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BIOENVISION INC  
Form 10-Q  
May 09, 2007

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 March 31, 2007

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

Commission File # 001-31787

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

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

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 May 3, 2007, there were 55,035,739 shares of the issuer's common stock, par value \$.001 per share (the "Common Stock") outstanding.

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BIOENVISION, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

|   | March 31,<br>2007      |
|---|------------------------|
|   | -----<br>(unaudited)   |
| ASSETS  |                        |
| Current assets  |                        |
| Cash and cash equivalents   | \$ 9,812,027           |
| Short-term investments  | 10,801,269             |
| Accounts receivable, net of allowances of \$849,331 and \$898,714   | 8,570,906              |
| Inventories   | 1,079,713              |
| Other current assets  | 1,995,051              |
|   | -----                  |
| Total current assets  | 32,258,966             |
| Property and equipment, net   | 354,953                |
| Intangible assets, net  | 6,891,907              |
| Goodwill  | 1,540,162              |
| Other assets  | 253,861                |
| Deferred costs  | 3,342,597              |
|   | -----                  |
| Total assets  | \$ 44,642,446<br>===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY  |                        |
| Current liabilities   |                        |
| Accounts payable  | \$ 4,018,178           |
| Accrued expenses  | 10,422,939             |
| Accrued dividends payable   | 55,478                 |
| Deferred revenue  | 513,662                |
|   | -----                  |
| Total current liabilities   | 15,010,257             |
| Deferred revenue  | 6,685,470              |
|   | -----                  |
| Total liabilities   | 21,695,727<br>-----    |
| Commitments and contingencies   |                        |
| Stockholders' equity  |                        |
| Convertible participating preferred stock - \$0.001 par value; 20,000,000 shares authorized; 2,250,000 shares issued and outstanding at March 31, 2007 and June 30, 2006 (liquidation preference \$6,750,000) | 2,250                  |
| Common stock - par value \$0.001; 70,000,000 shares authorized; 43,085,406 and 41,456,616 shares issued and outstanding at March 31, 2007 and June 30, 2006, respectively                                     | 43,085                 |
| Additional paid-in capital  | 136,774,165            |
| Accumulated deficit   | (113,557,059)          |
| Receivable from stockholder   | -                      |
| Accumulated other comprehensive loss  | (315,722)              |
|   | -----                  |
| Total stockholders' equity  | 22,946,719             |

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Total liabilities and stockholders' equity

\$ 44,642,446  
=====

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

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

|   | Three months ended<br>March 31, |             |
|---|---------------------------------|-------------|
|   | 2007                            | 2006        |
|   | -----                           | -----       |
| Revenue   |                                 |             |
| Net product sales   | \$ 3,981,444                    | \$ 124,021  |
| Licensing and royalty revenue   | 976,052                         | 502,581     |
| Research and development contract revenue   | -                               | 1,114,481   |
|   | -----                           | -----       |
| Total revenue   | 4,957,496                       | 1,741,091   |
|   | -----                           | -----       |
| Costs and expenses  |                                 |             |
| Cost of products sold, including royalty expense of \$854,000 and \$316,000 for the three months ended March 31, 2007 and 2006, respectively, and \$1,974,000 and \$847,000 for the nine months ended March 31, 2007 and 2006, respectively | 985,197                         | 386,811     |
| Research and development  | 4,722,263                       | 2,785,001   |
| Selling, general and administrative   | 6,930,633                       | 6,913,691   |
| Depreciation and amortization   | 275,422                         | 247,361     |
|   | -----                           | -----       |
| Total costs and expenses  | 12,913,515                      | 10,332,881  |
|   | -----                           | -----       |
| Loss from operations  | (7,956,019)                     | (8,591,791) |
| Interest and finance charges  | (9,384)                         |             |
| Interest income   | 267,069                         | 453,481     |
|   | -----                           | -----       |
| Net loss  | (7,698,334)                     | (8,138,301) |
| Preferred stock dividend  | (83,218)                        | (83,211)    |

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|  |                |               |
|--|----------------|---------------|
| Loss applicable to common stockholders   | \$ (7,781,552) | \$ (8,221,52) |
|  | =====          | =====         |
| Basic and diluted net loss per share applicable to common stockholders         | \$ (0.18)      | \$ (0.2)      |
|  | =====          | =====         |
| Weighted average shares used in computing basic and diluted net loss per share | 43,055,592     | 40,870,68     |
|  | =====          | =====         |

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

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BIOENVISION, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY  
FOR THE NINE MONTHS ENDED MARCH 31, 2007  
(unaudited)

|   | Convertible Participating Preferred Stock |          | Common Stock |           | Additional Paid-in Capital | Accumulated Deficit |       |
|---|---|----------|--------------|-----------|----------------------------|---------------------|-------|
|   | Shares                                    | Amount   | Shares       | Amount    |                            |                     |       |
|   | -----                                     | -----    | -----        | -----     | -----                      | -----               | ----- |
| 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                                 |   |          |              |           |                            | (26,736,435)        |       |
| Cumulative preferred stock dividend                     |   |          |              |           |                            | (253,356)           |       |
| Currency translation adjustment                         |   |          |              |           |                            |                     |       |
| Due from stockholder                                    |   |          |              |           |                            |                     |       |
| Offering costs (see Note 14)                            |   |          |              |           | (406,275)                  |                     |       |
| Employee and board of director stock-based compensation |   |          | 31,100       | 31        | 2,853,707                  |                     |       |
| Warrants exercised for common stock                     |   |          | 1,597,690    | 1,597     | 721,737                    |                     |       |
|   | -----                                     | -----    | -----        | -----     | -----                      | -----               | ----- |
| Balance at March 31, 2007                               | 2,250,000                                 | \$ 2,250 | 43,085,406   | \$ 43,085 | \$136,774,165              | \$ (113,557,059)    | \$    |
|   | =====                                     | =====    | =====        | =====     | =====                      | =====               | ===== |

