

Edgar Filing: BIOENVISION INC - Form 10-Q

BIOENVISION INC  
Form 10-Q  
November 09, 2006

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2006

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

Commission File # 0-24875

BIOENVISION, INC.  
(Exact name of issuer as specified in its charter)

Delaware  
-----  
State or other jurisdiction  
of incorporation or organization

13-4025857  
-----  
IRS Employer ID No.

345 Park Avenue, 41st Floor, New York, NY 10154  
-----

(Address of principal executive offices)

(212) 750-6700  
-----

(Issuer's Telephone Number)

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding twelve months (or such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by checkmark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of October 19, 2006, there were 41,458,616 shares of the issuer's common stock, par value \$.001 per share (the "Common Stock") outstanding.

C O N T E N T S

Edgar Filing: BIOENVISION INC - Form 10-Q

| PART I FINANCIAL INFORMATION  | Page |
|---|------|
|   | ---- |
| Item 1. Consolidated Financial Statements   |      |
| Condensed Consolidated Balance Sheets -<br>As of September 30, 2006 (Unaudited) and June 30, 2006                               | 2    |
| Condensed Consolidated Statements of Operations (Unaudited) -<br>For the three months ended September 30, 2006 and 2005         | 3    |
| Condensed Consolidated Statement of Stockholders' Equity (Unaudited) -<br>For the three months ended September 30, 2006         | 4    |
| Condensed Consolidated Statements of Comprehensive Loss (Unaudited) -<br>For the three months ended September 30, 2006 and 2005 | 4    |
| Condensed Consolidated Statements of Cash Flows (Unaudited) -<br>For the three months ended September 30, 2006 and 2005         | 5    |
| Notes to Condensed Consolidated Financial Statements (Unaudited)  | 6    |
| Item 2. Management's Discussion and Analysis of Financial Condition<br>and Results of Operations                                | 13   |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk  | 18   |
| Item 4. Controls and Procedures   | 18   |
| PART II OTHER INFORMATION   |      |
| Item 1. Legal Proceedings   | 19   |
| Item 1A. Risk Factors   | 19   |
| Item 2. Unregistered Sales of Equity Securities and Use of Proceeds   | 19   |
| Item 3. Defaults Upon Senior Securities   | 19   |
| Item 4. Submission of Matters to a Vote of Security Holders   | 19   |
| Item 5. Other Information   | 19   |
| Item 6. Exhibits  | 20   |
| SIGNATURES  |      |

BIOENVISION, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

September 30,

Edgar Filing: BIOENVISION INC - Form 10-Q

|  | 2006          |
|--|---------------|
|  | -----         |
| ASSETS   | (unaudited)   |
| Current assets   |               |
| Cash and cash equivalents  | \$ 4,215,118  |
| Short-term securities  | 31,562,264    |
| Accounts receivable, less allowances of \$899,000  | 3,233,091     |
| Inventories  | 425,402       |
| Other current assets   | 1,460,491     |
|  | -----         |
| Total current assets   | 40,896,366    |
| Property and equipment, net  | 288,193       |
| Intangible assets, net   | 7,337,322     |
| Goodwill   | 1,540,162     |
| Other assets   | 897,051       |
| Deferred costs   | 3,463,197     |
|  | -----         |
| Total assets   | \$ 54,422,291 |
|  | =====         |
| LIABILITIES AND STOCKHOLDERS' EQUITY   |               |
| Current liabilities  |               |
| Accounts payable   | \$ 3,154,171  |
| Accrued expenses   | 8,064,329     |
| Accrued dividends payable  | 57,328        |
| Deferred revenue   | 513,662       |
|  | -----         |
| Total current liabilities  | 11,789,490    |
| Other liabilities  | 703,074       |
| Deferred revenue   | 6,942,306     |
|  | -----         |
| Total liabilities  | 19,434,870    |
|  | -----         |
| Commitments and contingencies  |               |
| Stockholders' equity   |               |
| Convertible participating preferred stock - \$0.001 par value;<br>20,000,000 shares authorized; 2,250,000 shares issued and<br>outstanding at September 30, 2006 and June 30, 2006 (liquidation<br>preference \$6,750,000) | 2,250         |
| Common stock - par value \$0.001; 70,000,000 shares authorized;<br>41,458,616 and 41,456,616 shares issued and outstanding at<br>September 30, 2006 and June 30, 2006, respectively  | 41,459        |
| Additional paid-in capital   | 134,229,990   |
| Accumulated deficit  | (98,778,030)  |
| Receivable from stockholder  | (300,000)     |
| Accumulated other comprehensive loss   | (208,248)     |
|  | -----         |
| Total stockholders' equity   | 34,987,421    |
|  | -----         |
| Total liabilities and stockholders' equity   | \$ 54,422,291 |
|  | =====         |

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

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

-2-

### BIOENVISION, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

|  | Three months<br>September<br>2006<br>----- |
|--|--|
| Revenue  |  |
| Product sales  | \$ 1,874,494                               |
| Licensing and royalty revenue  | 990,078                                    |
| Research and development contract revenue  | -  |
|  | -----                                      |
| Total revenue  | 2,864,572<br>-----                         |
| Costs and expenses   |  |
| Cost of products sold, including royalty expense of \$361,000 and \$201,000 for the three months ended September 30, 2006 and 2005, respectively | 422,728                                    |
| Research and development   | 9,269,582                                  |
| Selling, general and administrative  | 5,468,891                                  |
| Depreciation and amortization  | 241,700                                    |
|  | -----                                      |
| Total costs and expenses   | 15,402,901<br>-----                        |
| Loss from operations   | (12,538,329)                               |
| Interest and finance charges   | (47,684)                                   |
| Interest income  | 460,319                                    |
|  | -----                                      |
| Net loss   | (12,125,694)                               |
| Preferred stock dividend   | (85,068)                                   |
|  | -----                                      |
| Loss applicable to common stockholders   | \$ (12,210,762)<br>=====                   |
| Basic and diluted net loss per share applicable to common stockholders   | \$ (0.29)                                  |

Edgar Filing: BIOENVISION INC - Form 10-Q

|   |            |
|---|------------|
| Weighted average shares used in computing<br>basic and diluted net loss per share | 41,456,942 |
|---|------------|

