

BIOENVISION INC  
Form POS AM  
August 05, 2005

As filed with the Securities and Exchange Commission on August 5, 2005

Registration No. 333-115816

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

\_\_\_\_\_  
**POST-EFFECTIVE AMENDMENT NO. 3 TO FORM S-3 ON**

**FORM S-1**

**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

**BIOENVISION, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)  
345 Park Avenue, 41st Floor

13-4025857  
(I.R.S. Employer Identification No.)

New York, New York 10154

(212) 750-6700

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**David P. Luci, Esq.**

**Chief Financial Officer and General Counsel**

**Bioenvision, Inc.**

**345 Park Avenue, 41st Floor**

**New York, New York 10154**

Edgar Filing: BIOENVISION INC - Form POS AM

**(212) 750-6700**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

**Luke P. Iovine, III, Esq.**

**Paul, Hastings, Janofsky & Walker LLP**

**75 East 55th Street**

**New York, NY 10022**

**(212) 318-6000**

**Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.**

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434 under the Securities Act, please check the following box.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

---

**EXPLANATORY NOTE**

We have previously registered 30,164,746 common shares pursuant to a Registration Statement on Form SB-2 filed with the Securities and Exchange Commission on May 24, 2004 (File No. 333-115816), as amended on Form SB-2 filed with the SEC on June 21, 2004 (File No. 333-115816), as further amended on Form S-3 filed with the SEC on October 13, 2004 (File No. 333-115816) and as further amended on Form S-3 filed with the SEC on November 16, 2004 (File No. 333-115816).

---

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**SUBJECT TO COMPLETION DATED AUGUST 4, 2005**

**PRELIMINARY PROSPECTUS**

## **Bioenvision, Inc.**

### **27,083,742 Shares of Common Stock**

This prospectus covers 27,083,742 shares of our common stock that the selling stockholders named herein may offer and sell from time to time.

The selling stockholders may sell the shares directly or through broker-dealers or underwriters, at various times and in various types of public or private transactions, including in the open market, in negotiated transactions or by any combination of these methods, at prevailing market prices or at privately negotiated prices. Each selling stockholder will determine the selling price of his or its shares at the time of sale, and will receive all of the net proceeds from the sales and pay all brokerage commissions and similar selling expenses, if any. We will pay the expenses incident to the registration of the shares, but we will not receive any proceeds from the sale of the shares by the selling stockholders.

The selling stockholders and any agents, broker-dealers or underwriters that are involved in selling their shares may be deemed to be underwriters within the meaning of the Securities Act of 1933 and any commissions received by them and any profit on the resale of the shares may be deemed to be underwriting commissions or discounts under that Act.

Our common stock is included for quotation on the Nasdaq National Market under the symbol **BIVN**. The last reported sales price of shares of our common stock on August 1, 2005, was \$7.65 per share.

**See Risk Factors beginning on page 9 to read about risks that you should consider before buying our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission or other regulatory body has approved or disapproved these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2005

**TABLE OF CONTENTS**

**Page**

|                                     |    |
|-------------------------------------|----|
| SUMMARY                             | 2  |
| THE OFFERING                        | 6  |
| SUMMARY CONSOLIDATED FINANCIAL DATA | 7  |
| RISK FACTORS                        | 9  |
| FORWARD-LOOKING STATEMENTS          | 23 |
| USE OF PROCEEDS                     | 24 |
| MARKET PRICE OF OUR COMMON STOCK    | 25 |
| DIVIDEND POLICY                     | 25 |
| SELLING STOCKHOLDERS                | 26 |
| DESCRIPTION OF OUR CAPITAL STOCK    | 33 |

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with information that differs from what is contained in this prospectus. If any person does provide you with information that differs from what is contained in this prospectus, you should not rely on it. This prospectus is not an offer to sell or the solicitation of an offer to buy any securities other than the securities to which it relates, nor an offer or solicitation in any jurisdiction where offers or sales are not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, even though this prospectus may be delivered or shares may be sold under this prospectus at a later date.

