

Edgar Filing: BIOENVISION INC - Form 10QSB/A

BIOENVISION INC
Form 10QSB/A
August 09, 2002

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

Amendment No. 2
To
FORM 10-QSB/A

[X] Quarterly Report pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

For the quarterly period ended March 31, 2002

File # 0-24875

BIOENVISION, INC.

(Exact name of registrant as specified in its charter)

Delaware

State of Incorporation

13-4025857

IRS Employer ID No.

One Rockefeller Plaza, Suite 1600, New York, NY 10020

(Address of principal Executive Offices)

Registrant's Telephone Number (212) 445-6582

Check here whether the issuer (1) has filed all reports required to be
filed by Sections 13 or 15(d) of the Securities Exchange Act of 1934 during the
preceding 12 months (or for 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 April 30, 2002, the following shares of the Registrant's common
stock were issued and outstanding: Common Stock, \$0.001 par value per share
16,687,786.

INDEX

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Edgar Filing: BIOENVISION INC - Form 10QSB/A

Condensed Consolidated Balance Sheets	1
Condensed Consolidated Statements of Operations	2
Condensed Consolidated Statements of Cash Flows	3
Note A. Organization and Significant Accounting Policies	4
Note B. Property, Plant, and Equipment	5
Note C. Patent and Licensing Rights	6
Note D. License and Co-Development Agreement	7
Note E. Stockholders' Transactions	7
Note F. Related Party Transactions	8
Note G. Subsequent Events	9
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	10
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	16

Bioenvision, Inc. and Subsidiaries
(a Development Stage company)

Condensed Consolidated Balance Sheets

ASSETS

Current assets
 Cash
 Deferred costs
 Deferred financing costs

Total current assets

Edgar Filing: BIOENVISION INC - Form 10QSB/A

	March 31,		March 31,	
	2002	2001	2002	
Contract revenue	\$ 184,091	\$ 1,108,000	\$ 552,273	\$
Costs and expenses				
Research & development costs	283,805	1,015,327	687,020	
Administrative expenses	185,181	277,875	488,837	
Interest and finance charges	458,628	4,909	912,258	
Depreciation and amortization	231,982	296	241,699	
	1,159,596	1,298,407	2,329,814	
Net loss	\$ (975,505)	\$ (190,407)	\$ (1,777,541)	\$
Basic & diluted net loss per share	\$ (0.07)	\$ (0.02)	\$ (0.17)	\$
Weighted average shares used in computing basic and diluted net loss per share	14,045,109	7,976,419	10,435,997	

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

- 2 -

Bioenvision, Inc. and Subsidiaries
(a Development Stage company)

Condensed Consolidated Statements of Cash Flow
(Unaudited)

	Nine months ended March 31, 2002
Cash flows from operating activities	
Net loss	\$ (1,777,541)

Edgar Filing: BIOENVISION INC - Form 10QSB/A

Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	241,699
Financing charges - non-cash	906,125
Gain on sale of fixed assets	--
Provision of free rent	--
Compensation cost for options issued to non employees	--
Compensation cost for shares issued to non employees	--
Changes in operating assets and liabilities	
Accounts receivable	--
Deferred costs	276,136
Deferred revenue	(552,273)
Accounts payable	(28,810)
Officers' salaries	105,067
Other accrued expenses and liabilities	(1,434)
Net cash used in operating activities	(831,031)
Cash flows from investing activities	
Capital expenditures, net	--
Proceeds from sale of fixed assets, net	--
Purchase of intangible assets	--
Net cash used in investing activities	--
Cash flows from financing activities	
Bank overdraft	33,094
Proceeds from issuance of common stock	--
Loan financing	797,937
Net cash provided by financing activities	831,031
Effect of exchange rate on cash	--
Net increase in cash and equivalents	--
Cash and equivalents, beginning of year	--
Cash and equivalents, end of year	--
Supplemental disclosure of cash flow information	
Interest paid	\$ 1,625
Supplemental disclosure of non-cash financing and investing activities:	
Non cash issuance of warrants related to Jano financing agreement	\$ --
Non cash conversion of officers salary into common stock	910,681
Non cash conversion of trade payables into common stock	322,613
Non cash issuance of warrants related to SCO financing agreement	1,755,000
Non cash issuance of stock related to Pathagon acquisition	12,600,000

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

Edgar Filing: BIOENVISION INC - Form 10QSB/A

BIOENVISION, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2002

(Unaudited)