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

-3-

BIOENVISION, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2006  
(unaudited)

|   | Convertible<br>Participating<br>Preferred<br>Shares | Amount   | Common Stock<br>Shares | Amount    | Additional<br>Paid-in<br>Capital | Accumulated<br>Deficit |       |
|---|---|----------|------------------------|-----------|----------------------------------|------------------------|-------|
|   | -----   | -----    | -----                  | -----     | -----                            | -----                  | ----- |
| Balance at July 1, 2006                                       | 2,250,000   | \$ 2,250 | 41,456,616             | \$ 41,457 | \$133,604,996                    | \$ (86,567,268)        | \$    |
| Net loss for the period                                       |   |          |                        |           |                                  | (12,125,694)           |       |
| Cumulative preferred<br>stock dividend                        |   |          |                        |           |                                  | (85,068)               |       |
| Currency translation<br>adjustment                            |   |          |                        |           |                                  |                        |       |
| Due from stockholder  |   |          |                        |           |                                  |                        |       |
| Employee and board of<br>director stock-based<br>compensation |   |          |                        |           | 622,496                          |                        |       |
| Warrants exercised for<br>common stock                        |   |          | 2,000                  | 2         | 2,498                            |                        |       |
| Balance at September 30,<br>2006                              | 2,250,000   | \$ 2,250 | 41,458,616             | \$ 41,459 | \$134,229,990                    | \$ (98,778,030)        | \$    |
|   | =====   | =====    | =====                  | =====     | =====                            | =====                  | ===== |

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
(unaudited)

Edgar Filing: BIOENVISION INC - Form 10-Q

|  | Three months ended<br>September 30, |                |
|--|-------------------------------------|----------------|
|  | 2006                                | 2005           |
|  | ----                                | ----           |
| Loss applicable to common stockholders | \$ (12,210,762)                     | \$ (4,889,660) |
| Foreign currency translation loss      | (55,140)                            | (49,440)       |
|  | -----                               | -----          |
| Comprehensive Loss                     | \$ (12,265,902)                     | \$ (4,939,100) |
|  | =====                               | =====          |

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

-4-

BIOENVISION, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(unaudited)

|   | Three mo<br>Septe |
|---|-------------------|
|   | 2006              |
|   | -----             |
| Cash flows from operating activities:   |                   |
| Net loss  | \$ (12,125,694)   |
| Adjustments to reconcile net loss to net<br>cash used in operating activities |                   |
| Depreciation and amortization   | 241,700           |
| Stock-based compensation  | 622,496           |
| Deferred revenue  | (128,418)         |
| Deferred costs  | 60,300            |
| Changes in operating assets and liabilities:                                  |                   |
| Accrued interest on investments   | (428,619)         |
| Accounts receivable   | (775,451)         |
| Inventories   | 15,414            |
| Other current assets  | (597,774)         |
| Other assets  | (173,308)         |
| Accounts payable and accrued expenses   | 3,015,713         |
| Other liabilities   | 703,074           |
|   | -----             |
| Net cash used in operating activities   | (9,570,567)       |
| Cash flows from investing activities:   |                   |
| Additions to intangible assets  | -                 |
| Capital expenditures  | (41,692)          |
| Redemption of short-term securities   | 10,503,461        |
| Purchase of short-term securities   | -                 |
|   | -----             |
| Net cash provided by (used in) investing activities                           | 10,461,769        |

Edgar Filing: BIOENVISION INC - Form 10-Q

|   |              |
|---|--------------|
| Cash flows from financing activities:                 |              |
| Proceeds from exercise of options and warrants        | 2,500        |
| Due from shareholder                                  | 40,606       |
| Dividends paid  | (84,144)     |
|   | -----        |
| Net cash used in financing activities                 | (41,038)     |
| Effect of exchange rates on cash and cash equivalents | (12,983)     |
|   | -----        |
| Net increase (decrease) in cash and cash equivalents  | 837,181      |
| Cash and cash equivalents, beginning of period        | 3,377,937    |
|   | -----        |
| Cash and cash equivalents, end of period              | \$ 4,215,118 |
|   | =====        |

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

-5-

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

NOTE 1 - Basis of Presentation

Description of Business

The Company is a product-oriented biopharmaceutical company primarily focused upon the acquisition, development, distribution and marketing of compounds and technologies for the treatment of cancer, autoimmune disease and infection. Its product pipeline includes Evoltra(R) (Clofarabine), Modrenal(R) (for which Bioenvision has obtained regulatory approval for marketing in the United Kingdom for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy), and certain anti-infective technologies including the OLIGON(R) technology; an advanced biomaterial that has been incorporated into various Federal Drug Administration, or FDA, approved medical devices and Suvus(R), an antimicrobial agent currently in clinical development for refractory chronic hepatitis C infection.

Basis of Presentation

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of normal recurring adjustments, necessary to present fairly the condensed consolidated financial position of the Company as of September 30, 2006, the condensed consolidated statements of operations for the three months ended September 30, 2006 and 2005, the condensed consolidated statement of stockholders' equity for the three months ended September 30, 2006, and the condensed consolidated statements of cash flows for the three months ended September 30, 2006 and 2005.

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

The condensed consolidated balance sheet at June 30, 2006 has been derived from the audited consolidated financial statements at that date, but does not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. For further information, refer to the audited consolidated financial statements and footnotes thereto included in the Form 10-K filed by the Company for the year ended June 30, 2006.

The condensed consolidated results of operations for the three months ended September 30, 2006 and 2005 are not necessarily indicative of the results to be expected for any other interim period or for the full year. Certain reclassifications of balances previously reported have been made to conform to the current presentation.

### Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact, if any, of the provisions of SFAS 157.

On September 13, 2006, the Securities and Exchange Commission "SEC" issued Staff Accounting Bulletin No. 108 ("SAB 108"). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a potential current year misstatement. Prior to SAB 108, companies might evaluate the materiality of financial statement misstatements using either the income statement or balance sheet approach, with the income statement approach focusing on new misstatements added in the current year, and the balance sheet approach focusing on the cumulative amount of misstatement present in a company's balance sheet. Misstatements that would be material under one approach could be viewed as immaterial under another approach, and not be corrected. SAB 108 now requires that companies view financial statement misstatements as material if they are material according to either the income statement or balance sheet approach. The Company has analyzed SAB 108 and determined that it will have no impact on the reported results of operations or financial condition of the Company.

### NOTE 2 - Accounting for Stock-based Compensation

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



# Edgar Filing: BIOENVISION INC - Form 10-Q

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

### NOTE 2 - Accounting for Stock-based Compensation - continued

the grant date fair value estimated in accordance with the provisions of SFAS 123 (R). Prior to the adoption of SFAS 123 (R), the Company had accounted for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees", as permitted by SFAS 123. Under APB Opinion No. 25, no stock-based employee compensation cost was reflected in reported net loss, when options granted to employees have an exercise price equal to or greater than the market value of the underlying common stock at the date of grant.