---

**SUMMARY**

*You should read the following summary together with the more detailed information regarding us and the securities being offered for sale by means of this prospectus and our financial statements and notes to those statements appearing elsewhere in this prospectus. The summary highlights information contained elsewhere in this prospectus. The terms Bioenvision, the company, we, our and us refer to Bioenvision, Inc. and its consolidated subsidiaries unless the context suggests otherwise. The term you refers to a prospective investor.*

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. The FDA recently approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL. We believe clofarabine is the first new medicine initially approved in the United States for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for all cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is marketing clofarabine under the brand name Clolar in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL with the European Medicines Evaluation Agency, or EMEA. If approved, we anticipate commencing sales in Europe during the second half of calendar 2005 through a dedicated European sales force.

We are selling our second product, Modrenal, in the United Kingdom, through our sales force of eight sales specialists. Modrenal is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and we have initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden. In addition to clofarabine and Modrenal, we are developing Virostat for Hepatitis C.

**Products and pipeline**

| Candidate            | Indication                                          | Status                                                             | U.S. rights | Ex-U.S. rights |
|----------------------|-----------------------------------------------------|--------------------------------------------------------------------|-------------|----------------|
| Clofarabine (Clolar) | Relapsed or Refractory Acute Lymphoblastic Leukemia | Marketed in U.S. (pediatric);<br>Filed in E.U. (pediatric)         | Genzyme     | Bioenvision    |
|                      | Acute Myelogenous Leukemia                          | Phase II in E.U. (adult)                                           | Genzyme     | Bioenvision    |
|                      | Refractory Chronic Lymphocytic Leukemia             | Phase II in U.S. (adult)                                           | Genzyme     | Bioenvision    |
|                      | Solid Tumors                                        | Phase I (Intravenous)                                              | Genzyme     | Bioenvision    |
|                      | Solid Tumors                                        | Phase I (Oral)                                                     | Genzyme     | Bioenvision    |
|                      | Non-Cancer                                          | Developmental                                                      | Bioenvision | Bioenvision    |
| Modrenal             | Breast Cancer                                       | Marketed in U.K.;<br><br>Phase IV in U.K.;<br><br>Phase II in E.U. | Bioenvision | Bioenvision    |
|                      | Prostate Cancer                                     | Phase II in U.S.                                                   | Bioenvision | Bioenvision    |
| Virostat             | Hepatitis C                                         | Investigator<br>Sponsored Phase II in Europe<br>and Middle East    | Bioenvision | Bioenvision    |





## Our Products

### Clofarabine (Clolar)

On December 28, 2004, clofarabine was approved by the FDA after a fast track review for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two prior regimens. Genzyme currently maintains rights to market the drug for all cancer indications in the U.S. and Canada and we will receive a royalty on these sales. Genzyme is marketing clofarabine under the brand name Clolar. We also submitted a Marketing Authorization Application, or MAA, the European equivalent of a U.S. new drug application, or NDA, with the EMEA in July 2004 for European approval of clofarabine in relapsed or refractory pediatric acute leukemia. We expect an opinion from the EMEA in mid-2005. Clofarabine received Orphan Drug designation in the U.S. and in Europe, which provides ten years of marketing exclusivity in Europe and seven years of marketing exclusivity in the U.S. Further, in July 2004, the FDA granted a six-month extension of the marketing exclusivity for clofarabine in pediatric ALL under the federal Best Pharmaceuticals for Children Act.

Pediatric leukemia is the most prevalent form of cancer among children up to age 19 in the U.S. It is estimated that approximately 3,400 children were diagnosed with leukemias in the U.S. in 2004, with ALL accounting for over 75% of the incidence rate. Although survival rates for childhood leukemia have improved significantly since the early 1970s, approximately 20% of pediatric patients with ALL and 60% of pediatric patients with AML do not achieve long-term survival and we believe there is a medical need for new agents to treat this population of patients. Clofarabine is approved for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two prior regimens. The adult leukemia market represents a potentially significantly larger commercial opportunity with over 11,500 patients with AML and over 8,000 patients with chronic lymphocytic leukemia, or CLL, diagnosed each year within the U.S. Based on population and incidence rates data, we believe that the E.U. patient population with pediatric leukemias and adult AML and CLL approximates that of the U.S.

Clofarabine is a purine nucleoside analog, which is a small molecule, that we are developing with Genzyme, our co-development partner, for the treatment of acute and chronic leukemias, lymphomas and solid tumors. Clofarabine attacks cancer cells by damaging DNA in cancer cells, preventing DNA repair by damaged cancer cells, damaging the cancer cell's important control structures, and initiating the process of programmed cell death, or apoptosis, in cancer cells. Clofarabine appears to combine many of the favorable properties of the two most commonly used purine nucleoside analog drugs, fludarabine and cladribine, but appears to have greater potency at damaging the DNA of leukemia cells and a broader range of clinical activity.