NOTE A - ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Description of business:

Bioenvision, Inc. ("Bioenvision" or "the Company") is a development stage biopharmaceutical company whose primary business focus is the acquisition, development and distribution of products and technologies for the treatment of cancer. The Company has acquired development and marketing rights to a portfolio of four platform technologies. These platforms have resulted in the development of the Company's two leading products, Modrenal(R) and clofarabine, as well as twelve other products that are in various stages of development. The Company has received regulatory approval in the United Kingdom to market Modrenal(R) for the treatment of post-menopausal breast cancer. In January 2002, the Company's European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. A co-development partner has also applied for orphan drug status in the United States of America for clofarabine. The application is currently pending.

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. ("Pathagon"), the successor in interest to Bridge Blood Technologies L.L.C., d/b/a Pathagon, a privately held company focused on the development of novel anti-infective products and technologies. Pathagon's principal products, OLIGON(R) and methylene blue, are ready for market. 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. With the acquisition, the Company adds rights to OLIGON(R) and methylene blue to its portfolio of products.

Basis of presentation:

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Inter-company accounts and transactions have been eliminated. The financial information included in these financial statements is unaudited but, in the opinion of management, reflects all normal recurring adjustments necessary for a fair presentation of the results for the interim periods. The interim results of operations and cash flows are not necessarily indicative of those results and cash flows for the entire year. These financial statements should be read in conjunction with the financial statements and notes to the financial statements contained in the Annual Report on Form 10-K for the fiscal year ended June 30, 2001 of the Company. The balance sheet information as of June 30, 2001 has been derived from audited statements at that date.

Operations to date and financing plans:

Edgar Filing: BIOENVISION INC - Form 10QSB/A

The Company plans to continue to fund its development expenses through additional capital raising activities, including one or more offerings of equity and/or debt through private placements and/or public offerings. The Company is also actively seeking strategic alliances in order to develop and market its range of products.

In August 2001, the Company obtained an unsecured financing facility with Jano Holdings for \$1,000,000, bearing interest at a rate of 8% per annum. The Company had utilized approximately \$290,000 of the available facility as of March 31, 2002. Accrued interest on the facility utilized amounted to \$9,811 as of March 31, 2002.

In November 2001, the Company announced the appointment of SCO Financial Group LLC as its financial advisor, and that SCO Capital Partners LLC ("SCO Capital") extended a \$1 million secured credit line (the "Facility") to the Company. The Facility provides for up to \$1,000,000 in short term financing available in four tranches of \$250,000, subject to criteria, conditions, and covenants set forth in the agreement. The Facility is secured by the pledge of certain assets of the Company and bears interest at a rate of 6% per annum. The Company had utilized the maximum availability through March 31, 2002 of \$500,000 as of March 31, 2002. Accrued interest on the facility utilized amounted to \$8,125 as of March 31, 2002.

The Company's officers and former outside counsel have agreed to defer salaries and certain fees, respectively, until the Company has obtained sufficient long-term funding. Deferred salaries and fees amounted to approximately \$105,000 through March 31, 2002. In May 2001, the Company's officers agreed to accept 705,954 shares of the Company's 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, the Company's 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 Company's Board approved a plan to repay certain trade debt with shares of the Company's common stock, and a total of 146,499 shares of common stock were issued for the repayment of \$168,473.

- 4 -

BIOENVISION, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2002

(Unaudited)

NOTE A - ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES - continued

In May 2002, the Company sold shares of its newly-created Series A Convertible Participating Preferred Stock to raise capital (the "May 2002 Private Placement"). Through May 14, 2002, the Company has sold 5,683,332 shares of Series A Convertible Participating Preferred Stock in the May 2002 Private Placement for aggregate gross proceeds of \$17,049,999. A portion of the proceeds were used to repay the Jano Holdings and SCO Capital obligations as well as the deferred salaries and fees amounting to \$105,000 and fees related to the transaction. (See note G)

Edgar Filing: BIOENVISION INC - Form 10QSB/A

Foreign currency translation

Through June 30, 2001, the functional currency of the Company was the Pound Sterling and its reporting currency was the United States dollar. Translation adjustments arising from differences in exchange rates from these transactions were reported as accumulated other comprehensive income in stockholders' equity (deficit). Effective July 1, 2001, the functional and reporting currency is the United States dollar.