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CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS  
(unaudited)

|  | Three months ended<br>March 31, |  |                |          |
|--|---------------------------------|--|----------------|----------|
|  | 2007                            |  | 2006           | 200      |
|  | ----                            |  | ----           | ----     |
| Loss applicable to common stockholders | \$ (7,781,552)                  |  | \$ (8,221,521) | \$ (26,9 |
| Foreign currency translation loss      | (24,715)                        |  | (20,366)       | (1       |
|  | -----                           |  | -----          | -----    |
| Comprehensive Loss                     | \$ (7,806,267)                  |  | \$ (8,241,887) | \$ (27,1 |
|  | =====                           |  | =====          | =====    |

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

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

|  |    | Nine         |
|--|----|--------------|
|  |    | 2007         |
|  |    | -----        |
| Cash flows from operating activities:                                      |    |              |
| Net loss   | \$ | (26,736,435) |
| Adjustments to reconcile net loss to net cash used in operating activities |    |              |
| Depreciation and amortization  |    | 757,256      |
| Stock-based compensation   |    | 2,853,738    |
| Deferred revenue   |    | (385,255)    |
| Deferred costs   |    | 180,900      |
| Provision for bad debts and shareholder receivable                         |    | 354,489      |
| Other non-cash items   |    | -            |
| Changes in operating assets and liabilities:                               |    |              |
| Accrued interest on investments  |    | (904,374)    |
| Accounts receivable  |    | (5,446,780)  |
| Inventories  |    | (602,284)    |
| Other current assets   |    | (560,608)    |
| Other assets   |    | (36,199)     |

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|   |              |
|---|--------------|
| Accounts payable                                      | 2,066,746    |
| Accrued expenses                                      | 2,929,725    |
|   | -----        |
| Net cash used in operating activities                 | (25,529,081) |
|   | -----        |
| Cash flows from investing activities:                 |              |
| Additions to intangible assets                        | -            |
| Capital expenditures                                  | (178,026)    |
| Release of restricted cash                            | -            |
| Redemption of short-term investments                  | 31,740,212   |
| Purchase of short-term investments                    | -            |
|   | -----        |
| Net cash provided by (used in) investing activities   | 31,562,186   |
|   | -----        |
| Cash flows from financing activities:                 |              |
| Offering costs  | (54,229)     |
| Proceeds from exercise of warrants                    | 723,334      |
| Due from shareholder                                  | 40,606       |
| Preferred dividends paid                              | (252,430)    |
|   | -----        |
| Net cash provided by (used in) financing activities   | 457,281      |
|   | -----        |
| Effect of exchange rates on cash and cash equivalents | (56,296)     |
|   | -----        |
| Net increase (decrease) in cash and cash equivalents  | 6,434,090    |
| Cash and cash equivalents, beginning of period        | 3,377,937    |
|   | -----        |
| Cash and cash equivalents, end of period              | \$ 9,812,027 |
|   | =====        |

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

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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 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

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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. 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.

### 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 March 31, 2007, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended March 31, 2007 and 2006, the condensed consolidated statement of stockholders' equity for the nine months ended March 31, 2007 and the condensed consolidated statements of cash flows for the nine months ended March 31, 2007 and 2006.

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 and nine months ended March 31, 2007 and 2006 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 February 2007, Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities- Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets and liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and other eligible financial instruments. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and the Company is currently evaluating its impact.

In December 2006, the FASB issued a FASB Staff Position ("FSP") Emerging Issues Task Force ("EITF") Issue No. 00-19-2 "Accounting for Registration Payment Arrangements" ("FSP 00-19-2") which addresses an issuer's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No.5 "Accounting for Contingencies". The guidance in FSP 00-19-2 amends FASB Statements No. 133, "Accounting for Derivative Instruments and Hedging Activities", and FASB Statement No.150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", and FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" to include



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scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of this FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company has analyzed the provisions of FSP 00-19-2 and determined that it will not have a material effect on the Company's consolidated financial statements.

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

#### NOTE 1 - Basis of Presentation - continued

In September 2006, the FASB issued SFAS 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.

In September 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.

In June 2006, the FASB ratified the consensus of EITF Issue No. 06-3, "How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement" ("EITF 06-3"). EITF 06-3 indicates that the income statement presentation on either a gross basis or a net basis of the taxes within the scope of the issue is an accounting policy decision. The Company's accounting policy is to present the taxes within the scope of EITF 06-3 on a net basis. The adoption of EITF 06-3 in the second fiscal quarter of 2007 did not result in a change to the Company's accounting policy and, accordingly, did not have any effect on the Company's consolidated financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 ("FIN 48"). This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. This interpretation prescribes that a company should use a more likely than not recognition threshold based on

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the technical merits of the tax position taken. Tax positions that meet the more likely than not recognition threshold should be measured in order to determine the tax benefit to be recognized in the financial statements. FIN 48 is effective in fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on the results of operations or financial condition of the Company.

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

The Company accounts for stock-based compensation in accordance with SFAS No. 123 (revised 2004), "Share-Based Payment" ("SFAS 123 (R)"). For the three months ended March 31, 2007 and 2006, the Company recorded, as a component of net loss, employee stock-based compensation expense of \$1,154,000 and \$2,058,000, respectively. For the nine months ended March 31, 2007 and 2006, the Company recorded, as a component of net loss, employee stock-based compensation expense of \$2,887,000 and \$2,999,000, respectively. As of March 31, 2007, the total compensation cost related to unvested equity awards granted to employees but not yet recognized is approximately \$4,300,000. This cost will be amortized on a straight-line basis over the remaining weighted average vesting period of 2.1 years. 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.