In the U.S., pivotal Phase II clinical trials were conducted for the treatment of relapsed or refractory acute leukemia in children and an NDA was filed by Genzyme with the FDA in March 2004, based upon the interim results of 70 patients enrolled in these two trials. In August of 2004, clinical data on an additional cohort of 14 patients were submitted to the FDA and of the aggregate ALL group of 49 patients, a 31% overall response rate was achieved, and of the aggregate AML group of 35 patients, a 26% overall response rate was achieved.

In Europe, we facilitated an investigator sponsored trial, or an IST, of clofarabine as first line therapy for older adult patients with AML who were unsuitable for intensive chemotherapy. The IST was closed to recruitment in August 2004 because a 67% overall response rate was achieved. This response rate was more than three times greater than the expected response rate under the current standard of care for this patient population and the investigator determined that these positive results warranted accelerated initiation of the pivotal Phase II regulatory study of clofarabine as a first-line treatment for older adult patients newly diagnosed with AML. We expect to complete the Phase II trial in mid-2005 and anticipate that it will form the basis for an E.U. regulatory submission for approval in this indication.

On December 1, 2004 the FDA's Oncologic Drug Advisory Committee, or ODAC, convened to determine if clinical data from Phase II trials in relapsed and refractory pediatric ALL and AML demonstrated a durable clinical response that would predicate a clinical benefit in future clinical administration. The panel voted in favor of the approval of clofarabine for pediatric ALL under its accelerated approval pathway and voted against immediate use in pediatric AML, requesting additional information. In connection with the approval that was granted by the FDA, Genzyme is required to conduct further control studies of clofarabine to verify and describe its clinical benefit.



Clofarabine is currently being evaluated in an IST Phase II clinical trial for refractory CLL in the U.S. In addition, in 2005 we intend to investigate clofarabine in European Phase II clinical trials for CLL and indolent lymphoma. In pre-clinical studies, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the lung, colon, kidney, breast, pancreas and prostate, as well as its action against leukemia cells. The initial data from the Phase I clinical trials indicate activity for clofarabine in certain solid tumor types. We believe this level of activity against solid tumors distinguishes clofarabine from other purine nucleoside analogs. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon, pancreatic, lung, breast and prostate cancer. Currently, we anticipate the initial Phase I clinical trials for clofarabine, using both the oral and intravenous formulations, in solid tumors will be completed by end of calendar 2005.

Pursuant to the terms of our co-development agreement with Genzyme, the successor-in-interest to ILEX Oncology, Inc., both parties are required to share promptly all information, including clinical data, generated under the co-development program and Genzyme is obligated to pay all of the U.S. and Canadian research and development costs and 50% of all approved ex-U.S. and Canada research and development costs (except for Japan and Southeast Asia). If additional resources are required above the agreed upon costs, we may elect to pay these additional costs and certain of these payments will be credited against future royalty payments to Genzyme at the rate of \$1.50 for every \$1.00 of additional expenditures. Under the co-development agreement with Genzyme, we receive royalties on Genzyme's annual net sales on a sliding scale based on the level of annual net sales. Similarly, we pay a royalty to Genzyme and Southern Research Institute, the inventor of clofarabine, on our European annual net sales.

Pursuant to the terms of our co-development agreement with Southern Research Institute, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications except for U.S. and Canadian cancer indications and except for any indications in Japan and Southeast Asia. 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 expect to expire in 2021. In addition, we hold an exclusive option from Southern Research Institute to market and distribute clofarabine in Japan and Southeast Asia for all human applications. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in Japan and Southeast Asia.

### **Modrenal**

We currently market Modrenal (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 eight sales specialists and two marketing executives selling and marketing Modrenal in the U.K.

Modrenal's licensed indication enables us to promote Modrenal for use immediately after relapse to initial hormone therapy such as tamoxifen or one of a class of drugs known as aromatase inhibitors. However, we are initially positioning Modrenal as a third or fourth line treatment option in post-menopausal advanced breast cancer. In the five largest E.U. countries (France, Germany, Italy, Spain and the U.K.), we believe approximately 520,000 women are currently living with post-menopausal advanced breast cancer of which over a third require third or fourth line agents following prior treatment failure.