Impact of recently issued accounting pronouncements

In August 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". This statement is effective for fiscal years beginning after December 31, 2001. This supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of", while retaining many of the requirements of such statement. The Company does not believe that this statement will have a material effect on the Company's financial statements.

NOTE B - PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consists of the following:

	March 31, 2002
Office equipment	\$ 4,303
Motor vehicles	36,603

	40,906
Less: Accumulated depreciation	36,894

	\$ 4,012
	=====

- 5 -

BIOENVISION, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2002

(Unaudited)

NOTE C - PATENT AND LICENSING RIGHTS

	March 31, 2002
Patent and licensing rights	\$ 12,660,122
Less: Accumulated amortization	161,538

	\$ 12,498,584
	=====

On February 1, 2002, the Company completed the acquisition of Pathagon. The

Edgar Filing: BIOENVISION INC - Form 10QSB/A

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) from November 22, 2001, the day of the Company's announcement of the agreed upon acquisition. The purchase price was allocated to the acquired patent and licensing rights of OLIGON(R) and methylene blue, respectively, net of assumed liabilities of \$108,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of these assets. No goodwill was recorded on the transaction. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro-forma results and balances since the beginning of the fiscal year are not materially different. Amortization of patents and licensing rights amounted to \$161,538 for the three months ended March 31, 2002, and for the next five fiscal years will amount to approximately: June 30, 2002, 406,000; 2003, 974,000; 2004, 974,000; 2005, 974,000; 2006, 974,000.

The Company now has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro and in vivos 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(R) 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 which destroy bacteria, fungi and other pathogens. The Company intends to commercialize the technology in partnership with leading medical devices manufacturers.

NOTE D - LICENSE AND CO-DEVELOPMENT AGREEMENTS

Southern Research Institute

In August 1998, Southern Research Institute, Birmingham, Alabama, entered into an agreement with a wholly-owned subsidiary of the Company, which was subsequently assigned to the Company, to co-develop purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. Under the terms of a co-development agreement with Southern Research Institute, the Company acquired the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by the Company and by Southern Research Institute from the technology. The lead compound of these purine-based nucleosides is known as clofarabine.

Ilex Oncology, Inc.

In March 2001, the Company entered into a co-development agreement with Ilex Oncology, Inc. ("Ilex") on March 9, 2001 for the development of clofarabine.

Edgar Filing: BIOENVISION INC - Form 10QSB/A

Under the terms of that co-development agreement, Ilex is required to pay all development costs of clofarabine in the United States of America ("United States") and Canada, and 50% of approved development costs worldwide outside the United States 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 has retained the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia). The Company also retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. Assuming completion of development responsibilities by Ilex, the Company will pay Ilex a royalty on sales of clofarabine outside the United States, Canada, Japan and Southeast Asia, and Ilex will have United States and Canadian distribution rights and will pay the Company a royalty on sales of clofarabine in the United States and Canada. In addition, the Company is entitled to receive certain milestone payments from Ilex. 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 upon an average price of the Company's common stock around the date of exercise. Under the co-development agreement, Ilex also pays royalties to Southern Research Institute based upon achievement of certain milestones. The Company continues to pay royalties to Southern Research Institute in respect to clofarabine.

- 6 -

BIOENVISION, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2002

(Unaudited)

NOTE D - LICENSE AND CO-DEVELOPMENT AGREEMENTS - continued

As of March 31, 2002, the Company has reported deferred revenue of \$552,273 related to the contract with Ilex Oncology Inc. 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 represents royalty payments that became due and payable upon the Company's execution of the co-development agreement with Ilex Oncology. 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 March 31, 2002, the Company has deferred costs of \$245,455.

In January 2002, the Company's European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Ilex has also applied for orphan drug status in the United States for clofarabine. The application is currently pending.

Dana Farber

Edgar Filing: BIOENVISION INC - Form 10QSB/A

On August 20, 2001 the Company entered into a three year agreement with Dana-Farber / Partners Cancer Care, Inc., ("DF/PCC"). The agreement calls for DF/PCC to conduct a clinical study of trilostane. The Company holds an exclusive license, until the expiration of existing and new patents related to trilostane, to market trilostane in major international territories, and an agreement with a United Kingdom company to co-develop trilostane for other therapeutic indications. The DF/PCC study will be a Phase II study of trilostane for androgen independent prostate cancer. The Company has agreed to provide DF/PCC with a \$40,000 grant in support of the study.

Note E - STOCKHOLDERS' TRANSACTIONS

In August 2001, the Company issued 208,333 shares to officers of the Company.