Upon adoption of SFAS 123 (R), beginning July 1, 2005, the Company reversed the unrecognized deferred compensation costs associated with options granted to certain employees of approximately \$136,000 with a corresponding reduction to the Company's additional paid-in capital. The Company also no longer re-measures the intrinsic value of the 380,000 re-priced options granted to an officer of the Company. The Company recognizes compensation expense for stock option awards to employees based on their grant-date fair value. The Company recorded, as a component of net loss, employee stock-based compensation expense of \$614,000 and \$459,000 for the three months ended September 30, 2006 and 2005, respectively. As of September 30, 2006, the total compensation cost related to unvested equity awards granted to employees but not yet recognized is approximately \$3,460,000. There were no option grants to employees during the three months ended September 30, 2006. The weighted average fair value per share for stock options granted to employees during the three months ended September 30, 2005 was \$4.64. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model which incorporates the following weighted average assumptions:

|   | Three Months Ended<br>September 30,<br>-----<br>2005<br>----- |
|---|---|
| Risk-free interest rate                   | 3.99%-4.07%   |
| Expected weighted average term (in years) | 3.5   |
| Expected weighted average volatility      | 80%   |
| Expected dividend yield                   | 0%  |

As required by SFAS 123 (R), management made an estimate of expected forfeitures for all unvested awards and is recognizing compensation costs only for those equity awards expected to vest. This cost will be amortized on a straight-line basis over the remaining weighted average vesting period of 1.7 years.

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

|                         | Number<br>of Shares<br>----- | Weighted<br>Average<br>Exercise Price<br>----- | Weighted<br>Average<br>Remaining<br>Contractual<br>Life<br>---- | Aggr<br>Intr<br>Val<br>--- |
|-------------------------|------------------------------|--|---|----------------------------|
| Balance - June 30, 2006 | 4,641,000                    | \$ 4.24  | 4.44  | \$ 11,27                   |
| Granted                 | -                            |  |   |                            |

Edgar Filing: BIOENVISION INC - Form 10-Q

|                                  |           |         |      |          |
|----------------------------------|-----------|---------|------|----------|
| Exercised                        | -         |         |      |          |
| Cancelled                        | -         |         |      |          |
| Forfeited                        | (10,000)  | 8.05    |      |          |
|                                  | -----     |         |      |          |
| Balance - September 30, 2006     | 4,631,000 | 4.23    | 6.88 | \$ 11,22 |
|                                  | =====     |         |      |          |
| Exercisable - September 30, 2006 | 3,253,000 | \$ 3.09 | 6.09 | \$ 6,00  |

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 (R) and EITF No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services." Under EITF No. 96-18, where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument.

-7-

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

NOTE 3 - Accounts Receivable

Our accounts receivable are primarily due from wholesale distributors and our co-development partners. One customer comprises approximately 21% and 52% of revenues earned for the three months ended September 30, 2006 and 2005, respectively. Based on our evaluation of the collectibility of the accounts receivable due from this customer, we believe that the balance relating to research and development reimbursements may not be collectible and, therefore, have reserved this balance at September 30, 2006. Another customer comprises approximately 52% and 0% of revenues earned for the three months ended September 30, 2006 and 2005, respectively.

NOTE 4 - Inventories

Inventories are stated at the lower of cost or market, with cost being determined under the first-in, first-out method. We only capitalize inventory that is produced for commercial sale. Manufacturing costs incurred to produce clofarabine prior to approval were recorded as research and development costs. The Company periodically reviews inventory on hand. Items considered outdated or obsolete are reduced to their estimated net realizable value.

|                   | September 30,<br>2006 | June 30,<br>2006 |
|-------------------|-----------------------|------------------|
|                   | ----                  | ----             |
| Raw materials     | \$ -                  | \$ 118,213       |
| Work-in-progress  | 338,797               | 180,048          |
| Finished goods    | 86,605                | 129,253          |
|                   | -----                 | -----            |
| Total inventories | \$ 425,402            | \$ 427,514       |
|                   | =====                 | =====            |

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

### NOTE 5 - Intangible Assets

Intangible assets at September 30, 2006 and June 30, 2006 are as follows:

|                                | September 30,<br>2006<br>---- | June 30,<br>2006<br>---- |
|--------------------------------|-------------------------------|--------------------------|
| Patents and licensing rights   | \$9,382,450                   | \$9,382,450              |
| Other intangible assets        | 298,505                       | 298,505                  |
|                                | -----                         | -----                    |
|                                | 9,680,955                     | 9,680,955                |
| Less: accumulated amortization | (2,343,633)                   | (2,131,435)              |
|                                | -----                         | -----                    |
| Total intangible assets, net   | \$7,337,322<br>=====          | \$7,549,520<br>=====     |

Amortization of patents, licensing rights and other intangible assets amounted to approximately \$212,000 and \$201,000 for the three months ended September 30, 2006 and 2005, respectively, and are amortized over periods generally ranging from 1-20 years. Amortization for each of the next five fiscal years will amount to approximately \$800,000 annually.

-8-

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

### NOTE 6 - Accrued Expenses

Below is a breakdown of our accrued expenses at September 30, 2006 and June 30, 2006.

|                                  | September 30,<br>2006<br>---- | June 30,<br>2006<br>---- |
|----------------------------------|-------------------------------|--------------------------|
| Accrued research and development | \$5,302,882                   | \$4,389,951              |
| Accrued professional fees        | 370,666                       | 493,924                  |
| Accrued compensation fees        | 670,451                       | 702,097                  |
| Accrued other                    | 1,720,330                     | 878,473                  |
|                                  | -----                         | -----                    |
| Total accrued expenses           | \$8,064,329<br>=====          | \$6,464,445<br>=====     |

Accrued research and development expenses include amounts relating to clinical trials, pre-clinical operating costs and amounts due on the license to develop, manufacture, market, distribute and sell Evoltra(R) in Japan and Southeast Asia. Accrued other includes inventories, marketing costs, royalties due on product sales and other operating expense accruals.