Modrenal has been extensively studied in clinical trials in the U.S., Europe and Australia, and an analysis, known as a meta-analysis, of a series of these clinical studies, that included 714 patients with post-menopausal advanced breast cancer who received Modrenal has been conducted. Overall, a clinical benefit rate of 35% was achieved in patients with both hormone-sensitive and hormone-insensitive breast cancers. Generally, a clinical benefit is achieved when a patient's disease disappears, is decreased by greater than fifty percent or is stabilized for at least six months. In a sub-set analysis of these clinical trial data, a clinical benefit rate of 46% was achieved for 351 patients with hormone-sensitive breast cancer who had responded to one or more prior hormonal therapies and were given Modrenal upon relapse of the cancer. In one of the studies which was conducted in Australia, a clinical benefit rate of 55% was achieved for 64 patients who received Modrenal having previously responded to tamoxifen and subsequently relapsed. We believe these data compare favorably to currently marketed aromatase inhibitors and other agents given as second line or subsequent therapies. Furthermore, Modrenal has an acceptable side-effect profile. On the basis of these data, Modrenal was granted a product license in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.



We began marketing Modrenal in May 2003 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. We also intend to seek regulatory approval for Modrenal in the U.S. as a therapy for hormone-sensitive breast cancers and hormone independent prostate cancers, but this strategy is dependent upon the results of the ongoing clinical trials and our resource capability. Our ongoing clinical trials in breast cancer target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as tamoxifen or any of the aromatase inhibitors. In addition, there is an ongoing Phase II clinical trial of Modrenal in the U.S. that is focused on patients who have androgen independent prostate cancer and have a rising prostate specific antigen, or PSA, level.

In mid-2005 we began enrollment in a U.K., Phase IV study in post-menopausal advanced breast cancer, a Phase II study in pre-menopausal breast cancer and a Phase II study in neo-adjuvant, pre-operative breast cancer. In Europe, we have initiated the filing process for mutual recognition for approval of Modrenal on a country-by-country basis. Each such approval, if granted, would be based upon Modrenal's approval in the U.K. for post-menopausal advanced breast cancer following relapse to initial hormone therapy. We anticipate such approvals would be granted, on a country-by-country basis, within nine to 12 months following each such filing, but grant of any such approval is entirely within the control of the individual regulatory authorities.

We have the exclusive right to market and distribute Modrenal throughout the world for all human applications, except for South Africa and Japan where the drug is marketed for the treatment of low-renin hypertension. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the marketing of Modrenal. Given that we have new patent applications filed, which are subject to issuance, we expect the last of our underlying patents to expire in 2020.

#### **Virostat**

Virostat is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. Virostat, especially when irradiated by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Investigator sponsored Phase II clinical trials have been initiated in Europe and the Middle East to study Virostat's use in treating Hepatitis C.

Blood transfusions are required to treat a variety of medical conditions and, to meet that need, over 90 million blood donations occur each year. Of these, approximately 39 million donations occur in North America, Western Europe and Japan. We licensed from Oklahoma Medical Research Foundation the rights to use a range of thiazine dyes, including Virostat, for their use in in vitro and in vivo inactivation of pathogens in biological fluids.

#### **Corporate Information**

We were incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed our name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in January 1999. Our principal executive offices are located at 345 Park Avenue, 41st Floor, New York, New York 10154. Our telephone number is (212) 750-6700 and our fax number is (212) 750-6777. Our website is [www.bioenvision.com](http://www.bioenvision.com). Information included or referred to on our website is not incorporated by reference in or otherwise a part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

**The Offering**

Common stock offered by selling stockholders  
Common stock to be outstanding as of August 1, 2005  
Use of proceeds

27,083,742 shares.

40,569,567 shares.

We will not receive any proceeds from the sale of shares in this offering. We may receive consideration upon the exercise of options and will receive consideration upon the conversion of warrants which we intend to use for general corporate purposes.

Trading

Our common stock currently trade on the Nasdaq National Market under the symbol BIVN.

Risk Factors

You should carefully consider all of the information in this prospectus. In particular, you should evaluate the information under Risk Factors beginning on page 9 of this prospectus before deciding whether to invest in our common stock.

