

Edgar Filing: BIOENVISION INC - Form 10QSB

BIOENVISION INC
Form 10QSB
November 14, 2002

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-QSB

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

For the quarterly period ended September 30, 2002

Commission File # 0-24875

BIOENVISION, INC.

(Exact name of registrant 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

As of October 25, 2002, the following shares of the Registrant's common stock, par value \$.001 per share (the "Common Stock"), were issued and outstanding: 16,887,786 shares of Common Stock

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

INDEX

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed Consolidated Balance Sheets	1
Condensed Consolidated Statements of Operations	2
Condensed Consolidated Statements of Cash Flows	3
Note A. General	4
Note B. Interim Financial Statements	4

Edgar Filing: BIOENVISION INC - Form 10QSB

Note C. Net Loss Per Share	4
Note D. Acquisition of Pathagon	5
Note E. License and Co-Development Agreements	6
Note F. Stockholders' Transactions	7
Note G. Stock-Based Compensation	7
Item 2. Management's Discussion and Analysis or Plan of Operation	9
Item 4. Controls and Procedures	14
PART II - OTHER INFORMATION	
Item 1. Legal Proceedings	15
Item 2. Changes in Securities	15
Item 3. Defaults upon Senior Securities	15
Item 4. Submission of Matters to a Vote of Security Holders	15
Item 5. Other information	15
Item 6. Exhibits and Reports on Form 8-K	15
SIGNATURES	

Bioenvision, Inc. and Subsidiaries
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 200
ASSETS	-----
Current assets	
Cash and cash equivalents	\$ 10,
Restricted cash	
Deferred costs - current	
Accounts receivable	
Prepaid expenses	

Total current assets	11,
Property and equipment, net	
Intangible assets, net	16,
Goodwill	4,
Security deposits	

Total assets	\$ 32,

Edgar Filing: BIOENVISION INC - Form 10QSB

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities	
Accounts payable	\$ 1,
Accrued expenses	
Accrued dividends payable	
Directors loans payable	
Officers salaries	
Deferred revenue	

Total current liabilities	2,
Deferred tax liability - non current	7,

Total liabilities	9,

Stockholders' equity	
Preferred stock- \$0.001 par value; 5,920,000 authorized and 5,916,966 shares issued and outstanding	
Common stock - par value \$0.01; authorized 50,000,000 and shares issued and outstanding 16,887,786 shares at September 30 and June 30, 2002, respectively	
Additional paid-in-capital	45,
Accumulated deficit	(23,
Accumulated other comprehensive income	

Stockholders' equity	22,

Total liabilities and stockholders' equity	\$ 32,
	=====

The accompanying footnotes are an integral part of these financial statements

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	200

	(unaud
Contract revenue	\$

Costs and expenses	
Research and development	
General and administrative	1,
Interest and finance charges, net	

Edgar Filing: BIOENVISION INC - Form 10QSB

Depreciation and amortization	-----
Total costs and expenses	2,
Other income	
Net loss before income tax benefit	(2,
Income tax benefit	-----
Net loss	(1,
Cumulative preferred stock dividend	(
Net loss available to common stockholders	\$ (2,
Basic and diluted net loss per share	=====
Weighted average shares used in computing basic and diluted net loss per share	16,
	=====

The accompanying footnotes are an integral part of these financial statements

Bioenvision, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	200

	(unaud
Cash flows from operating activities	
Net loss	\$ (1,
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	
Amortization of deferred tax liability	(
Compensation costs - options issued to nonemployees	
Noncash interest and finance charge - options issued	
Changes in assets and liabilities	
Accounts receivable	
Deferred financing fees	
Deferred costs	
Deferred revenue	(
Accounts payable	
Prepaid expenses	(
Security deposits	(

Edgar Filing: BIOENVISION INC - Form 10QSB

Officer's salary for equity conversion	
Accrued dividends payable	
Other accrued expenses and liabilities	(

Net cash used in operating activities	(1,

Cash flows from investing activities	
Capital expenditures	
Restricted cash	(

Net cash used in investing activities	(

Cash flows from financing activities	
Loan payable	
Bank overdraft	

Net cash provided by financing activities	-----
Net (decrease) increase in cash and equivalents	(1,
Cash and cash equivalents, beginning of period	12,

Cash and cash equivalents, end of period	\$ 10,
	=====
Supplemental disclosure of cash flow information	
Interest paid	\$
	=====

The accompanying footnotes are an integral part of these financial statements

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

September 30, 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 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.

Edgar Filing: BIOENVISION INC - Form 10QSB

("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 SFAS 141.

Prior to the acquisition of Pathagon and the May 2002 private placement in which the Company raised gross proceeds of \$17.7 million, 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 September 30, 2002 and the consolidated results of operations for the three months ended September 30, 2002 and 2001, and cash flows for the three months ended September 30, 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 2002 and 2001 financial statements have been reclassified to conform to the 2002 presentation.

The consolidated results of operations for the three months ended September 30, 2002 and 2001 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

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 5,234,544 and 4,854,444 shares of common stock have not been included in the calculation of net loss per share for the three months ended September 30, 2002 and 2001, respectively, as their effect would have been antidilutive.