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

### NOTE 7 - Comprehensive Loss

Our comprehensive loss includes loss applicable to common stockholders and unrealized gains (losses) from foreign currency translations to the US dollar, the reporting currency of the Company. The functional currency of Bioenvision Limited, the Company's wholly-owned subsidiary, organized under the laws of the United Kingdom with offices in Edinburgh, Scotland, is the Pound Sterling. We translate assets and liabilities to their US dollar equivalents at rates in effect at the balance sheet date and record translation adjustments in accumulated other comprehensive loss. We translate statement of operations accounts at average rates for the period.

### NOTE 8 - Net Loss Per Share of Common Stock Applicable to Common Stockholders

We compute loss per common share in accordance with SFAS No. 128, "Earnings Per Share" ("SFAS 128"). Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. As the Company incurred net losses for the three months ended September 30, 2006 and 2005, the basic earnings per share equals the diluted earnings per share. Options and warrants to purchase 11,451,480 and 11,234,314 shares of common stock have not been included in the calculation of net loss per share for the three months ended September 30, 2006 and 2005, respectively, as their effect would have been anti-dilutive. Additionally, convertible participating preferred stock that is convertible into 4,500,000 shares of common stock have not been included in the calculation of net loss per share for each of the three months ended September 30, 2006 and 2005, as their effect would have been anti-dilutive.

### NOTE 9 - Geographic Information

We have one operating segment and define geographical regions as countries in which we operate. Our corporate headquarters in the United States collects licensing, royalties and research & development contract revenue from our arrangements with external customers and our co-development partners. Our wholly-owned subsidiary, Bioenvision Limited, is located in the United Kingdom and manages our product sales. The following table reconciles our revenues by geographic region to the consolidated total:

|                | Three Months Ended<br>September 30, | Three Months Ended<br>September 30, |
|----------------|-------------------------------------|-------------------------------------|
|                | -----<br>2006<br>-----              | -----<br>2005<br>-----              |
| United States  | \$ 990,078                          | \$ 400,130                          |
| United Kingdom | 1,874,494                           | 270,088                             |
|                | -----                               | -----                               |
| Total Revenue  | \$ 2,864,572<br>=====               | \$ 670,218<br>=====                 |

-9-

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

### NOTE 10 - Short-term Financing

During the three months ended September 30, 2006, the Company borrowed \$5,000,000 in conjunction with a promissory note signed with our financial institution. All amounts drawn were fully repaid as of September 30, 2006.

### NOTE 11 - License and Co-Development Agreements

#### Clofarabine (Evoltra(R))

The Company has a license from SRI to develop, manufacture, market, distribute and sell a class of purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia, lymphoma and certain solid tumor cancers. The lead compound of these purine-based nucleosides is known as clofarabine (Evoltra(R)). The Company received regulatory approval for Evoltra(R) from the European Medicines Agency on May 31, 2006 under the centralized approval process for treatment of acute lymphoblastic leukemia, or ALL, in pediatric patients who have relapsed or are refractory to at least two prior regimens of treatment.

Under the terms of the agreement with SRI, the Company was granted the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by the Company and by SRI from the technology. Initially, the Company is developing Evoltra(R) for the treatment of leukemia and lymphoma and studying its potential role in treatment of solid tumors.

To facilitate the development of Evoltra(R) in March 2001, the Company entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX"), our sub-licensor until it was acquired by Genzyme Corporation ("Genzyme") on December 21, 2004, for the development of Evoltra(R) in cancer indications. Under the terms of the co-development agreement, Genzyme is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia), in each case, for the development of Evoltra(R) in cancer indications. Currently, the Company has billed but not recorded approximately \$4,600,000 of revenue relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of Evoltra(R) outside the United States. If and when the Company has determined that collectibility is reasonably assured, the Company will record the revenue. Genzyme is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada for certain cancer indications. The Company retains the right to handle those matters in all territories outside the United States and Canada and retains the right to handle these matters in the U.S. and Canada in all non-cancer indications. The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States and Canada. Under the co-development agreement, Genzyme will have certain rights if it performs its development obligations in accordance with that agreement. The Company is required to pay Genzyme a royalty on direct sales outside the U.S., Canada, Japan and Southeast Asia. In turn, Genzyme, which would have U.S. and Canadian distribution rights in cancer indications, is paying the Company a royalty on sales in the U.S. and Canada. Under the terms of the co-development agreement, Genzyme also pays royalties to SRI based on certain milestones. The Company also is obligated to pay certain royalties to SRI with respect to Evoltra(R).

The Company received a nonrefundable upfront payment of \$1,350,000 when it

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

entered into the co-development agreement with Genzyme and received an additional \$3,500,000 in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application (NDA) for clofarabine with the FDA, the Company received an additional (i) \$2,000,000 in April 2004 and (ii) \$2,000,000 in September 2004. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight-line basis over the related service period, through March 2021. For each of the three months ended September 30, 2006 and 2005, the Company recognized revenues of approximately \$110,000 in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Genzyme. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis over the related service period, concurrent with the revenue that is recognized in connection with these research and development costs through 2021. The Company recognized approximately \$55,000 for each of the three months ended September 30, 2006 and 2005.

-10-

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

#### NOTE 11 - License and Co-Development Agreements - continued

In September 2006, the Company obtained the exclusive license to develop, manufacture, market, distribute and sell Evoltra(R) in Japan and Southeast Asia. We made an initial payment of \$2,500,000 cash to SRI upon execution of this agreement and are obligated to pay SRI additional milestone payments and royalties during the term of this agreement.

#### Modrenal(R)

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

The Company received a nonrefundable upfront payment of \$1,250,000 when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, currently through September 2022. The Company recognized revenues of approximately \$15,000, respectively, in connection with the upfront payment from Dechra for each of the three months ended September 30, 2006 and 2005.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made

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

to Stegram and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with the Dechra agreement. Research and development costs related to this agreement include approximately \$3,000 for each of the three months ended September 30, 2006 and 2005.

### NOTE 12 - Marketing and Distribution Agreements

In March 2006, the Company entered into a Marketing and Distribution Agreement with Mayne Pharma Limited, a public company in Australia, to develop, market and distribute Evoltra(R) in Australia and New Zealand in certain cancer indications. The Company anticipates entering into similar arrangements with other marketing and distribution partner(s) around the world (outside North America) to capitalize on the commercial potential of Evoltra(R), with a fully integrated sales and marketing team being a primary focus for the sales and marketing partner(s) the Company may select at any time or from time to time.

### NOTE 13 - Stockholders' Transactions

#### Stock Options

The Company grants stock options to members serving on the Board of Directors. The Company recognized \$8,800 and \$14,000 as consulting expense during the three months ended September 30, 2006 and 2005, respectively, related to such options granted.

