

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

Further, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. We are not presently considering any such transactions, and we do not presently expect to acquire any significant assets over the coming 12 month period, but if any such opportunity arises and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

The Company has the following commitments as of September 30, 2003:

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

In management's opinion, cash flows from operations and borrowing capacity combined with cash on hand will provide adequate flexibility for funding the Company's working capital obligations for the next twelve months. However, there can be no assurance that suitable debt or equity financing will be available for the Company. The Company has a commitment under its operating lease with the New York office. The Company leases 3,299 square feet under a lease that expires on September 30, 2005. The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision, Ltd.

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. In the event of a voluntary or involuntary liquidation or dissolution of the Company, before any distribution of assets shall be made to the holders of the Company's securities which are junior to the preferred stock (such as the common stock), holders of the preferred stock shall be paid out of the assets of the Company legally available for distribution to the Company's stockholders an amount per share equal to the initial original issue price (\$3.00) subject to certain adjustments plus all accrued but unpaid dividends on such preferred stock.

Subsequent Events

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In October 2003, the Company, through its wholly-owned subsidiary, Bioenvision Limited, entered into an Employment Agreement with Mr. Hugh S. Griffith, pursuant to which Mr. Griffith continues to serve in his capacity as Commercial Director (Europe) of the Company. Under this contract, the term is six months, with automatic six-month extensions thereafter unless either party provides written notice to the contrary. The employment agreement provides for an initial base salary of (pound)120,000 per annum, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to employees of the Company or its subsidiaries. In addition, Mr. Griffith received options to purchase 300,000 shares of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.45 per share, which vest in equal installments on the first, second and third anniversary of the date of the agreement.

In October 2003, the Company, through its wholly-owned subsidiary, Bioenvision Limited, entered into an Employment Agreement with Mr. Ian Abercrombie, pursuant to which Mr. Abercrombie continues to serve in his capacity as Sales Manager (Europe) of the Company. Under this contract, the term is six months, with automatic six-month extensions thereafter unless either party provides written notice to the contrary. The employment agreement provides for an initial base salary of (pound)75,000 per annum, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to employees of the Company or its subsidiaries. In addition, Mr. Abercrombie received options to purchase 50,000 shares of the Company's common stock, par value \$.001 per share, at an exercise price of \$1.29 per share, which vest in equal installments on the first and second anniversary of the date of the agreement.

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### ITEM 4. CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

An evaluation of the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q was made under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer. Based upon this evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q the Company's disclosure controls and procedures (a) are effective to ensure that information required to be disclosed by the Company in reports filed or submitted under the Exchange Act is timely recorded, processed, summarized and reported and (b) include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in reports filed or submitted under the Exchange Act is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

#### Changes in Internal Controls

There was no change in our "internal control over financial reporting" (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting

BIOENVISION, INC. AND SUBSIDIARIES

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleges a breach of contract by the Company and demands judgment against the Company for \$112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary judgment and RLB filed its response on October 27, 2003. On November 12, 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. No assurance can be given that RLB will not appeal the court's decision, but management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations.

Item 2. Changes in Securities

None

Item 3. Defaults upon Senior Securities

None

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

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

Item 5. Other information

There is no other information to report that is material to the Company's financial condition not previously reported.

Item 6. Exhibits and Reports on Form 8-K

A) Exhibits

- 10.1 Employment Agreement, made effective as of October 23, 2002, by and between Bioenvision Limited and Hugh S. Griffith.
- 10.2 Employment Agreement, made effective as of January 6, 2003, by and between Bioenvision Limited and Ian Abercrombie.
- 31.1 Certification of Christopher B. Wood, Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of David P. Luci, Director of Finance, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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- 32.1 Certification of Christopher B. Wood , Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of David P. Luci, Director of Finance, pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.

(B) Reports on Form 8-K: None.

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### 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, 2003      By: /s/ Christopher B. Wood M.D.  
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Christopher B. Wood M.D.  
Chairman and Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2003      By: /s/ David P. Luci  
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David P. Luci  
Director of Finance and General Counsel  
(Principal Accounting Officer)

### EXHIBIT INDEX

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