

Edgar Filing: BIOENVISION INC - Form 10QSB

BIOENVISION INC
Form 10QSB
February 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 December 31, 2002
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

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 X No
--- ---

As of January 28, 2003, there were 16,887,786 shares of the issuer's common stock, par value \$.001 per share (the "Common Stock") outstanding.

Transitional small Business Disclosure Format (Check One): YES [] No [X]

C O N T E N T S

Condensed Consolidated Balance Sheets
Condensed Consolidated Statements of Operations
Condensed Consolidated Statements of Cash Flows

Edgar Filing: BIOENVISION INC - Form 10QSB

Notes to Condensed Consolidated Financial Statements

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

	December 31, 2002
	----- (unaudited)
ASSETS	
Current assets	
Cash and cash equivalents	\$ 9,619,152
Restricted cash	290,000
Deferred costs - current	
Accounts receivable	50,000
Prepaid expenses	56,767

Total current assets	10,015,919
Property and equipment, net	46,686
Intangible assets, net	16,325,319
Goodwill	4,704,100
Security deposits	79,111

Total assets	\$ 31,171,135 =====
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities	
Accounts payable	\$ 492,534
Accrued expenses	849,359
Accrued dividends payable	573,884
Deferred revenue - current	

Total current liabilities	1,915,777
Deferred tax liability - noncurrent	7,351,800

Total liabilities	9,267,577 -----
Stockholders' equity	
Preferred stock - \$0.001 par value; 5,920,000 shares authorized	

Edgar Filing: BIOENVISION INC - Form 10QSB

and 5,916,966 shares issued and outstanding	5,917
Common stock - par value \$0.01; 50,000,000 shares authorized and 16,887,786 shares issued and outstanding at December 31 and June 30, 2002, respectively	16,887
Additional paid-in capital	45,914,055
Accumulated deficit	(24,185,647)
Accumulated other comprehensive income	152,346

Stockholders' equity	21,903,558

Total liabilities and stockholders' equity	\$ 31,171,135
	=====

The accompanying notes are an integral part of these statements.

- 1 -

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended December 31,		
	2002	2001	2002
	(unaudited)	(unaudited)	(unaudited)
Contract revenue	\$ 209,091	\$ 184,091	\$ 418,000
Costs and expenses			
Research and development	322,481	199,234	842,000
General and administrative	548,231	146,937	1,692,000
Depreciation and amortization	334,683	4,859	667,000
	-----	-----	-----
Total costs and expenses	1,205,395	351,030	3,202,000
Loss from operations	(996,304)	(166,939)	(2,784,000)
Interest income (expense)			
Interest and finance charges		(233,634)	(325,000)
Interest income	40,768		89,000
	-----	-----	-----
	40,768	(233,634)	(235,000)
Net loss before income tax benefit	(955,536)	(400,573)	(3,019,000)
Income tax benefit	152,100		304,000

Edgar Filing: BIOENVISION INC - Form 10QSB

Net loss	(803,436)	(400,573)	(2,715,796)
Cumulative preferred stock dividend	(221,279)		(442,558)
Net loss available to common stockholders	\$ (1,024,714)	\$ (400,573)	\$ (3,158,354)
Basic and diluted net loss per share of common stock	\$ (0.06)	\$ (0.05)	\$ (0.05)
Weighted average shares used in computing basic and diluted net loss per share	16,887,786	8,713,376	16,887,786

The accompanying notes are an integral part of these statements.

-2-

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months ended December 31, 2002 (unaudited)
Cash flows from operating activities	
Net loss	\$ (2,715,796)
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	667,021
Financing charges - noncash	
Amortization of deferred tax liability	(304,200)
Compensation costs - options issued to nonemployees	422,500
Changes in assets and liabilities	
Deferred costs	184,091
Deferred revenue	(368,181)
Accounts payable	58,218
Prepaid expenses	(56,767)
Security deposits	(79,111)
Officer's salary - accrued	
Other accrued expenses and liabilities	(664,497)
Net cash used in operating activities	(2,856,722)