In August 2001, the Company converted 150,000 of options previously issued to outside consultants to 150,000 shares of common stock.

In October 2001, the Company issued 134,035 shares to officers as payment for salaries accrued to September 30, 2001. In October 2001, the Company issued 146,499 shares as payment for trade payables to certain creditors.

In connection with securing the Facility with SCO Capital in November 2001, the Company issued warrants to purchase 1,500,000 shares of the Company's common stock at a strike price of \$1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The Company measured the fair market value of the warrants and recorded deferred financing costs of \$1,755,000, which will be amortized over the term of the Facility. During the quarter ended March 31, 2002, the Company recorded interest expense of \$438,750 relating to the amortization of such costs. Unamortized costs amounted to \$1,096,875 as of March 31, 2002.

Additional warrants to acquire 1,500,000 shares with similar terms were also granted to SCO Capital. The warrants expired unexercised on February 16, 2002 and could only have been exercised if the Company had failed to complete the acquisition of Pathagon. On February 1, 2002 the Company completed the acquisition of Pathagon.

- 7 -

BIOENVISION, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2002

(Unaudited)

Note E - STOCKHOLDERS' TRANSACTIONS - continued

On February 1, 2002, in connection with the Company's acquisition of Pathagon, the Company issued 7,000,000 shares of its common stock. In connection with the closing of the acquisition of Pathagon, the Company also entered into Registration Rights Agreements with the persons or entities, who were shareholders of Pathagon registering the offer and resale of the shares of common stock issued in the acquisition. The Company is required to prepare and file with the U.S. Securities and Exchange Commission a registration statement

Edgar Filing: BIOENVISION INC - Form 10QSB/A

on Form SB-1 or such other form as may then be available and appropriate for use by the Company to register the offer and resale of those shares upon the earlier to occur of (a) the date which is six (6) months after February 1, 2002, or (b) the Company's preparation and filing of a registration statement to register the offer and resale of securities of the Company in connection with any other financing. Those shareholders also have certain demand registration and piggyback registration rights. However, each shareholder party to the Registration Rights Agreement also agreed not to dispose of any securities in a market transaction, if so requested by the Company or any underwriters managing an underwritten offering of the Company's securities, or any regulatory authority, for 180 days from the effective date of such registration with respect to the underwriter's request or such longer period as requested by any such regulatory authority.

On March 12, 2002, a majority of the Company's shareholders 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.

In March 2002, the Company issued 735,984 shares of common stock to its officers and directors as payment for salaries accrued through June 30, 2001 of \$910,000.

NOTE F - RELATED PARTY TRANSACTIONS

On September 8, 1998, the Company entered to an agreement with Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, whereby Glen Investments agreed to loan funds to the Company on an as-needed basis based upon previously agreed budgets. Mr. Leech is a private investor who is also the sole owner of Phoenix Ventures Limited, a Guernsey (Channel Islands) corporation and the holder of approximately 19% of the outstanding shares of common stock of the Company. The loan facility was not utilized during the year and was terminated in August 2001. In connection with this facility, the residual finance charge of \$207,500 related to the remaining life of the facility was amortized through August 2001.

Included in accounts payable and accrued liabilities are interest free loans payable to Christopher B. Wood, the Company's Chairman of the Board and Chief Executive Officer, amounting to \$124,338 as of March 31, 2002.

In May 1998, Bioheal Limited, a subsidiary of Bioenvision, entered into an agreement with Mr. Wood to co-develop a gene marker and immunomodulator system for use in gene therapy and related technologies. Under the terms of the agreement, Bioheal was granted the exclusive license to make, use and sell products derived from technology, and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by Bioheal and its collaborators from the technology for a term expiring on the date of expiration of all current and future patents covered by the agreement, subject to earlier termination under certain circumstances. In consideration of the licenses granted to Bioheal, Bioheal agreed to pay to Dr. Wood, among other things, a royalty of 10% of the gross sales revenues of all products, less and discounts or deductions for value-added taxes. In addition, Bioheal has agreed to pay, among other things, certain costs associated with pre-clinical development and clinical trials of such products. Under the terms of the agreement, the pre-clinical costs are not to exceed \$1,500,000, and the clinical trial costs are not to exceed \$4,000,000, unless agreed by both parties.

BIOENVISION, INC. AND SUBSIDIARIES
(A Development Stage Company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2002

(Unaudited)

NOTE G - SUBSEQUENT EVENTS

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 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 demand and piggyback registration rights.