- 4 -

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

September 30, 2002

(Unaudited)

Edgar Filing: BIOENVISION INC - Form 10QSB

NOTE D - ACQUISITION OF PATHAGON

	September 30, 2002	June 30, 2002
	-----	-----
	(unaudited)	
Patent and licensing rights	\$ 17,452,673	\$ 17,487,548
Less: accumulated amortization	862,794	565,756
	-----	-----
	\$ 16,589,879	\$ 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 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.

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

- 5 -

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

September 30, 2002

(Unaudited)

NOTE E - LICENSE AND CO-DEVELOPMENT AGREEMENTS

Clofarabine

We have a license from Southern Research Institute, 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 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

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

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.

Deferred revenue

As of September 30, 2002, the Company reported deferred revenue of \$184,091 related to the contract with ILEX. The Company is 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.

Deferred costs

Deferred costs represent costs that are associated with the negotiation and execution of the co-development agreement with ILEX. Since the revenue related to the co-development agreement will be realized over the life of the agreement, the Company has deferred the costs related to the ILEX agreement. The Company will amortize such costs ratably, on a straight-line basis concurrent with development activities through December 2002. As of September 30, 2002, the Company has deferred costs of \$92,046.

- 6 -

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

September 30, 2002

(Unaudited)

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

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.

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 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.

- 7 -

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

September 30, 2002

(Unaudited)

Edgar Filing: BIOENVISION INC - Form 10QSB

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 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 period 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 \$2.00 per share, which equaled the stock price on the date of grant.

- 8 -

BIOENVISION, INC. AND SUBSIDIARIES

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

The information set forth in this Report on Form 10-QSB including, without limitation, that contained in this Item 2, Management's Discussion and Analysis and 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 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 recently 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 recently 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 Consolidated Financial Statements for the year ended June 30, 2002 included in the Company's annual report on Form 10-KSB.

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.

Edgar Filing: BIOENVISION INC - Form 10QSB

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

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, 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. 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.

- 9 -

BIOENVISION, INC. AND SUBSIDIARIES

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

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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).

Modrenal(TM)

We plan to launch Modrenal(TM), by late 2002 in the United Kingdom, where we have obtained regulatory approval for its use in the treatment of post-menopausal breast cancer. 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 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 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

BIOENVISION, INC. AND SUBSIDIARIES

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

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

Results of Operations

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

- 11 -

BIOENVISION, INC. AND SUBSIDIARIES

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

The Company reported revenues of \$209,000 and \$184,000 for the three-month periods ended September 30, 2002 and 2001, respectively. 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-month period ended September 30, 2002 and 2001 were \$520,000 and \$204,000, respectively. The increase in research and development costs is primarily attributable to the anticipated increase in drug development activities resulting from the capital obtained in connection with the May 2002 financing.

Administrative expenses for the three-month period ended September 30, 2002 and 2001 were \$1,145,000 and \$157,000, respectively. The increase in administrative expenses of approximately \$988,000 is primarily attributable to a \$98,000 non-cash stock based compensation charge resulting from the extension of the terms of certain options issued to consultants during the quarter ended September 30, 2002. The extension of the terms of certain options also resulted in a non-cash stock based interest charge of \$325,000. The Company also incurred legal and other professional fees of approximately \$700,000 and salaries of \$141,000 during the three-months ended September 30, 2002.

Depreciation and amortization expense totaled \$332,000 and \$5,000 for the three-month period ended September 30, 2002 and 2001, respectively. 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 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

Edgar Filing: BIOENVISION INC - Form 10QSB

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 is scheduled to complete Phase II trials of clofarabine and make another payment to us. A total of \$184,000 of that payment was recognized as contract revenue for the three-month period ended September 30, 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 technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. We are not presently

- 12 -

BIOENVISION, INC. AND SUBSIDIARIES

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

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.

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.

Edgar Filing: BIOENVISION INC - Form 10QSB

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.

- 13 -

BIOENVISION, INC. AND SUBSIDIARIES

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

Subsequent Events

Mr. Hugh Griffith commenced employment with Bioenvision Ltd., a wholly owned subsidiary of the Company, on October 6, 2002. Mr. Griffith will serve as Commercial Director (Europe) and will be responsible for Bioenvision's marketing campaign for modrenal, which is approved in the United Kingdom for the treatment of advanced post-menopausal breast cancer, and for Bioenvision's sales and marketing initiatives for all other approved products throughout Europe which, initially, includes methylene blue and OLIGON.

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.

- 14 -

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

Edgar Filing: BIOENVISION INC - Form 10QSB

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

- 99.1 Certificate of Chief Executive Officer
- 99.2 Certificate of Chief Accounting Officer

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

- 15 -

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, 2002 By: /s/ Christopher B. Wood M.D.
Christopher B. Wood M.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: November 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.;

Edgar Filing: BIOENVISION INC - Form 10QSB

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 employees who have a significant role in the registrant's internal controls; and
6. 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: November 14, 2002

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:

1. I have reviewed this quarterly report on Form 10-QSB of Bioenvision, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue

Edgar Filing: BIOENVISION INC - Form 10QSB

- 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 employees who have a significant role in the registrant's internal controls; and
 6. 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: November 14, 2002

/s/ David P. Luci

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

EXHIBIT INDEX

Exhibit No.

- 99.1 Certificate of Chief Executive Officer
- 99.2 Certificate of Chief Accounting Officer