Edgar Filing: BIOENVISION INC - Form 10QSB

Cash flows from investing activities	
Purchase of intangible assets	(67,786)
Capital expenditures	(48,860)
Restricted cash	(290,000)

Net cash used in investing activities	(406,647)

Cash flows from financing activities	
Bank overdraft	
Other liabilities - related party	

Net cash provided by financing activities	-

Net (decrease) increase in cash and equivalents	(3,263,369)

Cash and equivalents, beginning of period	12,882,521

Cash and equivalents, end of period	\$ 9,619,152
	=====
Supplemental disclosure of cash flow information:	
Cash paid during the period for	
Interest	\$ -
	=====

The accompanying notes are an integral part of these statements.

-3-

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

December 31, 2002

(Unaudited)

NOTE A - GENERAL

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(TM). Modrenal(TM) is approved for marketing in the U.K. for advanced breast cancer. The Company's plan is to bring Modrenal(TM) into the 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.

The Company was incorporated as Express Finance, Inc. under the laws of the

Edgar Filing: BIOENVISION INC - Form 10QSB

State of Delaware on August 16, 1996, and changed its name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998.

On February 1, 2002, the Company completed the acquisition of Pathagon, Inc. ("Pathagon"), a privately held company focused on the development of novel anti-infective products and technologies. Pathagon's principal products are OLIGON(TM) and methylene blue. Affiliates of SCO Capital Partners LLC, the Company's financial advisor and consultant, owned 82% of Pathagon prior to the acquisition. The Company acquired 100% of the outstanding shares of Pathagon in exchange for 7,000,000 shares of the Company's Common Stock. The acquisition has been accounted for as a purchase business combination in accordance with Statement of Financial Accounting Standards ("SFAS") 141.

In May 2002, Bioenvision consummated a private placement financing pursuant to which Bioenvision raised gross proceeds of \$17.7 million and issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock, par value \$.001 per share, for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of Common Stock (the "Private Placement"). See Note F below.

Prior to the acquisition of Pathagon and the Private Placement, the Company devoted most of its efforts to establishing a new business (raising capital, research and development, etc.) and had been a development stage enterprise. Management believes it now has the financial resources to market some of the Company's late-stage products, which could lead to significant revenues from royalty payments and sales revenues. Accordingly, the financial statements no longer reflect the required disclosure for a Development Stage Enterprise.

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 December 31, 2002 and the consolidated results of operations for the three months and six months ended December 31, 2002 and 2001, and cash flows for the six months ended December 31, 2002 and 2001.

The condensed consolidated balance sheet at June 30, 2002 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, 2002.

Certain amounts in the 2001 financial statements have been reclassified to conform to the 2002 presentation.

The condensed consolidated results of operations for the three months and six months ended December 31, 2002 and 2001 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

-4-

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

December 31, 2002

(Unaudited)

Edgar Filing: BIOENVISION INC - Form 10QSB

NOTE C - 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 6,234,544 and 4,854,444 shares of common stock have not been included in the calculation of net loss per share for the three months and six months ended December 31, 2002 and 2001, respectively, as their effect would have been antidilutive.

NOTE D - ACQUISITION OF PATHAGON

	December 31, 2002	June 30, 2002
	(unaudited)	
Patent and licensing rights	\$17,520,460	\$17,487,548
Less accumulated amortization	1,195,141	565,756
	\$16,325,319	\$16,921,792
	=====	=====

On February 1, 2002, the Company completed the acquisition of Pathagon. The acquisition was accounted for as a purchase business combination in accordance with SFAS 141. The Company issued 7,000,000 shares of common stock to complete the acquisition, which was valued at \$12,600,000 based on the 5-day average trading price of the stock (\$1.80) surrounding November 22, 2001, the day of the Company's announcement of the agreed-upon acquisition. The acquired patents and licensing rights of OLIGON(TM) and methylene blue (collectively referred to as "Purchased Technologies") were recorded at their fair market value as determined by an outside consultant, which was approximately \$17,576,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of these assets. Since the estimated fair value of the Purchased Technologies was at least equal to the amount paid, the purchase price, net of assumed liabilities, was allocated to Purchased Technologies. The transaction qualified as a tax-free merger that resulted in a difference between the tax basis value of the assets acquired and the fair market value of the patents and licensing rights. As a result, a deferred tax liability was recorded for approximately \$7,909,000. The purchase price exceeded the fair market value of the net assets acquired, resulting in the recording of Goodwill of \$4,704,100. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro forma financials would not be meaningful and thus are not presented.