Through May 14, 2002, the Company has sold 5,683,332 shares of Series A Convertible Participating Preferred Stock in the May 2002 Private Placement \$3.00 per share, resulting in aggregate gross proceeds of \$17,049,999. A portion of the proceeds to the Company were used to retire the outstanding loan obligations to Jano Holdings and SCO Capital, and the related credit facilities were terminated. A portion of the proceeds were also used to repay deferred salaries and fees to officers of the Company amounting to \$105,000.

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. The Company is required to pay OMRF \$100,000 and issue 200,000 shares of the Company's common stock and a five-year warrant to purchase an additional 200,000 shares of common stock and an annual license fee of \$10,000. The exercise price of the warrant is \$2.33 per share, subject to adjustment.

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

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

Edgar Filing: BIOENVISION INC - Form 10QSB/A

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, 2001 included in the Company's annual report on Form 10-K.

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

Bioenvision is an emerging biopharmaceutical company. Our primary business focus is the acquisition, development and distribution of drugs to treat cancer. Our two lead drugs are Modrenal(R), which is our first product to receive regulatory approval (in the United Kingdom) for marketing for treatment of post-menopausal breast cancer treatment, and clofarabine, which we licensed from Southern Research Institute in 1998. To facilitate our development of clofarabine, we

Edgar Filing: BIOENVISION INC - Form 10QSB/A

entered into a co-development agreement with Ilex Oncology, Inc. ("Ilex") in March 2001, under which Phase II clinical trials of clofarabine are currently being conducted. In January 2002, the Company's European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Ilex has also applied for orphan drug status in the United States of America ("United States") for clofarabine. The application is currently pending. We have made solid progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have continued to incur losses during this 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 market and distribute our two lead drugs. We anticipate that revenues derived from the two lead drugs will permit us to further develop the twelve other 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 our lead product, Modrenal(R), 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, but 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 are also developing anti-infective technologies, including the OLIGON(R) technology, an advanced biomaterial that has been approved for certain indications by the FDA in the U.S., and is being sold by Edwards Lifesciences Corp. (NYSE:EW), and the use of thiazine dyes, such as methylene blue, which we intend to commercialize for in vitro and in vivo inactivation of pathogens in biological fluids.

- 10 -

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

We plan to commence marketing our first lead product, Modrenal(R), by late 2002 in the United Kingdom, where we have obtained regulatory approvals for its use in the treatment of post-menopausal breast cancer. Modrenal(R) has a unique and previously unrecognized mode of action and is the first drug in a new class of agents that modulates hormone binding to the newly described second estrogen receptor, ER. We intend to seek regulatory approval for Modrenal(R) in the United States as a second line therapy for hormone sensitive breast cancers. We believe that the potential market for Modrenal(R), based upon the sales of currently available drugs for hormonal therapy for breast cancers, is in excess of \$1.8 billion of sales per annum worldwide. The results of extensive clinical trials to date with Modrenal(R) show that it is at least as effective in second 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-refractory. Furthermore, our management currently intends to price Modrenal(R) in such a way as to make treatment with Modrenal(R) compare very favorably, on a price basis, with the cost of treatment with the existing drugs used for second line therapy. We believe that this should result in cost benefits for physicians, patients and health-care systems.

Modrenal(R) has other applications as well. We expect to commence marketing Modrenal(R) in other European countries for the treatment of Cushing's disease in the second quarter of 2002, and in the United States for the treatment of Cushing's disease in the third quarter of 2002, subject to obtaining the necessary regulatory approvals.

Based on third party studies conducted to date, we believe that our second lead

Edgar Filing: BIOENVISION INC - Form 10QSB/A

product, clofarabine, may be effective in the treatment of leukemia and lymphoma. To expedite the commercialization of our second lead product, clofarabine, we have recently entered into a co-development agreement with Ilex.

At a recent IX International Workshop On Chronic Lymphocytic Leukemia (IWCLL), in San Diego, Professor William Plunkett from the Leukemia Section of the MD Anderson Cancer Center presented an update on the metabolic effects of clofarabine, a new purine nucleoside analogue that is currently in advanced clinical trials for acute leukemia. Cellular pharmacodynamic data from Dr. Plunkett's group was also presented in abstract form at the 93rd Annual Meeting of the American Association of Cancer Research (AACR) in San Francisco. The data presented at both forums reinforces previous study results suggesting that clofarabine has novel anti-cancer activity and a pharmacokinetic/dynamic profile that clearly differentiates it from other currently marketed purine analogues such as Fludara(R) (fludarabine) and Leustatin(R) (cladribine).