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

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

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

|                              | Number<br>of Shares<br>----- | Weighted<br>Average<br>Exercise Price<br>----- | Weighted<br>Remain<br>Contra<br>Li<br>--- |
|------------------------------|------------------------------|--|---|
| Balance - June 30, 2006      | 4,641,000                    | \$ 4.24  | 4.  |
| Granted                      | 1,255,000                    | 4.78   |   |
| Exercised                    | -                            |  |   |
| Cancelled                    | (2,000)                      | 8.05   |   |
| Forfeited                    | (13,000)                     | 7.39   |   |
|                              | -----                        |  |   |
| Balance - March 31, 2007     | 5,881,000<br>=====           | 4.35   | 7.  |
| Exercisable - March 31, 2007 | 4,167,000                    | \$ 3.73  | 6.  |

(a) The intrinsic value is the amount by which the market price at the end of the period of the underlying share of stock exceeds the exercise price of the

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stock option.

Options granted to employees during the nine months ended March 31, 2007 totaled 1,255,000 and had a weighted average fair value of \$2.34. Options granted to employees during the nine months ended March 31, 2006 totaled 1,202,000 and had a weighted average fair value per share of \$3.67. Options exercised by employees during the three and nine months ended March 31, 2006 had an intrinsic value of approximately \$1,323,000.

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:

|   | Nine Months Ended<br>March 31,<br>2007 |
|---|--|
| Risk-free interest rate                   | 4.43% - 4.84%                          |
| Expected weighted average term (in years) | 3.95                                   |
| Expected weighted average volatility      | 59%                                    |
| Expected dividend yield                   | 0%                                     |

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.

Refer to Note 13 for further discussion of equity instruments granted.

#### NOTE 3 - Accounts Receivable and Significant Customers

The Company's accounts receivable are primarily due from hospitals, clinical trial centers, and our co-development partners. One customer comprised approximately 46% and 16% of revenues earned for the nine months ended March 31, 2007 and 2006, respectively. Another customer comprised approximately 17% and 37% of revenues earned for the nine months ended March 31, 2007 and 2006, respectively. Based on our evaluation of the collectibility of the accounts receivable due from this customer, the Company believes that the balance relating to research and development reimbursements may not be collectible and, therefore, have reserved this balance at March 31, 2007 and June 30, 2006.

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

#### NOTE 4 - Inventories

Inventories are stated at the lower of cost or market, with cost being

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determined under the first-in, first-out method. The Company only capitalizes 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.

|                   | March 31,<br>2007<br>---- | June 30,<br>2006<br>---- |
|-------------------|---------------------------|--------------------------|
| Raw materials     | \$ 144,525                | \$ 118,213               |
| Work-in-progress  | 917,575                   | 180,048                  |
| Finished goods    | 17,613                    | 129,253                  |
|                   | -----                     | -----                    |
| Total inventories | \$ 1,079,713<br>=====     | \$ 427,514<br>=====      |

NOTE 5 - Intangible Assets

Intangible assets at March 31, 2007 and June 30, 2006 are as follows:

|                                | March 31,<br>2007<br>---- | June<br>200<br>---- |
|--------------------------------|---------------------------|---------------------|
| Patents and licensing rights   | \$ 9,382,450              | \$ 9,3              |
| Other intangible assets        | 298,505                   | 2                   |
|                                | -----                     | -----               |
|                                | 9,680,955                 | 9,6                 |
| Less: accumulated amortization | (2,789,048)               | (2,1                |
|                                | -----                     | -----               |
| Total intangible assets, net   | \$ 6,891,907<br>=====     | \$ 7,5<br>=====     |

Amortization of patents, licensing rights and other intangible assets amounted to approximately \$238,000 and \$220,000 for the three months ended March 31, 2007 and 2006, respectively, and are amortized over periods generally ranging from 1-20 years. Amortization amounted to approximately \$658,000 and \$651,000 for the nine months ended March 31, 2007 and 2006, respectively. Amortization for each of the next five fiscal years will amount to approximately \$800,000 annually.

NOTE 6 - Accrued Expenses

Below is a breakdown of our accrued expenses at March 31, 2007 and June 30, 2006.

|  | March 31,<br>2007<br>---- | June<br>200<br>---- |
|--|---------------------------|---------------------|
|--|---------------------------|---------------------|

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|                                  |               |        |
|----------------------------------|---------------|--------|
| Accrued research and development | \$ 6,626,755  | \$ 4,3 |
| Accrued sales and marketing      | 1,031,696     | 3      |
| Accrued professional fees        | 556,943       | 4      |
| Accrued compensation             | 550,410       | 7      |
| Accrued other                    | 1,657,135     | 5      |
|                                  | -----         | -----  |
| Total accrued expenses           | \$ 10,422,939 | \$ 6,4 |
|                                  | =====         | =====  |

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, royalties due on product sales, expenses associated with the registered direct offering and other operating expense accruals.

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

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 common 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 common 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 and nine months ended March 31, 2007 and 2006, the basic loss per common share equals the diluted loss per common share. Options and warrants to purchase 10,823,148 and 11,940,314 shares of common stock have not been included in the calculation of net loss per common share for the three and nine months ended March 31, 2007 and 2006, 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 common share for each of the three and nine months ended March 31, 2007 and 2006, as their effect would have been anti-dilutive.

NOTE 9 - Geographic Information

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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 currently manages our product sales in Europe. Our wholly-owned subsidiary, Bioenvision JapanCo., Ltd, is located in Tokyo and is focused on product development in Japan and Southeast Asia. Currently, there is no sales activity in Japan. The following table reconciles our revenues by geographic region to the consolidated total:

|                | Three Months Ended<br>March 31, |                       | Nine Mon<br>Marc       |
|----------------|---------------------------------|-----------------------|------------------------|
|                | 2007                            | 2006                  | 2007                   |
| United States  | \$ 976,052                      | \$ 502,584            | \$ 2,775,484           |
| United Kingdom | 3,981,444                       | 1,238,511             | 9,543,223              |
| Total Revenue  | \$ 4,957,496<br>=====           | \$ 1,741,095<br>===== | \$ 12,318,707<br>===== |

NOTE 10 - Short-term Financing

In August 2006, the Company borrowed \$1,500,000 in conjunction with a promissory note signed with our financial institution. In September 2006, the Company borrowed an additional \$3,500,000. 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 Southern Research Institute ("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

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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 myelodysplastic syndrome (MDS) and solid tumors.