The Company now has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro and in vivo inactivation of pathogens in biological fluids. Methylene blue is one of only two compounds used commercially to inactivate pathogens in blood products, and is currently used in many European countries to inactivate pathogens in fresh frozen plasma. The Company believes that, as a result of the mechanism of action of its proprietary technology, its systems also have the potential to inactivate many new pathogens before they are identified and before tests have been developed to detect their presence in the blood supply. Because the Company's systems are being designed to inactivate rather than merely test for pathogens, the Company's systems also have the potential to reduce the risk of transmission of pathogens that would remain undetected by testing.

The OLIGON(TM) technology is a patented antimicrobial technology that can be incorporated into the manufacturing process of many implantable devices. The patented process, involving two dissimilar metals (silver and platinum) creates

Edgar Filing: BIOENVISION INC - Form 10QSB

an electrochemical reaction that releases silver ions that destroy bacteria, fungi and other pathogens. The Company intends to commercialize the technology in partnership with leading medical devices manufacturers.

-5-

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

December 31, 2002

(Unaudited)

On May 6, 1997, Baxter Healthcare Corporation, acting through its Edwards Clinical-Care Division ("Edwards"), entered into an Exclusive License Agreement with Implemed, Inc. ("Implemed"), a predecessor in interest to the Company. Pursuant to the terms of the License Agreement, among other things, Edwards licensed certain intellectual property technology relating to the manufacture of antimicrobial polymers from Implemed.

On May 7, 2002, the Company executed an amendment to the original license agreement between Oklahoma Medical Research Foundation ("OMRF") and Bridge Therapeutic Products, Inc. ("BTP"), a predecessor of Pathagon, relating to the licensing of methylene blue. Under the terms of the amendment, OMRF agreed to the assignment of the original license agreement by BTP to Pathagon. Pursuant to the amendment, the Company paid OMRF \$100,000 and issued 200,000 shares of the Company's Common Stock and a five-year warrant to purchase an additional 200,000 shares of Common Stock. The exercise price of the warrant is \$2.33 per share, subject to adjustment. The Company capitalized the costs of approximately \$1,145,600 related to this amendment as an intangible asset and will amortize this asset over the remaining life of the methylene blue license agreement.

NOTE E - LICENSE AND CO-DEVELOPMENT AGREEMENTS

Clofarabine

We have a license from Southern Research Institute, which is located in 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. Under the terms of the agreement with Southern Research Institute, we were 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 us and by Southern Research Institute from the technology. We plan to develop Clofarabine initially for the treatment of leukemia and lymphoma and to study its potential role in the treatment of solid tumors.

To facilitate the development of Clofarabine, we 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). ILEX is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada. The Company retains the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia). The

Edgar Filing: BIOENVISION INC - Form 10QSB

Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. Under the co-development agreement, ILEX will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay ILEX a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. In turn, ILEX, which would have U.S. and Canadian distribution rights, would pay the Company a royalty on sales in the U.S. and Canada. In addition, the Company is entitled to certain milestone payments. 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 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. The Company continues to pay royalties to Southern Research Institute in respect to Clofarabine.

-6-

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

December 31, 2002

(Unaudited)

Modrenal (TM)

We hold an exclusive license, until the expiration of existing and new patents related to Modrenal(TM) (trilostane), to market trilostane in major international territories, and an agreement with a United Kingdom company to co-develop trilostane for other therapeutic indications. Trilostane currently is manufactured by third-party contractors in accordance with good manufacturing practices. We have no plans to establish our own manufacturing facility for trilostane, but will continue to use third-party contractors.