Extensive preclinical and mechanistic studies, like the work presented, have provided much of the rationale for the rapidly advancing clofarabine clinical development program. Preliminary results from two ongoing advanced clinical studies, indicate that clofarabine may be an effective treatment for acute relapsed/refractory leukemias in adult and pediatric patients. According to researchers at the MD Anderson Cancer Center, interim Phase II study results showed that adults with acute myelogenous leukemia (AML) achieved a 45 percent CR rate and acute lymphocytic leukemia (ALL) patients achieved a 20 percent CR rate when treated with clofarabine as a single agent. Data from a separate Phase I dose-escalation study demonstrated a 45 percent CR rate in children with acute leukemias who were refractory to previous therapy. Trials in pediatric acute leukemias are currently ongoing in the US and are planned to commence in Europe later this year.

Clofarabine exhibits the mechanistically favorable properties of both Fludara and cladribine in terms of DNA chain termination and inhibition of ribonucleotide reductase, respectively. In several preclinical models, when compared to Fludara, clofarabine has shown several-fold greater lymphocytic potency. It also appears to work through a unique additional mechanism, whereby it directly damages the mitochondria in cancer cells and induces apoptosis (Blood 2000 96: 3537). Additionally, because clofarabine is a potent inhibitor of DNA repair, the Company, along with its North American licensee ILEX, plans to explore the potential use of clofarabine in combination with DNA damaging agents. This type of strategy has already been validated through the combination of Fludara with Cytosan (cyclophosphamide) in the treatment of CLL.

With the completion of the acquisition of Pathagon in February 2002, the Company acquired patent and licensing rights of OLIGON(R) and methylene blue. The Company now has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro and in vivos 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.

- 11 -

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

Edgar Filing: BIOENVISION INC - Form 10QSB/A

OF OPERATIONS - continued

The OLIGON(R) 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 which destroy bacteria, fungi and other pathogens. The Company intends to commercialize the technology in partnership with leading medical devices manufacturers.

We have had discussions with potential product co-development partners over the past year and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans.

We are considered a development-stage company for accounting purposes because we have not generated any material revenues to date. Accordingly, we have no relevant operating history upon which an evaluation of our performance and prospects can be made. We are prone to all of the risks to the establishment of any new business venture. 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

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(R), 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

Edgar Filing: BIOENVISION INC - Form 10QSB/A

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 \$184,000 and \$1,108,000 for the three-month periods ended March 31, 2002 and 2001, respectively. For the nine months ended March 31, 2002 and 2001, the Company reported revenues of \$552,000 and \$1,358,000, respectively. Revenues reflect the Company's agreement with Ilex. Research and development costs for the three-month and nine month period ended March 31, 2002 were \$284,000 and \$687,000, respectively, compared to the three-month and nine-month period ended March 31, 2001 of \$1,015,000 and \$1,441,000, respectively. Administrative expenses for the three month and nine-month period ended March 31, 2002 were \$185,000 and \$489,000, respectively, a decrease of \$304,000 and \$592,000 from the three and nine month periods ended March 31, 2001 of \$278,000 and \$870,000, respectively. The decrease reflects the Company's reduction of its non-development expenses until additional funding is secured. Administrative expenses are comprised mainly of legal, accounting and other professional fees. The Company reported interest and finance charges of \$912,000 for the nine months ended March 31, 2002, an increase of \$900,000 from the nine months ended March 31, 2001. This increase reflects deferred charges related to the Company's financing agreement in August 2001, with Kevin Leech and SCO Capital in November 2001. Depreciation and amortization expense totaled \$232,000 and \$242,000 in the three and nine-month period ended March 31, 2002, respectively, compared to \$300 and \$8,000 in the three and nine-month period ended March 31, 2001, respectively. The increase in amortization is related to the amortization of certain intangible assets acquired by the Company in its acquisition of Pathagon.

- 12 -

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

Liquidity and Capital Resources

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.