Plan of Distribution

The shares of common stock offered for resale may be sold by the selling stockholders pursuant to this prospectus in the manner described under Plan of Distribution on page 72.

**SUMMARY CONSOLIDATED FINANCIAL DATA**

The following tables summarize our consolidated financial data. You should read the summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus, and the Management's Discussion and Analysis of Financial Condition and Results of Operations section and other financial information included in this prospectus.

| <b><u>Income Statement Data</u></b>                            | <b>Year Ended June 30,</b> |                    |                    |                    |                    | <b>Nine Months Ended</b> |                    |
|----------------------------------------------------------------|----------------------------|--------------------|--------------------|--------------------|--------------------|--------------------------|--------------------|
|                                                                | <b><u>2004</u></b>         | <b><u>2003</u></b> | <b><u>2002</u></b> | <b><u>2001</u></b> | <b><u>2000</u></b> | <b><u>March 31,</u></b>  | <b><u>2004</u></b> |
|                                                                | As Restated (1)            | As Restated (1)    | As Restated (1)    |                    |                    | As Restated (2)          | As Restated (2)    |
| Revenues                                                       | \$3,102,214                | \$504,857          | \$802,965          | \$245,455          | \$-                | \$3,660,220              | \$1,750,000        |
| Cost of sales                                                  | -                          | -                  | -                  | -                  | -                  | 229,417                  | -                  |
| Operating expenses                                             |                            |                    |                    |                    |                    |                          |                    |
| Research and development                                       | 4,882,574                  | 1,689,278          | 1,912,258          | 1,565,908          | 984,460            | 5,986,496                | 2,545,000          |
| General and administrative                                     | 9,082,420                  | 4,567,413          | 2,127,664          | 550,215            | 486,627            | 6,885,382                | 7,079,000          |
| Depreciation and amortization                                  | <u>1,348,064</u>           | <u>1,344,969</u>   | <u>579,342</u>     | <u>22,809</u>      | <u>11,644</u>      | <u>1,028,197</u>         | <u>1,023,000</u>   |
| Total operating expenses                                       | <u>15,313,058</u>          | <u>7,601,660</u>   | <u>4,619,264</u>   | <u>2,138,932</u>   | <u>1,482,731</u>   | <u>13,900,075</u>        | <u>10,647,000</u>  |
| Loss from operations                                           | (12,210,844)               | (7,096,803)        | (3,816,299)        | (1,893,477)        | (1,482,731)        | (10,469,272)             | (8,887,000)        |
| Other income (expense)                                         | <u>99,763</u>              | <u>(186,426)</u>   | <u>(2,172,682)</u> | <u>(228,787)</u>   | <u>(12,778)</u>    | <u>297,479</u>           | <u>49,460</u>      |
| Loss from continuing operations                                | (12,111,081)               | (7,283,229)        | (5,988,981)        | (2,122,264)        | (1,495,509)        | (10,171,793)             | (8,837,540)        |
| Income tax benefit                                             | <u>1,459,814</u>           | <u>2,117,103</u>   | <u>1,168,145</u>   | -                  | -                  | -                        | <u>1,065,000</u>   |
| Net loss                                                       | (10,651,267)               | (5,166,126)        | (4,820,836)        | (2,122,264)        | (1,495,509)        | (10,171,793)             | (7,772,540)        |
| Cumulative preferred stock dividend                            | <u>(856,776)</u>           | <u>(877,818)</u>   | <u>(9,482,667)</u> | -                  | -                  | <u>(319,935)</u>         | <u>(587,000)</u>   |
| Net loss available to shareholders                             | \$(11,508,043)             | \$(6,043,944)      | \$(14,303,503)     | \$(2,122,264)      | \$(1,495,509)      | \$(10,491,728)           | \$(8,359,540)      |
| Basic and diluted shares outstanding                           | 20,257,482                 | 16,920,939         | 12,184,152         | 8,121,255          | 7,430,965          | 31,907,864               | 18,120,000         |
| Basic and diluted net loss available to shareholders per share | \$ (0.57)                  | \$ (0.36)          | \$ (1.17)          | \$ (0.26)          | \$ (0.20)          | \$ (0.33)                | \$ (0.46)          |