NOTE F - STOCKHOLDERS' TRANSACTIONS

On March 12, 2002, a majority of the Company's stockholders delivered a written consent to authorize amendment of the Company's certificate of incorporation, approved by the Company's Board of Directors, to increase the number of authorized shares of common stock from 25,000,000 to 50,000,000 and to authorize the issuance of 10,000,000 shares of the Company's Preferred Stock. The shareholder action became effective, and the amendment was filed and became effective, on April 30, 2002.

Preferred Stock

On May 7, 2002, the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Participating Preferred Stock, par value \$0.001 per share ("Series A Preferred Stock"). Series A Preferred Stock may be converted into two 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 Preferred Stock also received, in respect of each share of Series A Preferred Stock purchased in the May 2002 Private Placement by the Company, one warrant to purchase one share of the Company's common stock at an initial exercise price of \$2.00, subject to adjustment. The purchasers of Series A Preferred Stock also received certain registration rights.

Edgar Filing: BIOENVISION INC - Form 10QSB

In May 2002, Bioenvision issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock in a private placement financing. The preferred stock has a par value of \$.001 per share and generally carries rights to vote with the holders of common stock as one class on a two-for-one basis. The preferred stock is convertible into the Company's common stock on a two-for-one basis subject to certain adjustments at the earlier to occur of (i) at the election of each holder from and after the issuance date, or (ii) the date at any time after the one-year anniversary of the issuance date upon which both (x) the average of the market price for a share of common stock for thirty consecutive trading days exceeds \$10.00 per share, subject to certain adjustments, and (y) the average of the trading volume for the Company's common stock during such period exceeds 150,000, subject to certain adjustments.

Upon conversion, the holder of the preferred stock will be required to pay to the Company, in cash, a conversion price equal to \$1.50 per share of common stock into which the shares of preferred stock are convertible.

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.

-7-

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

December 31, 2002

(Unaudited)

NOTE G - STOCK-BASED COMPENSATION

In April 2001, in accordance with the terms of the Company's stock option plan, the Company issued the following options at an exercise price of \$1.25 per option share, which immediately vested:

- o A total of 2,200,000 options to employees (Christopher B. Wood - 1,500,000 options; Stuart Smith - 500,000 options; and Thomas Scott Nelson - 200,000 options);
- o A total of 2,654,544 options to certain consultants to the Company; and
- o A total of 500,000 options to Phoenix Ventures, which were issued in connection with a credit facility made available to the Company by Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, a U.K. citizen and one of the Company's stockholders, which facility was terminated in August 2001.

Originally, the terms of the options were that each option could be exercised after April 30, 2001 for a period of three years, whereby the options would no longer be able to be exercised after April 30, 2004 unless otherwise agreed to with the Company. In July 2002, the Company changed the three-year term to a

Edgar Filing: BIOENVISION INC - Form 10QSB

five-year term. The extension of the foregoing options to a five-year term required the Company to record additional compensation, interest and finance charges and consulting fees and expenses of \$422,500 in the quarter ended September 30, 2002.

During the quarter ended September 30, 2002, the Company granted options to a new employee 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.

During the period ended December 31, 2002, the Company granted 800,000 options to employees to purchase 800,000 shares of common stock at an exercise price of \$1.45 per share, which equaled the stock price on the date of grant. The options vest equally over three years on their respective anniversary dates. Additionally, 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.

NOTE H - RELATED PARTY TRANSACTIONS

On December 31, 2002, the Company entered into a one-year employment agreement with its Chairman and Chief Executive Officer, Dr. Christopher Wood. The agreement calls for Dr. Wood to be paid a base salary of \$225,000, and an annual incentive bonus to be determined by the Company's compensation committee and approved by its Board of Directors. In addition, Dr. Wood was issued 500,000 options to purchase 500,000 shares of common stock at an exercise price equal to the average of the high and low bid price on December 31, 2002. Options vest ratably over a three-year period on each anniversary date.

NOTE I - NEW ACCOUNTING PRONOUNCEMENTS

In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." The new statement, which becomes effective December 2002, requires all entities with stock-based employee compensation arrangements to provide additional disclosures in their summary of significant accounting policies note; permits entities changing to the fair value method of accounting for employee stock compensation to choose from one of three transition methods; and requires interim-period pro forma disclosures if stock-based compensation is accounted for under the intrinsic value method in any period presented. The Company is still assessing this new standard but does not believe that it will have a material effect on its results of operations or financial condition upon adoption.