In March 2001, to facilitate the development of Evoltra(R), the Company entered into a co-development agreement with ILEX Oncology, Inc. 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 as a receivable 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. Under the co-development agreement, the Company offsets these amounts against any royalty which otherwise would be paid to Genzyme on our U.K. sales. 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. Under the circumstances, 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 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 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 March 31, 2007 and 2006, the Company recognized revenues of approximately \$110,000 in connection with the milestone payments received to date. For each of the nine months ended March 31, 2007 and 2006, the Company recognized revenues of approximately \$330,000 in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon

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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 March 31, 2007 and 2006 and approximately \$165,000 for each of the nine months ended March 31, 2007 and 2006.

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. Since taking on these rights, the Company has organized Bioenvision JapanCo., Ltd., a wholly-owned subsidiary of the Company ("JapanCo") and established an office in Tokyo.

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

NOTE 11 - License and Co-Development Agreements - continued

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. 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 ("Dechra") 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, in connection with the upfront payment from Dechra for each of the three months ended March 31, 2007 and 2006 and approximately \$45,000, for each of the nine months ended March 31, 2007 and 2006.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. ("Stegram") upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made 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 March 31, 2007 and 2006 and approximately \$9,000 for each of the nine months ended March 31, 2007 and 2006.

OLIGON(R)

In January 2007, the Company entered into a licensing arrangement with Foster Corporation ("Foster") to license out exclusive rights to manufacture, market and distribute the Company's proprietary anti-microbial OLIGON(R) technology.



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Under the terms of the license agreement, Bioenvision will have a revenue sharing arrangement on future sublicenses and a royalty on all sales by Foster, a Connecticut-based compounder of biomedical materials. Foster is required to comply with annual minimum marketing and research and development expenditures within the first five years of the term of the license.

### NOTE 12 - Marketing and Distribution Agreement

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. Mayne was acquired by Hospira, Inc. (NYSE:HSP) in February of 2007. 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

#### Convertible Preferred Stock

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. The Company has paid the dividend in cash to holders of its cumulative Series A Convertible Participating Preferred Stock through April 30, 2007.

#### Common Stock

On November 27, 2006, the Company issued 31,100 shares of common stock to an officer of the Company pursuant to the terms of his amended employment agreement dated January 6, 2006. The officer was entitled to receive 50,000 shares upon the appointment of a new chief financial officer, of which 18,900 shares were withheld to satisfy the officer's tax liability. In connection with such issuance we recognized approximately \$247,000 as compensation expense.

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
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### NOTE 13 - Stockholders' Transactions - continued

#### Stock Options

The Board of Directors adopted, and the stockholders approved, the 2003 Stock Incentive Plan at the Annual Meeting held in January 2004. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 6,750,000 shares reserved for grants of options under the plan and, at March 31, 2007, options to purchase 5,367,000 shares of common stock had been issued. The Company's policy is to issue new shares for option exercises. Stock options vest pursuant to individual stock option agreements. No

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options granted under the plan are exercisable after the expiration of ten years (or lesser at the discretion of the Board of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors or until expiration of the plan on November 17, 2013. Refer to Note 2 for discussion of the Company's determination of fair value for each stock option granted

During the nine months ended March 31, 2007, options to purchase 81,250 of the Company's common stock at a weighted average exercise price of \$4.94 per share were granted to members serving on the Board of Directors. The Company recognized \$33,000 and \$38,000 as consulting expense during the three months ended March 31, 2007 and 2006, respectively, and \$60,000 and \$66,000 as consulting expense during the nine months ended March 31, 2007 and 2006, respectively, related to options granted to board members.

Options granted to employees during the nine months ended March 31, 2007 totaled 1,255,000. Included in this total are 350,000 stock options at an exercise price of \$4.96 per share granted to an officer of the Company in conjunction with his employment agreement dated November 27, 2006 to serve as Chief Financial Officer. The Company recognized approximately \$78,000 and \$351,000, respectively, as compensation expense during the three and nine months ended March 31, 2007 in connection with said grant. Total compensation expense for options granted to employees was \$1,154,000 and \$2,057,000 for the three months ended March 31, 2007 and 2006, respectively, and \$2,641,000 and \$2,999,000 for the nine months ended March 31, 2007 and 2006, respectively. On March 30, 2006, the Company extended the exercise period of 1,500,000 vested options originally granted to an officer of the Company from five to ten years. The extension of the exercise period was treated as a modification of an award under SFAS 123 (R) and resulted in the immediate recognition of incremental compensation expense of approximately \$591,000.

There were no options exercised during the nine months ended March 31, 2007. During the nine months ended March 31, 2006, certain option holders of the Company exercised their options to acquire 190,000 shares of the Company's common stock, in which the Company received proceeds of approximately \$311,000. During the nine months ended March 31, 2006, certain non-employee option holders exercised their options pursuant to the cashless feature available to such option holders and the Company issued 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 and nine months ended March 31, 2007 and 2006.

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. All milestones were met as of September 30, 2005 related to said warrants. The Company recognized consulting expense of approximately \$0 and \$9,000 for the nine months ended March 31, 2007 and 2006, respectively.

During the nine months ended March 31, 2007, certain warrant holders exercised their warrants to acquire 1,597,690 shares of the Company's common stock. The Company received proceeds of \$723,000 from the exercise of such warrants. During the nine months ended March 31, 2006, certain warrant holders of the Company exercised their warrants to acquire 63,703 shares of the Company's common stock, in which the Company received proceeds of approximately \$51,000 from the

exercise of such warrants.

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

NOTE 13 - Stockholders' Transactions - continued

Receivable from Stockholder

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. In December 2006, the Company reserved for the remaining balance outstanding.