There were no options exercised for the three months ended September 30, 2006. During the three months ended September 30, 2005, certain non-employee holders of options exercised pursuant to the cashless exercise feature available to such option holders and the Company issued approximately 191,196 shares of its common stock in connection therewith.

#### Warrants

On August 4, 2004, the Company issued a warrant to a consultant pursuant to which said consultant has the right to purchase 40,000 shares of the Company's common stock at a price of \$7.22 per share, of which 20,000 warrants vested immediately and 20,000 vest upon satisfaction of certain milestones included in the warrant. No milestones were met during the three months ended September 30, 2006 and 2005.

On August 9, 2004, the Company issued two warrants to a consultant pursuant to which said consultant has the right to purchase an aggregate of 45,000 shares of the Company's common stock at a price of \$6.10 per share. The Company recognized consulting expense of approximately \$0 and \$9,000 for the three months ended September 30, 2006 and 2005, respectively. All milestones were

-11-

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

### NOTE 13 - Stockholders' Transactions - continued

met as of September 30, 2005 related to said warrants.

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

During the three months ended September 30, 2006, certain warrant holders exercised their warrants to acquire 2,000 shares of the Company's common stock. The Company received proceeds of approximately \$2,500 from the exercise of such warrants. During the three months ended September 30, 2005, certain warrant holders exercised their warrants to acquire 10,619 shares of the Company's common stock. The Company received proceeds of approximately \$76,000 from the exercise of such warrants.

### Shareholder Receivable

Subsequent to the exercise of an option by a former member of management on September 27, 2005, the Company became aware of the statutorily required withholding taxes due to the UK tax regulatory authority. In order to maintain compliance with the UK tax regulatory authority, the Company remitted the taxes due on behalf of the former employee in January 2006 and, in return, received a promissory note from the former member of management dated November 28, 2005 for \$340,606, of which \$40,606 has been collected. The payment of these taxes was not part of the option agreement. The Company has classified such note as a shareholder receivable in the equity section of the condensed consolidated balance sheets.

-12-

## BIOENVISION, INC. AND SUBSIDIARIES

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

Except for historical information contained herein, this quarterly report on Form 10-Q contains forward-looking statements within the meaning of the Section 21E of the Securities and Exchange Act of 1934, as amended, which involve certain risks and uncertainties. Forward-looking statements are included with respect to, among other things, the Company's current business plan and "Management's Discussion and Analysis of Results of Operations." These forward-looking statements are identified by their use of such terms and phrases as "intends," "intend," "intended," "goal," "estimate," "estimates," "expects," "expect," "expected," "project," "projected," "projections," "plans," "anticipates," "anticipated," "should," "designed to," "foreseeable future," "believe," "believes" and "scheduled" and similar expressions. The Company's actual results or outcomes may differ materially from those anticipated. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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

We are a product-oriented biopharmaceutical company primarily focused upon the acquisition, development, distribution and marketing of compounds and technologies for the treatment of cancer, autoimmune disease and infection. Our product pipeline includes Evoltra(R) (Clofarabine), Modrenal(R) (for which Bioenvision has obtained regulatory approval for marketing in the United Kingdom for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy), and certain anti-infective technologies including the OLIGON(R) technology; an advanced biomaterial that has been incorporated into



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

various FDA approved medical devices and Suvus(R), an antimicrobial agent currently in clinical development for refractory chronic hepatitis C infection.

Evoltra(R) is our lead product. In May 2006 the European Medicines Agency approved Evoltra(R) for the treatment of acute lymphoblastic leukemia (ALL) in pediatric patients who have relapsed or are refractory to at least two prior regimens. The licensed indication includes patients who were less than 21 years of age at the time of initial diagnosis of their leukemia. Evoltra(R) has been granted orphan drug designation, providing marketing exclusivity for 10 years in Europe, which 10-year period commenced in May 2006 upon our receipt of EMA marketing approval. We have a dedicated sales force in the U.K. and several other countries within the E.U. and will continue to expand our sales force as we continue to work through pricing and reimbursement in individual countries within the E.U.

In March 2006, we entered into a Marketing and Distribution Agreement with Mayne Pharma Limited, a public company in Australia, to sell, market and distribute Evoltra(R) (Clofarabine) in Australia and New Zealand in certain cancer indications. We anticipate entering into similar arrangements with other marketing and distribution partner(s) around the world (outside North America) to capitalize on the commercial potential of Evoltra(R) (Clofarabine), with a fully integrated sales and marketing team being a primary focus for the sales and marketing partner(s) we may select at any time or from time to time.

In September of 2006, the Company exercised its option from SRI to obtain an exclusive license to the patents and technology relating to Evoltra(R) to develop and commercialize products in Japan and Southeast Asia.

We also are developing Evoltra(R) for the treatment of adult acute myeloid leukemia (AML) as first-line therapy. The Company has completed enrollment of its Phase II clinical trial for the treatment of adult AML in elderly patients unfit for intensive chemotherapy and expects to file a Marketing Authorization Application in 2006 for this indication - the Company's first label-extension for Evoltra(R).

Also, in conjunction with our North American co-development partners, Genzyme Corporation, clofarabine (Evoltra(R)) is in clinical development for the treatment of myelodysplastic syndrome (MDS), chronic lymphocytic leukemia (CLL), chronic myeloid leukemia (CML), non-Hodgkin's lymphoma (NHL), multiple myeloma (MM), solid tumors and as a preconditioning regimen for transplantation.

Bioenvision is also conducting late-stage preclinical development of Evoltra(R) for the treatment of psoriasis and is planning further worldwide development of Evoltra(R) in autoimmune diseases.

Bioenvision holds an exclusive worldwide license for clofarabine. Bioenvision granted an exclusive sublicense to Genzyme to co-develop clofarabine for cancer indications in the US and Canada. Genzyme is commercializing clofarabine for certain cancer indications in the US and Canada under the brand name Clolar(R). Bioenvision holds an exclusive license in the US and Canada for all non-cancer indications. Bioenvision originally obtained clofarabine development and commercialization rights under patents held by Southern Research Institute.

In the U.S., in December 2004, the Food and Drug Administration, or FDA, approved clofarabine, for the treatment of pediatric acute lymphoblastic

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

leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine was the first new medicine initially approved in the U.S., for children with leukemia in more than a decade. Our U.S. partner, Genzyme Corporation, received Orphan Drug designation status for clofarabine in the U.S., providing marketing exclusivity for 7 years. Genzyme is marketing clofarabine under the brand name Clolar(R) in the U.S.