-8-

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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 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.

Summary of Significant Accounting Policies

Financial Reporting Release No. 60, which was released by the Securities and Exchange Commission, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of the consolidated financial statements. In addition, Financial Reporting Release No. 61 was released by the SEC, which requires all companies to include a discussion to address, among other things, liquidity, off-balance sheet arrangements, contractual obligations and commercial commitments. The following discussion is intended to supplement the summary of significant accounting policies as described in Note 1 of the Notes To Condensed Consolidated Financial Statements for the year ended June 30, 2002 included in the Company's annual report on Form 10-KSB for the period then ended.

These policies were selected because they represent the more significant accounting policies and methods that are broadly applied in the preparation of the consolidated financial statements.

Revenue Recognition. Non-refundable up-front payments received in connection with research and development collaboration agreements are deferred and recognized on a straight-line basis over the relevant periods in the agreement, generally the research or development period. Milestone and royalty payments, if any, are recognized pursuant to collaborative agreements upon the achievement of the specified milestones or sales transaction.

Stock Based Compensation - In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation, the Company applies Accounting Principles Board Opinion 25 and related interpretations in accounting for its stock option plan and, accordingly, does not recognize compensation expense for employee stock options granted with exercise prices equal to or greater than fair market value. Non-employee stock-based compensation arrangements are accounted for in accordance with the provisions of SFAS No. 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. Under EITF No. 96-18, as amended, 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

Use of Estimates. The preparation of financial statements in conformity with generally accepted accounting principles of the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates, and such differences may be material to the financial statements.

Overview

We are an emerging biopharmaceutical company. Our primary business focus is the acquisition, development and distribution of drugs to treat cancer. We have a broad range of products and technologies under development, but our two lead drugs are Clofarabine and Modrenal(TM).

Clofarabine

Edgar Filing: BIOENVISION INC - Form 10QSB

Based on third party studies conducted to date, we believe that Clofarabine may be effective in the treatment of leukemia and lymphoma. To expedite the commercialization Clofarabine in North America, we have entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX") under which Phase II clinical trials of Clofarabine are currently being

-9-

BIOENVISION, INC. AND SUBSIDIARIES

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

conducted. In Europe, the European Medicines Evaluation Agency (the "EMEA") granted a clinical trial exemption (a "CTX") and orphan drug designation for acute lymphocytic leukemia ("ALL"), which is held by the Company, and the Company has applied for orphan drug designation for acute myelogenous leukemia ("AML"). The Company plans to commence clinical trials in adult AML and pediatric acute leukemias in the first quarter of calendar year 2003. Receipt of orphan drug designation in Europe provides, for ALL, and would provide, for AML, the Company with a ten-year exclusivity period to market clofarabine for each such indication. Such marketing exclusivity would commence on the date of receipt of marketing approval for each indication. The EMEA granted orphan drug designation for ALL in January 2002 and the drug has also been granted orphan drug designation in the United States. Receipt of orphan drug designation in Europe for any indication includes a significant financial benefit to the Company because the Company is eligible to receive a fee waiver from the EMEA for each indication that receives the orphan drug designation. In addition, the Company has been granted a clinical trials exemption certificate ("CTX") from the Medicines Control Agency ("MCA") in the United Kingdom, which allows clinical trials to be performed with clofarabine.

In January 2003, the Company had a pre-registration meeting with the EMEA regarding its European development strategy, which is part of the global development strategy which the Company has implemented with ILEX for the development of clofarabine. In addition, the Company has retained RRD International LLC as global product development consultants to the Company in connection with the global development strategy for clofarabine and the Company's platform of other products and to assist the Company with its clinical development program for clofarabine and other products. In addition, the Company entered into a Consulting Agreement, dated December 31, 2002, with Dr. Deidre Tessman, pursuant to which Dr. Tessman serves as the Company's agent to administer its CTX and orphan drug designation and is part of the Company's management team which oversees the administration of clinical trials for clofarabine.