NOTE 14 - Subsequent Events

On April 5, 2007, we completed a registered direct offering in which we sold 8,000,000 common shares at \$3.75 per share, with net proceeds to the Company of approximately \$27.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

On April 20, 2007, Bioenvision Limited, a wholly owned subsidiary of Bioenvision, Inc. and its Medical Director, Dr. Andrew Saunders, entered into an agreement (the "Compromise Agreement"), pursuant to which the parties agreed Dr. Saunders' would no longer be employed by Bioenvision Limited effective April 9, 2007. Under the terms of the Compromise Agreement, Dr. Saunders received a lump sum payment of (pound)124,000 Sterling (approximately \$244,000), upon receipt by the Company of the fully executed Compromise Agreement, in consideration of a release by Dr. Saunders for the benefit of the Bioenvision Limited and any Associated Company (as defined in the Compromise Agreement), including its parent company, Bioenvision, Inc. In addition, Dr. Saunders received his normal salary, accrued holiday pay of 4 days and contractual benefits up to and including April 9, 2007, subject to deduction of tax and National Insurance in the normal manner.

On April 30, 2007, an affiliate of SCO Capital Partners LLC, exercised warrants to purchase an aggregate of 250,000 shares of the Company's common stock at a purchase price of \$1.50 per share. On May 2, 2007, SCO Capital Partners, exercised warrants to purchase an aggregate of 688,333 shares of the Company's common stock at a purchase price of \$1.50 per share. Also on May 2, 2007, Perseus-Soros Biopharmaceutical Fund, LP exercised warrants to purchase an aggregate of 3,000,000 shares of the Company's common stock at a purchase price of \$2.00 per share. All of these warrants were issued in connection with a private placement of preferred stock and warrants in May 2002 and would have expired if not exercised by May 7, 2007. As a result of the exercise of these warrants, the Company received aggregate net cash proceeds of approximately \$7.4 million.

## 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 and marketing of compounds and technologies for the treatment of cancer. 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 other products. We are also developing Suvus(R), which is currently in clinical development for refractory chronic hepatitis C infection.

Evoltra(R) is our lead product. In May 2006 the European Medicines Agency (the "EMA") 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 (ODD), 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 direct sales force in the U.K. and a dedicated sales force through Innovex in several other countries within the E.U. We will continue to increase either our direct sales force or our dedicated sales force through Innovex as we continue to work through reimbursement procedures and expand our marketing initiatives to exploit new commercial opportunities within the E.U. We continue to consider employing the Innovex sales force directly in continental Europe as well as other alternatives and we continue to analyze this potential growth opportunity as we continue our internal growth strategy.

On February 7, 2007, we announced that we filed with the EMA to expand the Evoltra(R) (clofarabine) label to include the treatment of acute myeloid leukemia (AML) in patients who are greater than or equal to 65-years-old and have one or more of the following: adverse cytogenetics, secondary AML, aged greater than or equal to 70 years, or have one or more significant comorbidity. This new target indication, if approved, represents a significant increase in

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the size of the potential market available to Evoltra(R). In addition, we have ODD in this new target indication which would provide further market exclusivity in the EU.

In March 2006, we entered into a Marketing and Distribution Agreement with Mayne Pharma Limited ("Mayne"), a public company in Australia, pursuant to which we have granted and Mayne has received certain marketing rights to sell, market and distribute Evoltra(R) (Clofarabine) in Australia and New Zealand in certain cancer indications. Mayne was acquired by Hospira, Inc. (NYSE:HSP) in February of 2007. We anticipate entering into similar arrangements around the world, from time to time, with other marketing and distribution partner(s) who have a fully integrated sales and marketing force in each such territory to further capitalize on the commercial potential of Evoltra(R).

In September 2006, the Company executed a License Agreement with SRI, pursuant to which the Company successfully licensed the manufacturing, marketing and distribution rights to clofarabine in Japan and Southeast Asia (the "Japan License"). The marketing rights in Japan and Southeast Asia had not been granted by SRI in its history and the Company considers the addition of these rights to be a significant development and a core asset. Since taking on these rights, the Company has organized Bioenvision JapanCo., Ltd., a wholly-owned subsidiary of the Company ("JapanCo"), and appointed Mr. Yashimaru Yamamoto as its director in charge of corporate and product development for JapanCo. Mr. David P. Luci, the Company's Executive Vice President and General Counsel, serves as Chairman of JapanCo and is responsible for JapanCo's early stage corporate and product development activities within the Company.

In addition to developing Evoltra(R) for the treatment of adult AML as first-line therapy in elderly patients considered unsuitable for intensive chemotherapy, we are also developing Evoltra(R) for use in combination with other agents for patients with AML considered suitable for intensive chemotherapy.

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), non-Hodgkin's lymphoma (NHL), solid tumors and as a preconditioning regimen for transplantation. Although we are currently not directly involved with these programs, Genzyme is required to share the data generated thereunder in accordance with the terms of our co-development agreement.

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We have completed preclinical development of a gel formulation of Evoltra(R) and have completed enrollment to two Phase I clinical studies of the gel in healthy volunteers and in patients with severe psoriasis. We are planning further worldwide development of Evoltra(R) in psoriasis and other autoimmune diseases.

We have an exclusive worldwide license for clofarabine. We granted an exclusive sublicense to Genzyme to co-develop clofarabine for certain 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). We hold an exclusive license in the US and Canada for all non-cancer indications. We 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

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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 1/2 years, expiring in 2012.

In the U.S. clofarabine is currently being evaluated in several investigator-sponsored studies for the treatment of a variety of hematological cancers including AML, MDS, CLL and NHL. In addition, commencing in calendar 2007 and 2008, we hope to further investigate clofarabine in European clinical trials for MDS, AML, CLL, NHL and solid tumor cancer indications. In pre-clinical studies, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the lung, ovary, colon, kidney, breast, pancreas and prostate, as well as its action against numerous leukemia cells. We believe the initial data from the Phase I clinical trials indicate sufficient possible activity for clofarabine in certain solid tumor types to warrant further clinical development.