| <b><u>Balance Sheet Data</u></b>     | <b>June 30,</b>    |                    |                    |                    |                    | <b>March 31,</b>   |                    |
|--------------------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
|                                      | <b><u>2004</u></b> | <b><u>2003</u></b> | <b><u>2002</u></b> | <b><u>2001</u></b> | <b><u>2000</u></b> | <b><u>2005</u></b> | <b><u>2004</u></b> |
|                                      | As Restated (1)    | As Restated (1)    | As Restated (1)    | As Restated (1)    |                    | As Restated (2)    | As Restated (2)    |
| Cash & cash equivalents              | \$19,165,675       | \$8,219,686        | \$12,882,521       | \$15               | \$70,624,319       | \$19,848,813       |                    |
| Intangibles, net                     | 14,563,660         | 15,779,399         | 16,921,793         | 20,991             | 13,799,903         | 14,801,470         |                    |
| Total assets                         | 42,170,844         | 26,173,132         | 32,380,545         | 139,253            | 93,374,040         | 40,119,394         |                    |
| Total current liabilities            | 3,460,419          | 2,264,896          | 2,395,596          | 1,342,845          | 5,281,098          | 3,657,668          |                    |
| Total debt                           | -                  | -                  | -                  | -                  | -                  | -                  |                    |
| Total shareholder s equity (deficit) | 30,800,827         | 21,323,737         | 25,554,551         | (1,203,592)        | 80,530,600         | 39,901,335         |                    |

| <b><u>Summary Cash Flow Data</u></b>                | <b>Year Ended June 30,</b> |                    |                    |                    |                    | <b>Nine Months Ended March 31,</b> |                    |
|-----------------------------------------------------|----------------------------|--------------------|--------------------|--------------------|--------------------|------------------------------------|--------------------|
|                                                     | <b><u>2004</u></b>         | <b><u>2003</u></b> | <b><u>2002</u></b> | <b><u>2001</u></b> | <b><u>2000</u></b> | <b><u>2005</u></b>                 | <b><u>2004</u></b> |
|                                                     | As Restated (1)            | As Restated (1)    | As Restated (1)    | As Restated (1)    |                    | As Restated (2)                    | As Restated (2)    |
| Net Cash (used in) Operating Activities             | (4,641,193)                | (4,411,581)        | (2,675,116)        | (3,056,835)        | (1,945,157)        | (7,263,786)                        | (6,651,771)        |
| Net Cash (used in) provided by Investing Activities | (130,917)                  | (541,254)          | (455,500)          | (1,760)            | 11,616             | (478,791)                          | (33,888)           |
| Net Cash provided by Financing Activities           | 15,730,847                 | -                  | 16,013,131         | 17,241             | 1,942,696          | 59,201,833                         | 3,314,786          |

(1) See note 9 of the audited consolidated financial statements which are included in this prospectus.

(2) See note I of the unaudited consolidated financial statements which are included in this prospectus.



## RISK FACTORS

You should carefully consider the following risks before you decide to buy our common stock. All known risks are presented in this prospectus. These risks may adversely affect our business, financial condition or operating results. If any of the events we have identified occur, the trading price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

### Risks Related to Our Business

*We have a limited operating history, which makes it difficult to evaluate our business and to predict our future operating results.*

Since our inception in August of 1996, we have been primarily engaged in organizational activities, including developing a strategic operating plan, entering into various collaborative agreements for the development of products and technologies, hiring personnel and developing and testing our products. We have not generated any material revenues to date. Accordingly, we have a limited operating history upon which an evaluation of our performance and prospects can be made.

*We have incurred significant net losses since commencing business and expect future losses.*

To date, we have incurred significant net losses, including net losses of approximately \$11,508,000 for the fiscal year ended June 30, 2004 and \$10,492,000 for the nine months ended March 31, 2005. At March 31, 2005, we had an accumulated deficit of approximately \$48,156,000. We anticipate that we may continue to incur significant operating losses for the foreseeable future. We may never generate material revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

*Clinical trials for our products are expensive and time consuming, and may not result in any viable products.*

Before obtaining regulatory approval for the commercial sale of a product, we must demonstrate through pre-clinical testing and clinical trials that a product candidate is safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process. We will incur substantial expense for, and devote a significant amount of time to pre-clinical testing and clinical trials. Even with Modrenal®, which is approved and marketed by us in the U.K. for the treatment of advanced, post-menopausal breast cancer, we are conducting a Phase II clinical trial in the U.S. regarding its treatment of prostate cancer and a Phase II clinical trial in the U.K. for its treatment of pre-menopausal breast cancer, each of which is a new potential indication for this approved drug.