Extensive pre-clinical 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(TM) (fludarabine) and Leustatin(TM) (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 AML achieved a complete remission (CR) rate, and ALL patients achieved a 20% CR rate when treated with Clofarabine as a single

Edgar Filing: BIOENVISION INC - Form 10QSB

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).

Modrenal(TM)

We plan to launch Modrenal (TM) in the first calendar quarter of 2003 in the United Kingdom, where we have obtained regulatory approval for its use in the treatment of post-menopausal breast cancer. As noted above, the Company has retained RRD International LLC as global product development consultants to the Company to assist with the global development strategy and clinical development program for its products, including, without limitation, Modrenal (TM). Our management believes that Modrenal(TM) works by a unique action as compared with other commercially available drugs to treat post-menopausal breast cancer. We believe that Modrenal(TM) 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(TM) 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(TM) 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

-10-

BIOENVISION, INC. AND SUBSIDIARIES

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

Tamoxifen(TM) or aromatase inhibitors. We believe that the potential market for Modrenal(TM), 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 trials to date with Modrenal(TM) 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(TM) refractory. Furthermore, our management currently intends to price Modrenal(TM) in such a manner as to make treatment with Modrenal(TM) 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 our development 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

Edgar Filing: BIOENVISION INC - Form 10QSB

our development portfolio. We currently plan to have as many as twelve products at market by the end of 2006. We intend to commence marketing on of our lead products, Modrenal(TM), and 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 acquisition of Pathagon, Inc. in February 2002, we have several anti-infective technologies. These include the OLIGON(TM) 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 anit-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. However, we have established an animal healthcare division to exploit some of those opportunities.

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;

-11-

BIOENVISION, INC. AND SUBSIDIARIES

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

- 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,

Edgar Filing: BIOENVISION INC - Form 10QSB

our business prospects, financial condition and results of operations would be materially adversely affected. The likelihood of our success must be considered in light of the development cycles of new pharmaceutical products and technologies and the competitive and regulatory environment in which we operate.

Results of Operations

We have acquired development and marketing rights to a portfolio of 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 \$209,000 and \$184,000 for the three-month period ended December 31, 2002 and 2001, respectively. For the six months ended December 31, 2002 and 2001 the company reported revenues of \$418,000 and \$368,000. Revenues reflect our agreements with our co-development partners and/or licensees in connection with our platform of drugs and technologies.

Research and development costs for the three-months ended December 31, 2002 and 2001 were \$322,000 and \$199,000, respectively, an increase of \$123,000. The increase is primarily attributable to the increased royalty payments under certain development contracts.

Research and development costs for the six-months ended December 31, 2002 and 2001 were \$842,000 and \$403,000, respectively, an increase of \$439,000. The increase reflects royalty payments under certain development contracts.

General and administrative expenses for the three-months ended December 31, 2002 and 2001 were \$ 548,000 and \$147,000 respectively, an increase of \$401,000. The increase is primarily attributable to rent (\$61,000), travel (\$80,000), printing (\$57,000), and consulting fees (\$290,000).

General and administrative expenses for the six-months ended December 31, 2002 and 2001 were \$1,931,000 and \$304,000, respectively, an increase of \$1,627,000. The increase is primarily attributable to increases in rent (\$64,000), printing (\$57,000) travel (\$136,000), investor relations (\$230,000), professional fees (\$300,000) and consulting fees (\$290,000). These increases, in general, reflect the Company's build out of its management team, operating infrastructure, increased activity related to patents and the launching of the Company's European sales office.

Depreciation and amortization expense for the three-month and six month period ended December 31, 2002 were \$335,000 and \$667,000 compared to the three-month and six-month period ended December 31, 2001 of \$5,000 and \$10,000. The increase in amortization is related to the amortization of certain intangible assets acquired by the Company in connection with its acquisition of Pathagon.