Pursuant to the terms of our co-development agreement with SRI, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications but have sub-licensed the marketing rights within cancer indications in North America to Genzyme. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the development and marketing of clofarabine, which we currently expect to expire in 2021.

To date, the majority of our development activities and resulting R&D expenditures have related to the development of clofarabine. Our primary business strategy has included taking clofarabine to market in the E.U. and using the proceeds from our resulting marketing efforts, in part, to expand the indications for clofarabine and to progress the other products and technologies in our pipeline.

We currently market Modrenal(R) (trilostane) in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. We have a team of six sales specialists and two marketing executives who dedicate a portion of their time selling and marketing Modrenal(R) (and Evoltra(R)) in the U.K.

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 with Suvus(R) for the treatment of chronic 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) an investigator-sponsored phase II clinical study has been completed in patients with hepatitis C viral infection. We have had discussions with potential product 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 to Dechra the marketing and development rights to Vetoryl(R) (trilostane), solely with respect to animal health applications, in the U.S. and Canada. 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. In January 2007, we entered into a licensing

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arrangement with Foster Corporation ("Foster") to license out exclusive rights to manufacture, market and distribute our proprietary anti-microbial OLIGON(R) technology. Under the terms of the license agreement, we will have a revenue sharing arrangement on future sublicenses and a royalty on all sales by Foster, a Connecticut-based compounder of biomedical materials. Foster is required to comply with annual minimum marketing and research and development expenditures within the first three years of the term of the license.

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

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:

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- 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 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;
- 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 other 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 March 31, 2007 and 2006 of approximately \$4,957,000 and \$1,741,000, respectively, representing an increase of approximately \$3,216,000. This increase is primarily due to increased product sales of \$3,857,000 as a result of Evoltra's approval in Europe. Prior to the approval, all product sales through the named patient program were reflected as research and development contract revenue. The Company recorded revenue for the nine months ended March 31, 2007 and 2006 of approximately \$12,319,000 and \$3,503,000, respectively, representing an increase

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of approximately \$8,816,000. This increase is primarily due to increased product sales of \$9,050,000 as a result of Evoltra's approval in Europe as well as an increase of approximately \$1,329,000 in license and royalty revenue due to increased royalties on US sales received from our co-development partner.

The cost of products sold for the three months ended March 31, 2007 and 2006 were approximately \$985,000 and \$387,000, respectively, representing an increase of approximately \$598,000. The cost of products sold reflects the direct costs associated with our product sales and includes royalty expense of \$854,000 and \$316,000 for the three months ended March 31, 2007 and 2006, respectively. The cost of products sold for the nine months ended March 31, 2007 and 2006 were approximately \$2,306,000 and \$1,153,000, respectively, representing an increase of approximately \$1,153,000. The cost of products sold reflects the direct costs associated with our product sales and includes royalty expense of \$1,974,000 and \$847,000 for the nine months ended March 31, 2007 and 2006, respectively. All direct costs associated with clofarabine sales were expensed in periods prior to the E.U. approval.

Research and development costs for the three months ended March 31, 2007 and 2006 were approximately \$4,722,000 and \$2,785,000, respectively, representing an increase of approximately \$1,937,000. Research and development costs for the nine months ended March 31, 2007 and 2006 were approximately \$18,307,000 and \$7,227,000, respectively, representing an increase of approximately \$11,080,000. 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:

| Product      | Three Months Ended<br>March 31, |              | Nine Months En<br>March 31, |               |
|--------------|---------------------------------|--------------|-----------------------------|---------------|
|              | 2007<br>----                    | 2006<br>---- | 2007<br>----                | 2006<br>----  |
| Evoltra (R)  | \$ 4,399,000                    | \$ 2,314,000 | \$ 16,150,000               | \$ 16,150,000 |
| Modrenal (R) | 304,000                         | 426,000      | 2,122,000                   | 2,122,000     |
| Suvus (R)    | 19,000                          | 45,000       | 35,000                      | 35,000        |
| Velostan     | -                               | -            | -                           | -             |

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|              |                       |                       |                        |                        |
|--------------|-----------------------|-----------------------|------------------------|------------------------|
| OLIGON (R)   | -                     | -                     | -                      | -                      |
| Gene Therapy | -                     | -                     | -                      | -                      |
| Total        | \$ 4,722,000<br>===== | \$ 2,785,000<br>===== | \$ 18,307,000<br>===== | \$ 18,307,000<br>===== |



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Evoltra(R) research and development costs for the three months ended March 31, 2007 and 2006 were approximately \$4,399,000 and \$2,314,000 respectively, representing an increase of approximately \$2,085,000. The increase is primarily due to 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, the enrollment of patients in our Phase II trial in Europe for the treatment of adult AML in elderly patients unfit for intensive chemotherapy, 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. Evoltra(R) research and development costs for the nine months ended March 31, 2007 and 2006 were approximately \$16,150,000 and \$5,744,000, respectively, representing an increase of approximately \$10,406,000. 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 September of 2006 as well as the aforementioned increase in the development activities and clinical trials of Evoltra(R) in Europe.

Modrenal(R) research and development costs for the three months ended March 31, 2007 and 2006 were approximately \$304,000 and \$426,000, respectively, representing a decrease of \$122,000. This decrease is due to a reduce rate of patient enrollment in the Phase II clinical trial in pre-menopausal breast cancer. Modrenal(R) research and development costs for the nine months ended March 31, 2007 and 2006 were approximately \$2,122,000 and \$1,341,000, respectively, representing an increase of \$781,000. The 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 March 31, 2007 and 2006 were approximately \$19,000 and \$45,000, respectively, representing a decrease of \$26,000. Suvus(R) research and development costs for the nine months ended March 31, 2007 and 2006 were approximately \$35,000 and \$142,000 respectively, representing a decrease of \$107,000. The decrease primarily reflects the costs associated with the investigator sponsored Phase II clinical trial conducted in Egypt in the prior period.