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. As of March 31, 2002, the Company has utilized \$290,000 of the facility. In November 2001, the Company entered into a senior, Secured Credit Facility (the "Facility") with SCO Capital Partners LLC. The 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 assets of the Company, and was established to bear interest on drawings at a rate of 6% per annum. As of March 31, 2002 the Company had utilized \$500,000 of the available facility. In addition, the Company's officers agreed to defer salaries, and our former outside counsel agreed to defer certain fees, until the Company obtained sufficient long-term funding. Deferred salaries and fees amounted to approximately \$105,000 through March 31, 2002. In May 2001, the Company's officers agreed to accept 705,954 shares of the Company's 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, the Company's officers agreed to accept 134,035 shares in settlement

Edgar Filing: BIOENVISION INC - Form 10QSB/A

of \$154,140 of additional outstanding accrued salaries to September 30, 2001. On October 17, 2001, the Company's Board approved a plan to repay certain trade debt with shares of the Company's 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 \$552,000 of that payment was recognized as contract revenue for the nine-month period ended March 31, 2002.

On May 7, 2002 the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Preferred Stock. The Series A Preferred Stock may be converted into shares of common stock at an initial conversion price of \$1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A 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 subject to adjustment. The purchasers of Series A Preferred Stock also received certain demand and piggyback registration rights.

Through May 14, 2002 the Company has sold 5,683,332 shares of Series A Convertible Participating Preferred Stock in the May 2002 Private Placement for \$3.00 per share, resulting in aggregate gross proceeds of \$17,049,999. A portion of the proceeds were used to repay the Jano Holdings and SCO Capital obligations, upon which those facilities were terminated as well as to repay deferred salaries and fees amounting to \$105,000 and to pay fees and expenses related to the transaction.

Plan of Operation

Our management believes that the net proceeds to the Company from the May 2002 Private Placement will be sufficient to continue currently planned operations over the next 12 months, and the Company 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 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 the interests of the Company to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

- 13 -

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

We are a development stage biopharmaceutical company with a primary business focus on the acquisition, development and distribution of drugs to treat cancer. 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.

Edgar Filing: BIOENVISION INC - Form 10QSB/A

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. ("Arnolds"), 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. Arnolds has licensed the drug from us for sale in the United Kingdom market in consideration of a payment of a 10% royalty to us on sales from April 2002.

We also plan to utilize a portion of the proceeds of the May 2002 Private Placement to initiate clinical trials of clofarabine in Europe. The emphasis will be on the use of clofarabine in the treatment of refractory acute leukemia in children and adults. The drug has received orphan drug designation in Europe.

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

In order to implement our business plan, we anticipate utilizing a portion of the proceeds of the May 2002 Private Placement to hire several key executives over the next few months, including a Chief Operating Officer and a Financial Officer, and to locate those individuals, as well as our President, in the United States. We also plan to gradually hire additional personnel to manage regulatory affairs, investor relations and certain administrative functions.

Recent Accounting Pronouncements

In August 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". This statement is effective for fiscal years beginning after December 31, 2001. This supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of", while retaining many of the requirements of such statement. The Company does not believe that this statement will have a material effect on the Company's financial statements.

- 14 -

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

There are currently no pending legal proceedings against the Company.

Item 2. Changes in Securities

During the quarter ended March 31, 2002, the Company issued 7,000,000 shares of common stock related to the acquisition of Pathagon. In March 2002, the Company issued 735,984 shares of common stock to its officers and directors as payment for salaries accrued through June 20, 2001 of \$910,000. The issuances of these securities were exempt from the registration requirements of the Securities Act under Section 4(2) and Regulation D of the Securities Act, as a transaction by an issuer not involving a public offering.

Item 3. Defaults upon Senior Securities

Edgar Filing: BIOENVISION INC - Form 10QSB/A

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:

Exhibit
No.

99.1 CEO Certification
99.2 CFO Certification

(b) Reports on Form 8-K:

The registrant filed a report on Form 8-K/A on January 8, 2002, reporting the closing of a credit facility with SCO Capital Partners.

The registrant filed a report on form 8-K on February 21, 2002 with respect to the Company's acquisition of Pathagon Inc., the successor in interest to Bridge Therapeutic Products, Inc.

The registrant filed a report on form 8-K/A on April 16, 2002, which included financial information of Pathagon as well as certain Pro-forma financial information.

- 15 -

SIGNATURES

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

Date: August 9, 2002 By: /s/ Christopher B. Wood, M.D.
Christopher B. Wood, M.D.
President.

/s/ Thomas S. Nelson, C.A.
Thomas S. Nelson C.A.
Chief Financial Officer

End of Filing

- 16 -