Edgar Filing: BIOENVISION INC - Form 10QSB

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

Liquidity and Capital Resources

We are actively seeking strategic alliances in order to develop and market our range of products. In August 2001, we obtained a \$1 million unsecured line of credit facility from Jano Holdings Limited, bearing interest at 8% per annum. In November 2001, we entered into a senior, Secured Credit Facility with SCO Capital Partners LLC. The credit facility was established for up to \$1,000,000 in short term financing, in four tranches of \$250,000, subject to satisfaction of certain conditions, secured by the pledge of certain of our assets, and was established to bear interest on drawings at a rate of 6% per annum. In addition, our officers agreed to defer salaries, and our former outside counsel agreed to defer certain fees, until we obtained sufficient long-term funding. Deferred salaries and fees amounted to approximately \$52,000 through June 30, 2002. In May 2001, our officers agreed to accept 705,954 shares of our common stock in settlement of \$910,681 of the outstanding accrued salaries through June 30, 2001. The shares were issued during the quarter ended March 31, 2002. On October 17, 2001, our officers agreed to accept 134,035 shares in settlement of \$154,140 of additional outstanding accrued salaries to September 30, 2001. On October 17, 2001, the board of directors approved a plan to repay certain trade debt with shares of our common stock, and a total of 146,499 shares of common stock were issued for the repayment of \$168,473.

We received initial payment from ILEX of \$1,350,000 which became non-refundable in March 2001 upon execution of the agreement with ILEX to co develop clofarabine. That sum will be recognized as income for accounting purposes on a straight line basis over the period from March 2001, when the payment was received, through December 31, 2002, when ILEX was scheduled to complete Phase II trials of clofarabine and make another payment to us. The Company is currently in discussions with ILEX regarding the status of this scheduled payment. A total of \$184,000 of that payment was recognized as contract revenue for the three-month period ended December 31, 2002.

On May 7, 2002 the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Participating Preferred Stock, par value \$0.001 per share ("Series A Preferred Stock"). Series A Preferred Stock may be converted into two 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, issuance's of cheap stock and other similar transactions. Holders of Series A Preferred Stock also received, in respect of each share of Series A Preferred Stock purchased in the May 2002 Private Placement, one warrant to purchase one share of the Company's common stock at an initial exercise price of \$2.00, per share subject to adjustment. The purchasers of Series A Preferred Stock also received certain registration rights.

Through May 16, 2002, Bioenvision sold an aggregate of 5,916,666 shares of Series A 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 \$17,500,000. 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 \$1,610,000 related to the transaction.

Our management believes that our net proceeds from the May 2002 private placement will be sufficient to continue currently planned operations over the next 12 months, and we will not intend to raise any additional funds during that period in order to fund operations. However, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new

Edgar Filing: BIOENVISION INC - Form 10QSB

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 or sell any significant assets over the coming 12 month period, but if any such opportunity presents itself and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose. We plan to utilize a portion of the proceeds of the May 2002 private placement to conduct clinical trials of our receptor modulation drug, trilostane, in the treatment of breast and prostate cancer. Further laboratory studies will be conducted to examine the effect of the drug on the hormone receptor.

The Company anticipates 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.

-13-

BIOENVISION, INC. AND SUBSIDIARIES

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

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.

Plan of Operation

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 intend to commence marketing one of our lead products, Modrenal(TM), and to continue developing 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.

On December 1, 2002, the Company appointed Mr. Ian Abercrombie to serve as Sales Manager (Europe). Mr. Abercrombie has joined Mr. Hugh Griffith, who serves as the Company's Commercial Director (Europe) and, together, Messrs. Griffith and Abercrombie are creating a worldwide marketing strategy for the Company's products and commencing the marketing of Modrenal (TM) in the United Kingdom. Further, Messrs. Griffith and Abercrombie are designing plans to expand the Company's marketing strategy throughout the European Community and to commence

Edgar Filing: BIOENVISION INC - Form 10QSB

pre-registration marketing activities with clofarabine worldwide, except for North America.

In addition, the Company entered into a Consulting Agreement, dated December 31, 2002, with Dr. Deidre Tessman, pursuant to which Dr. Tessman serves as the Company's agent to administer its CTX and orphan drug designation, in each case, for clofarabine, and is part of the Company's management team which oversees the administration of clinical trials for clofarabine.