There were no research and development costs associated with Velostan for the three and nine months ended March 31, 2007 and 2006 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.

There were no research and development costs for OLIGON(R) for the three and nine months ended March 31, 2007 and 2006 due to the Company's entering into a licensing arrangement with Foster to license out exclusive rights to manufacture, market and distribute the Company's proprietary anti-microbial OLIGON(R) technology in January 2007. No additional costs are expected to be incurred by the Company in connection with future development of OLIGON(R) by Foster.

There were no research and development costs associated with Gene Therapy for the three and nine months ended March 31, 2007 and 2006 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

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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 \$39,590,000; (ii) Modrenal(R) research and development costs have been approximately \$10,774,000; (iii) Velostan research and development costs have been approximately \$380,000; (iv) Suvus(R) research and development costs have been approximately \$543,000; (v) OLIGON 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 March 31, 2007 and 2006 were approximately \$6,931,000 and \$6,914,000, respectively, representing an increase of \$17,000. Selling, general and administrative expenses for the nine months ended March 31, 2007 and 2006 were approximately \$18,722,000 and \$12,383,000, respectively, representing an increase of \$6,339,000. This increase is primarily relating to the costs associated with the expanded sales and marketing and administrative infrastructure and costs associated with the internal build out of the Company. Other factors include an increase in stock-based compensation expense due to the issuance of common stock to an officer of the Company pursuant to the terms of his amended employment agreement and the granting of stock options to an officer as inducement to serve as the Chief Financial Officer to the Company.

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Depreciation and amortization expense for the three months ended March 31, 2007 and 2006 was approximately \$275,000 and \$247,000, respectively, representing an increase of \$28,000. Depreciation and amortization expense for each of the nine months ended March 31, 2007 and 2006 was approximately \$758,000 and \$729,000, respectively, representing an increase of \$29,000.

### 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 March 31, 2007, we had cash and cash equivalents and short-term investments totaling, in the aggregate, approximately \$20,613,000. On April 4, 2007, we completed a registered direct offering in which we sold 8,000,000 common shares at \$3.75 per share, with net proceeds to the Company of approximately \$27.6 million, after deducting underwriting discounts and commissions and estimated offering expenses. Management believes the Company has sufficient cash and cash equivalents, short-term investments 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

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to obtain additional financing, if required, would have a material adverse effect on our ability to continue our operations and implement our business plan.

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 nine months ended March 31, 2007 and 2006, net cash used in operating activities was approximately \$25,529,000 and \$14,828,000, respectively, representing an increase of approximately \$10,701,000. 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 nine months ended March 31, 2007 and 2006, net cash provided by (used in) investing activities was approximately \$31,562,000 and \$(7,759,000), respectively, representing an increase of approximately \$39,321,000. This increase is primarily due to the redemption of our certificates of deposit during the period. For the nine months ended March 31, 2007 and 2006, net cash provided by (used in) financing activities was approximately \$457,000 and \$(233,000) representing an increase of \$690,000. This increase is primarily due to proceeds from the exercise of warrants and cash received on a promissory note due from a shareholder.

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

|                         | 2007       | 2008         | 2009       | 2010         |
|-------------------------|------------|--------------|------------|--------------|
| Operating Leases        | \$ 295,486 | \$ 927,698   | \$ 373,757 | \$ 1,000,000 |
| Contractual obligations | 115,955    | 1,000,000    | 250,000    | 500,000      |
| Totals                  | \$ 411,441 | \$ 1,927,698 | \$ 623,757 | \$ 1,500,000 |

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.

### Subsequent Events

On April 5, 2006, we completed a secondary public offering in which we sold 8,000,000 common shares at \$3.75 per share, with net proceeds to the Company of approximately \$27.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

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As further described in the Company's current report on Form 8-K, filed on April 26, 2007, on April 20, 2007, Bioenvision Limited, a wholly owned subsidiary of Bioenvision, Inc. and its Medical Director, Dr. Andrew Saunders, entered into an agreement (the "Compromise Agreement"), pursuant to which the parties agreed Dr. Saunders' would no longer be employed by Bioenvision Limited effective April 9, 2007. Under the terms of the Compromise Agreement, Dr. Saunders received a lump sum payment of (pound)124,000 Sterling (approximately \$244,000), upon receipt by the Company of the fully executed Compromise Agreement, in consideration of a release by Dr. Saunders for the benefit of the Bioenvision Limited and any Associated Company (as defined in the Compromise Agreement), including its parent company, Bioenvision, Inc. In addition, Dr. Saunders received his normal salary, accrued holiday pay of 4 days and contractual benefits up to and including April 9, 2007, subject to deduction of tax and National Insurance in the normal manner.

As further described in the Company's current report on 8-K, filed on May 4, 2007, on April 30, 2007, an affiliate of SCO Capital Partners LLC, exercised warrants to purchase an aggregate of 250,000 shares of the Company's common stock at a purchase price of \$1.50 per share. On May 2, 2007, SCO Capital Partners, exercised warrants to purchase an aggregate of 688,333 shares of the Company's common stock at a purchase price of \$1.50 per share. Also on May 2, 2007, Perseus-Soros Biopharmaceutical Fund, LP exercised warrants to purchase an aggregate of 3,000,000 shares of the Company's common stock at a purchase price of \$2.00 per share. All of these warrants were issued in connection with a private placement of preferred stock and warrants in May 2002 and would have expired if not exercised by May 7, 2007. As a result of the exercise of these warrants, the Company received aggregate net cash proceeds of approximately \$7.4 million.

### Recent Accounting Pronouncements

In February 2007, Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities- Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 expands the use of fair value accounting but does not affect existing standards which require assets and liabilities to be carried at fair value. Under SFAS 159, a company may elect to use fair value to measure accounts and loans receivable, available-for-sale and held-to-maturity securities, equity method investments, accounts payable, guarantees, issued debt and other eligible financial instruments. SFAS 159 is effective for fiscal years beginning after November 15, 2007 and the Company is currently evaluating its impact.