The results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials as a number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays.

Completion of clinical trials for any product may take several or more years. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product candidate. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- inability of vendors to manufacture sufficient quantities of materials for use in clinical trials;
- slower than expected rate of patient recruitment or variability in the number and types of patients in a study;
- inability to adequately follow patients after treatment;

unforeseen safety issues or side effects;  
lack of efficacy during the clinical trials; or  
government or regulatory delays.

***A significant portion of our assets relate to ancillary products, which may not be successfully commercialized.***

Our ancillary products include OLIGON and Methylene Blue which are anti-microbial agents that we acquired in February 2002. As of March 31, 2005, the net intangible assets associated with these products amounted to approximately \$13.8 million and constituted approximately 15% of our total assets and approximately 17% of our stockholders' equity. We amortize approximately \$1.3 million of this amount each year for the estimated useful life of these products of approximately 13 years.

We do not currently devote any significant time or resources to the research and development of OLIGON and Methylene Blue and only intend to do so if, and to the extent, we successfully commercialize our lead drugs, clofarabine and Modrenal®, over the next two years. If we determine that the carrying amount of these assets is not recoverable, we would need to write down the value of these assets. Based on the estimated useful life of these assets of approximately 13 years and market considerations, no assurance can be given that there will not be an impairment of these assets in the future, which could result in a material impact on our future results of operations.

***We depend on our development agreement with Genzyme and if it does not proceed as planned, we may incur delay in the commercialization of clofarabine, which would delay our ability to generate revenues and cash flow from the sale of clofarabine.***

We have a co-development agreement with Genzyme, and pursuant to that agreement, Genzyme and any third party to which Genzyme grants a sublicense or transfer its obligations, has primary responsibility for conducting clinical trials and administering regulatory compliance and approval matters in the United States and Canada. While there are target dates for completion, the agreement permits Genzyme to continue working beyond those dates under certain circumstances. For example, under the co-development agreement, ILEX (Genzyme's predecessor in interest) was required to complete Pivotal Phase II Trials not later than December 31, 2002, but ILEX failed to do so. In this situation the co-development agreement provides that the milestone shall be adjusted such that Genzyme (successor in interest to ILEX) receives more time to complete the pivotal trials if the trials are ongoing at December 31, 2002 and progressing to completion within a reasonable time thereafter. Further, ILEX was required under the co-development agreement to have filed a New Drug Application by August 31, 2003, subject to extension if ILEX continues to use its reasonable efforts to promptly complete the filing after August 31, 2003. ILEX continued to use its reasonable efforts to complete the filing after August 31, 2003 and in October 2003, Ilex filed the first part of a rolling NDA with the FDA.

If Genzyme fails to meet its obligations under the co-development agreement, we could lose valuable time in developing clofarabine for commercialization both in the U.S. and in Europe. We can not provide assurance that Genzyme will not fail to meet its obligations under the co-development agreement. Development of compounds to the stage of approval includes inherent risk at each stage of development that FDA, in its discretion, will mandate a requirement not foreseeable by us or by Genzyme. There would also be testing delays if, for example, our sources of drug supply could not produce enough clofarabine to support the then ongoing clinical trials being conducted. If this were to occur, it could have a material adverse effect on our ability to develop clofarabine, obtain necessary regulatory approvals, and generate sales and cash flow from the sale of clofarabine.

If delays in completion constitute a breach by Genzyme or there are certain other breaches of the co-development agreement by Genzyme, then, at our discretion, the primary responsibility for completion would revert to us, but there is no assurance that we would have the financial, managerial or technical resources to complete such tasks in timely fashion or at all.

***We have limited experience in developing products and may be unsuccessful in our efforts to develop products.***

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. We are developing clofarabine 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 marketing partner. If the U.S. regulatory timeline is elongated, this could materially and adversely affect the European regulatory timeline for the approval of clofarabine.