We are marketing our second product, Modrenal(R), in the United Kingdom, or U.K., through our sales force of six sales specialists. Modrenal(R) is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.

With the approval of Evoltra(R) under the EMA's centralized process, we intend to continue to expand our sales force by adding six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden. Further, we intend to penetrate all of the other markets within the E.U. upon establishing traction in the E.U.'s major markets. Initially, outside the U.K., we maintain a fully dedicated sales force through Innovex, an affiliate of Quintiles Corporation, which we intend to convert to a direct sales force of our own by fourth quarter of calendar 2007.

In addition to Evoltra(R) and Modrenal(R), we are currently in clinical development of Suvus(R) for chronic hepatitis C. This product is also in pre-clinical development for the treatment of West Nile Virus and influenza.

Over the next 12 months, we intend to continue our internal growth strategy to provide the necessary regulatory, sales and marketing capabilities which will be required to pursue the expanded development programs described above.

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this early stage of our operations.

We anticipate that revenues derived from Evoltra(R) will permit us to further develop the other products currently in our product pipeline. In addition to clofarabine and Modrenal(R), we are performing development work Suvus(R) for the treatment of Hepatitis C. The work to date on these compounds has been limited because of the need to concentrate on Evoltra(R), but management believes these compounds have potential value. With Suvus(R) the Company has commenced a phase II clinical trial in patients with hepatitis C viral infection. We have had discussions with potential product co-development partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans. In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions.

In May 2003, we entered into a License and Sub-License Agreement with Dechra Pharmaceuticals, plc, or Dechra, pursuant to which we sub-licensed the marketing and development rights to Vetoryl(R) (trilostane), solely with respect to animal health applications, in the U.S. and Canada, to Dechra. We received \$1,250,000 in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try and capitalize on these types of opportunities as they arise. The Company also owns rights to OLIGON(R) technology and we have had discussions with potential product licensing partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans.

You should consider the likelihood of our future success to be highly

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

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 continue to establish and maintain relationships with manufacturers for our products;

-14-

- o respond to industry and competitive developments; and
- o attract, retain, and motivate qualified personnel.

We may not be successful in addressing these or any risks associated with our business and/or products. If we were unable to do so, our business prospects, financial condition and results of operations would be materially adversely affected. The likelihood of our success must be considered in light of the development cycles of new pharmaceutical products and technologies and the competitive and regulatory environment in which we operate.

### Results of Operations

The Company recorded revenue for the three months ended September 30, 2006 and 2005 of approximately \$2,865,000 and \$670,000 respectively, representing an increase of approximately \$2,195,000. This increase is primarily due to increased product sales of \$1,679,000 as a result of Evoltra's approval in Europe.

The cost of products sold for the three months ended September 30, 2006 and 2005 were approximately \$423,000 and \$328,000, respectively, representing an increase of approximately \$95,000. The cost of products sold reflects the direct costs associated with our sales of Modrenal(R) and includes royalty expense of \$361,000 and \$201,000 for the three months ended September 30, 2006 and 2005 respectively. The direct costs associated with clofarabine sales have been expensed in periods prior to the E.U. approval.

Research and development costs for the three months ended September 30, 2006 and 2005 were approximately \$9,270,000 and \$2,431,000, respectively, representing an increase of approximately \$6,839,000. Our research and development costs include costs associated with the six products shown in the table below, three of which the Company currently devotes time and resources:

Edgar Filing: BIOENVISION INC - Form 10-Q

| Product      | Three Months Ended<br>September 30, |                                |
|--------------|-------------------------------------|--------------------------------|
|              | 2006<br>----                        | 2005<br>----                   |
| Evoltra (R)  | \$ 8,483,000                        | \$ 2,138,000                   |
| Modrenal (R) | 773,000                             | 236,000                        |
| Suvus (R)    | 14,000                              | 57,000                         |
| Velostan     | -                                   | -                              |
| OLIGON (R)   | -                                   | -                              |
| Gene Therapy | -                                   | -                              |
| Total        | -----<br>\$ 9,270,000<br>=====      | -----<br>\$ 2,431,000<br>===== |

Evoltra(R) research and development costs for the three months ended September 30, 2006 and 2005 were approximately \$8,483,000 and \$2,138,000 respectively, representing an increase of approximately \$6,345,000. This substantial increase is primarily due to approximately \$4,000,000 of costs recorded in connection with the acquisition of the Japanese and Southeast Asian rights to Evoltra(R) which occurred in the quarter ended September 30, 2006. Other factors contributing to the increase in R&D costs include an increase in our development activities and clinical trials of Evoltra(R) in Europe, including the process of filing for approval in our first label extension for Evoltra, and certain non-cash expenses incurred for stock-based compensation relating to stock options granted to employees that devote their time to research and development activities.

Modrenal(R) research and development costs for the three months ended September 30, 2006 and 2005 were approximately \$773,000 and \$236,000, respectively, representing an increase of \$537,000. This increase is due primarily to the costs associated with our Phase II clinical trial in pre-menopausal breast cancer and Phase IV clinical trial in patients with post-menopausal breast cancer, which are each being conducted in the U.K.

Suvus(R) research and development costs for the three months ended September 30, 2006 and 2005 were approximately \$14,000 and \$57,000 respectively, representing a decrease of \$43,000. The decrease primarily reflects the costs associated with the investigator sponsored Phase II clinical trial conducted in Egypt prior to the quarter ended September 30, 2006.

-15-

There were no research and development costs associated with Velostan for the three months ended September 30, 2006 and 2005 because the Company has been working with its vendors on revising the manufacturing process to develop a raceamic form of the compound for use in the Company's clinical development program. No assurance can be given the Company will be able to create the L-form Velostan required for the clinical development program or, if it can, the timing of such development.

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

There was no research and development costs for OLIGON(R) for the three months ended September 30, 2006 and 2005 due to the Company's focus on Evoltra(R) and Modrenal(R) during this period.

There were no research and development costs associated with Gene Therapy for the three months ended September 30, 2006 and 2005 due to the Company's focus on Evoltra(R) and Modrenal(R) during this period. We anticipate that revenue derived from our two lead drugs, clofarabine and Modrenal(R) will permit us to further develop these products.