In December 2006, the FASB issued a FASB Staff Position Emerging Issues Task Force ("EITF") Issue No. 00-19-2 "Accounting for Registration Payment Arrangements" ("FSP 00-19-2") which addresses an issuer's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5 "Accounting for Contingencies". The guidance in FSP 00-19-2 amends FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", and FASB Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity", and FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of FSP00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior

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to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company has analyzed the provisions of FSP 00-19-2 and determined that it will not have a material effect on the Company's consolidated financial statements.

In September 2006, the FASB issued SFAS 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.

In September 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

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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.

In June 2006, the FASB ratified the consensus of EITF Issue No. 06-3, "How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement" ("EITF 06-3"). EITF 06-3 indicates that the income statement presentation on either a gross basis or a net basis of the taxes within the scope of the issue is an accounting policy decision. The Company's accounting policy is to present the taxes within the scope of EITF 06-3 on a net basis. The adoption of EITF 06-3 in the second fiscal quarter of 2007 did not result in a change to the Company's accounting policy and, accordingly, did not have any effect on the Company's consolidated financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 ("FIN 48"). This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. This interpretation prescribes that a company should use a more likely than not recognition threshold based on the technical merits of the tax position taken. Tax positions that meet the more likely than not recognition threshold should be measured in order to determine the tax benefit to be recognized in the financial statements. FIN 48 is effective in fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on the results of operations or financial condition of the Company.

### ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Our excess cash is invested in money market accounts and Certificates of

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Deposit with various short-term maturities. We hold no derivative financial instruments and we do not currently engage in hedging activities. As of March 31, 2007, 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, as well some exposure to foreign currency rate fluctuations arising from maintaining an office for the Company's Japan based wholly-owned subsidiary which transacts business in the local 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 March 31, 2007, there have been no changes in our internal controls over financial reporting that materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

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## BIOENVISION, INC. AND SUBSIDIARIES

### PART II - OTHER INFORMATION

#### ITEM 1. Legal Proceedings

None.

#### Item 1A. Risk Factors

We have limited experience in developing products and may be unsuccessful in our efforts to develop and commercialize our products, including our application for E.U. approval in adult AML.

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. In particular, we have submitted a filing for approval in patients with adult AML with the EMEA, and we are susceptible to the risk that our recent EMEA filing submission, which we announced we filed in February 2007 for the treatment of adult patients with AML, will not be approved or will not be approved on a timely basis in accordance with our expectations. No assurance can be given that management's

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development efforts and/or commercial expectations will be successful and accurate.

We are developing clofarabine in conjunction with Genzyme, our U.S. co-development partner since its acquisition of ILEX Oncology, which occurred on December 21, 2004. No assurance can be given that the operational and managerial relations with Genzyme will proceed favorably or that the timeline for development of clofarabine will not be elongated now that Genzyme has replaced ILEX as our U.S. cancer-indication marketing partner. No assurance can be given that we or Genzyme have the oncology experience required to work successfully with the applicable regulatory authorities to build upon the licensed indications for clofarabine.

With respect to Modrenal(R), our long-term drug development objectives for Modrenal(R) may include attempting to test the drug and get approval in the U.S. for treatment of advanced post-menopausal breast cancer patients. These trials would take significant time and resources and no assurance can be given that developing the drug in this indication will result in a U.S. approval for Modrenal(R) in advanced post-menopausal breast cancer patients.

Certain of our unapproved compounds or potential new indications for our approved drugs are not expected to be available for sale for at least several years, if at all. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

- o discovery during pre-clinical testing or clinical trials that the products are ineffective or cause harmful side effects;
- o failure to receive necessary regulatory approvals;
- o inability to manufacture on a large or economically feasible scale;
- o failure to achieve market acceptance; or
- o preclusion from commercialization by proprietary rights of third parties.

Most of the existing and future products and technologies developed by us will require extensive additional development, including pre-clinical testing and clinical trials, as well as regulatory approvals, prior to commercialization. Our product development efforts may not be successful. We may fail to receive required regulatory approvals from U.S. or foreign authorities for any indication. Any products, if introduced, may not be capable of being produced in commercial quantities at reasonable costs or being successfully marketed. The failure of our research and development activities to result in any commercially viable products or technologies would materially adversely affect our future prospects.

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

None.

### ITEM 3. Defaults Upon Senior Securities

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None.

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

None.

ITEM 5. Other Information

None.

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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 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) |



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- 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)

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- 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 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

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- 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)
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- 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)
- 10.22 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc.,

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- 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 dated 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 (26)
- 10.35 Employment Agreement by and between the Company and James S. Scibetta, dated November 27, 2006. (27)
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- 10.36 Amendment to Clofarabine Marketing and Development Agreement, by and between Bioenvision Inc. and Mayne Pharma Limited, dated November 2, 2006.(29)
- 10.37 Entrustment Agreement, by and between Bioenvision JapanCo Ltd. and Yoshimaru Yamamoto, dated January 31, 2007. (28)

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- 10.38                   Compromise Agreement by and between Bioenvision Limited and Dr. Andrew Saunders, dated April 20, 2007. (30)
- 14.1                   Bioenvision Inc.'s Code of Business Conduct and Ethics (19)
- 16.1                   Letter from Graf Repetti & Co., LLP to the Securities and 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 James S. Scibetta, 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.

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- (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.

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- (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.
- (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.

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- (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.
- (26) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q, for the three month period ended September 30, 2006.

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- (27) Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on November 30, 2006.
- (28) Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on February 6, 2007.
- (29) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q, for the three month period ended December 31, 2006.
- (30) Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on April 26, 2007.

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SIGNATURES

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

Date: May 9, 2007 By: /s/ Christopher B. Wood M.D.

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

Date: May 9, 2007 By: /s/James S. Scibetta

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James S. Scibetta  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