In December 2002, the Company's scientific advisory board convened at the meeting of the American Society of Hematologists in Philadelphia, PA and reviewed the clinical trial results to date and planned future clinical trials for clofarabine.

In addition, a provisional product license has been granted in the United Kingdom for the use of trilostane for the treatment of Cushing's disease in dogs. In November 2001, we granted to Arnolds Ltd., a major distributor of animal products in the United Kingdom, the right to market the drug for a six month trial period, after which time, if the results were satisfactory to Arnolds, we would enter into a licensing arrangement whereby Arnolds would pay royalties to us on sales from April 2002 onward. During the trial period, Arnolds has posted more than \$400,000 of sales of the drug, which is marketed in the United Kingdom as Veteryl(TM).

We also plan to utilize 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 for ALL and the Company has applied for orphan drug designation in Europe for AML.

-14-

BIOENVISION, INC. AND SUBSIDIARIES

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

We plan to identify licensing partners for OLIGON(TM) 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 that confirms proof of principal of our gene therapy technology and has added to the pre-clinical data that 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.

Subsequent Events

In January 2003, the Company entered into an agreement with RRD International LLC ("RRD"), pursuant to which RRD serves as the global product development consultant to the Company in connection with the development of clofarabine, Modrenal (TM) and OLIGON and assists with designing and managing the Company's clinical development program for the Company's products. The Company and RRD intend to further memorialize their agreement pursuant to a formal Master

Edgar Filing: BIOENVISION INC - Form 10QSB

Services Agreement which the parties intend to finalize and execute in the first quarter of calendar year 2003. The parties agreed that RRD would be granted a warrant to acquire 175,000 shares of the Company's Common Stock at an exercise price of \$2.00 per share

ITEM 4. CONTROLS AND PROCEDURES

Based on their evaluation, as of a date within 90 days of the filing of this Form 10-QSB, the Company's Chief Executive Officer and Director of Finance have concluded the Company's disclosure controls and procedures (as defined in Rules 13a-14 and 15d-14 under the Securities Exchange Act of 1934) are effective. There have been no significant changes in internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

-15-

BIOENVISION, INC. AND SUBSIDIARIES

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

There are currently no pending legal proceedings against the Company.

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

- 3.1 Amended and Restated Bylaws
- 10.1 Employment Agreement, dated as of December 31, 2002, by and between the Company and Dr. Christopher B. Wood
- 99.1 Certificate of Chief Executive Officer
- 99.2 Certificate of Chief Accounting Officer

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

-16-

SIGNATURES

Edgar Filing: BIOENVISION INC - Form 10QSB

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

Date: February 14, 2002

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

Date: February 14, 2002

By: /s/ David P. Luci
David P. Luci
Director of Finance and General Counsel
(Principal Accounting Officer)

Certificate of Chief Executive Officer.

I, Christopher B. Wood, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Bioenvision, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14 for the registrant and have:
 - a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c. presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b. any fraud, whether or not material, that involves management or other

Edgar Filing: BIOENVISION INC - Form 10QSB

- employees who have a significant role in the registrant's internal controls; and
- The registrant's other certifying officers and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: February 14, 2003

/s/Christopher B. Wood

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

Certificate of Chief Accounting Officer.

I, David P. Luci, certify that:

- I have reviewed this quarterly report on Form 10-QSB of Bioenvision, Inc.;
- Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
- Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
- The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14 for the registrant and have:
 - designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
- The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- The registrant's other certifying officers and I have indicated in this

Edgar Filing: BIOENVISION INC - Form 10QSB

quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: February 14, 2003

/s/ David P. Luci

David P. Luci
Director of Finance, General Counsel
and Corporate Secretary
(Principal Accounting Officer)

EXHIBIT INDEX

Exhibit No.

- 3.1 Amended and Restated Bylaws of Bioenvision, Inc.
- 10.1 Employment Agreement, dated December 31, 2002, by and between Bioenvision, Inc. and Dr. Christopher B. Wood
- 99.1 Certificate of Chief Executive Officer
- 99.2 Certificate of Chief Accounting Officer