The clinical trials and development strategy for Evoltra(R) and Modrenal(R), in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) clofarabine research and development costs have been approximately \$31,923,000; (ii) Modrenal(R) research and development costs have been approximately \$9,425,000; (iii) Velostan research and development costs have been approximately \$380,000; (iv) Suvus research and development costs have been approximately \$522,000; (v) OLIGON(R) research and development costs have been approximately \$24,000; and (vi) Gene Therapy research and development costs have been approximately \$451,000.

Selling, general and administrative expenses for the three months ended September 30, 2006 and 2005 were approximately \$5,469,000 and \$2,887,000, respectively, representing an increase of \$2,582,000. The increase is primarily due to the an increase in costs associated with the expanded sales and marketing and administrative infrastructure and costs associated with the internal build out of the Company.

Depreciation and amortization expense for the three months ended September 30, 2006 and 2005 were approximately \$242,000 and \$224,000, respectively, representing an increase of \$18,000.

### Liquidity and Capital Resources

We anticipate that we will continue to incur significant operating losses for the foreseeable future. There can be no assurance as to whether or when we will generate material revenue or achieve profitable operations.

On September 30, 2006, we had cash and cash equivalents and short term investments totaling, in the aggregate, approximately \$35,777,000. Management believes the Company has sufficient cash and cash equivalents, short-term securities and working capital to continue currently planned operations over the next 12 months.

However, we may need additional financing to continue to fund the research and development and marketing programs for our products and to generally expand and grow our business. Because we will be required to fund additional operating losses in the foreseeable future, our financial position will continue to deteriorate. We cannot be sure that we will be able to find financing in the future or, if found, such funding may not be on terms favorable to us. If adequate financing is not available, we may be required to delay, scale back, or eliminate some of our research and development programs, to relinquish rights to certain technologies or products, or to license third parties to commercialize technologies or products that we would otherwise seek to develop. Any inability to obtain additional financing, if required, would have a material adverse effect on our ability to continue our operations and implement our business plan.

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

Although we do not currently plan to acquire or obtain licenses for new technologies, if any such opportunity arises and our Board deems it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

For the three months ended September 30, 2006 and 2005, net cash used in operating activities was approximately \$9,571,000 and \$3,741,000, respectively, representing an increase of approximately \$5,830,000. This increase is primarily due to increased costs associated with (i) our expanded research and development activity, (ii) selling general and administrative expenses, including an increase in costs associated with the expanded sales and marketing and administrative infrastructure and costs associated with the internal build out of the Company and (iii) cash paid for insurance premiums. For the three months ended September 30, 2006 and 2005, net cash provided by (used in) investing activities was approximately \$10,462,000 and \$(15,314,000), respectively, representing an increase of approximately \$25,776,000. This increase is primarily due to the redemption of our certificates of deposit during the period. For the three months ended September 30, 2006 and 2005, net cash used in financing activities was approximately \$41,000 and \$84,000 representing a decrease of \$43,000. This decrease is primarily due to cash received on a promissory note due from a

-16-

shareholder.

The Company has the following commitments due over the next five fiscal years:

|                         | 2007         | 2008         | 2009       | 2010       | 2011         |
|-------------------------|--------------|--------------|------------|------------|--------------|
| Operating Leases        | \$ 796,911   | \$ 833,973   | \$ 372,073 | \$ 178,570 | \$ -         |
| Contractual obligations | 971,272      | 1,000,000    | 250,000    | 500,000    | 4,000,000    |
| Total                   | \$ 1,768,183 | \$ 1,833,973 | \$ 622,073 | \$ 678,570 | \$ 4,000,000 |
|                         |              |              |            |            |              |

The contractual obligations relate to minimum payments due for research conducted on Modrenal and minimum royalties due on our licenses.

Off-balance sheet arrangements

We have no off-balance sheet arrangements.

Other Events

As described in the Company's current report on Form 8-K, filed on September 18, 2006, on September 12, 2006, the Company entered into a License Agreement (the "Agreement") with SRI pursuant to which SRI granted the Company the exclusive license to its clofarabine patents and technology to develop and commercialize products in Japan, Indonesia, Malaysia, Taiwan, Hong Kong,

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

Singapore, Vietnam, Cambodia, Thailand, Laos, Philippines, and South Korea (collectively, the "Asian Territories"). The Company will be responsible for developing products relating to the license, as well as obtaining regulatory approval for such products, in the Asian Territories, including all associated expense. In consideration for the license, the Company, among other things, paid SRI \$2.5 million within two days after the effective date of the Agreement. The Company will also pay SRI \$1 million at the time either the Company or its sub-licensee obtains regulatory approval for clofarabine in any country within the Asian Territories. In addition, the Company will pay SRI royalty fees based on a percentage of net sales of its products in the Asian Territories, certain maintenance fees and a percentage of the sub-license revenue it receives. The Agreement will continue in effect unless earlier terminated by either the Company or SRI.

As described in the Company's current report on Form 8-K, filed on October 11, 2006, effective October 6, 2006, the board of directors (the "Board") of the Company voted to increase the number of directors from 5 to 6. On the same date, the Board, in accordance with the Company's director nomination policy, unanimously approved the election of Joseph P. Cooper as a director of the Company to fill the newly created vacancy on the Board. Mr. Cooper will serve until the 2006 annual meeting of stockholders, and until such time as his successor is duly elected and qualified, or until his earlier resignation or removal. The Board has determined that Mr. Cooper is "independent" under the Nasdaq Global Select Market and Nasdaq Global Market Listing Standards. There is no arrangement or understanding between Mr. Cooper and any other persons pursuant to which he was selected as a director. There are no relationships between Mr. Cooper and the Company or its subsidiaries that would require disclosure pursuant to Item 404(a) of Regulation S-K. In consideration for Mr. Cooper agreeing to serve on the Board, on October 6, 2006, the Company granted him an option to purchase 25,000 shares of the Company's common stock, which will vest in equal portions on the first and second anniversary of the grant date.

### Recent Accounting Pronouncements

In September 2006, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles and expands disclosures about fair value measurements. The provisions of SFAS 157 are effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact, if any, of the provisions of SFAS 157.

On September 13, 2006, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 108 ("SAB 108"). SAB 108 provides interpretive guidance on how the effects of the carryover or reversal of prior year misstatements should be considered in quantifying a potential current year misstatement. Prior to SAB 108, companies might evaluate the materiality of financial statement misstatements using either the income statement or balance sheet approach, with the income statement approach focusing on new misstatements added in the current year, and the balance sheet approach focusing on the cumulative amount of misstatement present in a company's balance sheet. Misstatements that would be material under one approach could be viewed as immaterial under another approach, and not be corrected. SAB 108 now requires that companies view financial statement misstatements as material if they are material according to either the income statement or balance sheet approach. The Company has

analyzed SAB 108 and determined that it will have no impact on the reported results of operations or financial condition of the Company.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Our excess cash is invested in Certificates of Deposit with various short-term maturities. We hold no derivative financial instruments and we do not currently engage in hedging activities. As of September 30, 2006, we do not have any outstanding debt. Accordingly, due to the maturity and credit quality of our investments, we are not subjected to any substantial risk arising from changes in interest rates, currency exchange rates and commodity and equity prices. However, the Company does have some exposure to foreign currency rate fluctuations arising from maintaining an office for the Company's U.K. based, wholly-owned subsidiary which transacts business in the local functional currency. Management periodically reviews such foreign currency risk and to date has not undertaken any foreign currency hedges through the use of forward exchange contracts or options and does not foresee doing so in the near future.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report on Form 10-Q. Based on this evaluation our principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the requisite time periods.

Changes in Internal Controls

During the quarterly period ended September 30, 2006, there have been no changes in our internal controls over financial reporting that materially affected or are reasonably likely to materially affect our internal control over financial reporting.

-18-

BIOENVISION, INC. AND SUBSIDIARIES

PART II - OTHER INFORMATION

ITEM 1. Legal Proceedings

We are not currently engaged in any legal proceedings.

Item 1A. Risk Factors



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

None.

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

None.

ITEM 3. Defaults Upon Senior Securities

None.

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

None.

ITEM 5. Other Information

None.

-19-

ITEM 6. EXHIBITS

| Exhibit<br>Number<br>----- | Description<br>-----   |
|----------------------------|--|
| 2.1                        | Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1) |
| 2.2                        | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)                                    |
| 3.1                        | Certificate of Incorporation of Registrant. (2)  |
| 3.1(a)                     | Amendment to Certificate of Incorporation filed January 29, 1999. (3)  |
| 3.1(b)                     | Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)  |
| 3.1(c)                     | Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)   |
| 3.1(d)                     | Certificate of Designations, Preferences and Rights of series A Preferred Stock (6)  |
| 3.1(e)                     | Certificate of Amendment to the Certificate of Incorporation, filed January 14, 2004 (15)  |
| 3.2                        | Amended and Restated By-Laws of the Registrant. (13)   |
| 4.1                        | Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of  |

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

Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)

- 4.2 Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 4.3 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 4.4 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 4.5 Form of Warrant (6)
- 4.6 Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
- 4.7 Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)
- 4.8 Common Stock and Warrant Purchase Agreement, dated as of March 22, 2004, by and among Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)

-20-

- 4.9 Registration Rights Agreement, dated March 22, 2004, by and between Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
- 4.10 Form of Warrant (16)
- 4.11 Bioenvision, Inc. 2003 Stock Incentive Plan (17)
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc.
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc.
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998. (3)
- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute

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

- to Eurobiotech Group, Inc. dated September 1, 1998. (3)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
- 10.8 Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003 (14)
- 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.14 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
- 10.15 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.16 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.17 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.18 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.19 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.20 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.21 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)

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

- 10.22 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
- 10.23 Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC(14)
- 10.24 Employment Agreement between Bioenvision Limited and Hugh Griffith, effective as of October 23, 2002 (18)
- 10.25 Employment Agreement between Bioenvision Limited and Ian Abercrombie, effective as of January 6, 2003 (18)
- 10.26 Amendment # 2 to the Co-Development Agreement between Bioenvision and ILEX Oncology, Inc. dated December 30, 2003.(21)
- 10.27 Amendment to the Co-Development Agreement between Bioenvision, Inc. and SRI, dated as of March 12, 2001.(21)
- 10.28 Letter Agreement For Co-Development Of An Oral Clofarabine Formulation and First Amendment to Co-Development Agreement ated March 12, 2001 between Bioenvision, Inc. and ILEX. (21)
- 10.29 Joinder made by Bioenvision, Inc., dated February 26, 2004 (22)
- 10.30 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Sterling SNIFF, dated as of August 12, 2005 (22)
- 10.31 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Steroid SpA, dated as of August 12, 2005 (22)
- 10.32 Amendment to Employment Agreement, by and between Bioenvision and David P. Luci, dated February 6, 2006 (23)
- 10.33 Clofarabine Marketing and Development Agreement, by and between Bioenvision Inc. and Mayne Pharma Limited, dated March 24, 2006 (24)
- 10.34\* License Agreement by and between Southern Research Institute and Bioenvision, Inc., dated September 12, 2006

\* Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

- 14.1 Bioenvision Inc.'s Code of Business Conduct and Ethics (19)
- 16.1 Letter from Graf Repetti & Co., LLP to the Securities and

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

- Exchange Commission, dated September 30, 1999. (9)
- 16.2 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
- 16.3 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
- 16.4 Letter from Grant Thornton LLP to the Securities and Exchange Commission , dated April 7, 2005 (20)
- 16.5 Letter from Deloitte & Touche LLP to the Securities and Exchange Commission , dated January19, 2006 (25)
- 21.1 Subsidiaries of the registrant (4)
- 31.1 Certification of Christopher B. Wood, Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of David P. Luci, Chief Accounting Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 
- (1) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 12, 1999.
- (2) Incorporated by reference and filed as an Exhibit to Registrant's Registration Statement on Form 10-12g filed with the SEC on September 3, 1998.
- (3) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.
- (4) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.
- (5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2002.
- (6) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2002.
- (7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.
- (8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.
- (9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.

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

- (10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.
- (11) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 6, 2001.
- (12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.
- (13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.
- (14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.
- (15) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2004.
- (16) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2004.
- (17) Registrant's definitive proxy statement on Schedule 14-A, filed in connection with the annual meeting held on January 14, 2004.
- (18) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended September 30, 2003.
- (19) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the year ended June 30, 2004.
- (20) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on April 7, 2005.
- (21) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB, filed with the SEC on October 13, 2005.
- (22) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended September 30, 2005.
- (23) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 10, 2006.
- (24) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q, for the three month period ended March 31, 2006.
- (25) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 20, 2006.

Edgar Filing: BIOENVISION INC - Form 10-Q

SIGNATURES

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

Date: November 9, 2006

By: /s/ Christopher B. Wood M.D.  
-----

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

Date: November 9, 2006

By: /s/ David P. Luci  
-----

David P. Luci  
Chief Financial Officer and General Counsel  
(Principal Financial and Accounting Officer)