With respect to our co-lead drug, Modrenal®, we currently have an Investigational New Drug Application filed with FDA to conduct a Phase II Clinical Trial in the U.S. to determine efficacy of Modrenal® in prostate cancer patients. This Phase II Clinical Trial is being conducted at the Mass General Hospital in Boston, MA. To our knowledge, Modrenal® has not been tested in this indication in the past and there can be no assurance that Modrenal® will be an effective therapy in prostate cancer. Further, our long-term drug development objectives for Modrenal® include attempting to test the drug and get approval in the U.S. for treatment of advanced post-menopausal breast cancer patients. These trials will take significant time and resource and no assurance can be given that developing the drug in this indication will result in a U.S. approval for Modrenal® in advanced post-menopausal breast cancer patients.

Generally, most products resulting from our or our collaborative partners' product development efforts 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:

- discovery during pre-clinical testing or clinical trials that the products are ineffective or cause harmful side effects;
- failure to receive necessary regulatory approvals;
- inability to manufacture on a large or economically feasible scale;
- failure to achieve market acceptance; or
- 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.

***Our industry is subject to extensive government regulation and our products require other regulatory approvals which makes it more expensive to operate our business.***

*Regulation in General.* Virtually all aspects of our business are regulated by federal and state statutes and governmental agencies in the U.S. and other countries. Failure to comply with applicable statutes and government regulations could have a material adverse effect on our ability to develop and sell products which would have a negative impact on our cash flow. The development, testing, manufacturing, processing, quality, safety, efficacy, packaging, labeling, record-keeping, distribution, storage and advertising of pharmaceutical products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies. These activities are also regulated by similar state and local agencies and equivalent foreign authorities. In our material contracts with vendors providing any portion of these types of services, we seek assurances that our vendors comply and will continue to maintain compliance with all applicable rules and regulations. This is the case, for example,

with respect to our contracts with Ferro Pfanstiehl and Penn Pharmaceuticals. No assurance can be given that our most significant vendors will continue to comply with these rules and regulations.

*FDA Regulation.* All pharmaceutical manufacturers in the U.S. are subject to regulation by the FDA under the authority of the Federal Food, Drug, and Cosmetic Act. Under the Act, the federal government has extensive administrative and judicial enforcement powers over the activities of pharmaceutical manufacturers to ensure compliance with FDA regulations. Those powers include, but are not limited to the authority to:

- initiate court action to seize unapproved or non-complying products;
- enjoin non-complying activities;
- halt manufacturing operations that are not in compliance with current good manufacturing practices prescribed by the FDA;
- recall products which present a health risk; and
- seek civil monetary and criminal penalties.

Other enforcement activities include refusal to approve product applications or the withdrawal of previously approved applications. Any enforcement activities, including the restriction or prohibition on sales of products marketed by us or the halting of manufacturing operations of us or our collaborators, would have a material adverse effect on our ability to develop and sell products which would have a negative impact on our cash flow. In addition, product recalls may be issued at our discretion or by the FDA or other domestic and foreign government agencies having regulatory authority for pharmaceutical product sales. Recalls may occur due to disputed labeling claims, manufacturing issues, quality defects or other reasons. Recalls of pharmaceutical products marketed by us may occur in the future. Any product recall could have a material adverse effect on our revenue and cash flow.

*FDA Approval Process.* We have a variety of products under development, including line extensions of existing products, reformulations of existing products and new products. All new drugs must be the subject of an FDA-approved new drug application before they may be marketed in the U.S. All generic equivalents to previously approved drugs or new dosage forms of existing drugs must be the subject of an FDA-approved abbreviated new drug application before they may be marketed in the U.S. In both cases, the FDA has the authority to determine what testing procedures are appropriate for a particular product and, in some instances, has not published or otherwise identified guidelines as to the appropriate procedures. The FDA has the authority to withdraw existing new drug application and abbreviated application approvals and to review the regulatory status of products marketed under the enforcement policy. The FDA may require an approved new drug application or abbreviated application for any drug product marketed under the enforcement policy if new information reveals questions about the drug's safety or effectiveness. All drugs must be manufactured in conformity with current good manufacturing practices and drugs subject to an approved new drug application or abbreviated application must be manufactured, processed, packaged, held and labeled in accordance with information contained in the new drug application or abbreviated application.

The required product testing and approval process can take a number of years and require the expenditure of substantial resources. Testing of any product under development may not result in a commercially-viable product. Further, we may decide to modify a product in testing, which could materially extend the test period and increase the development costs of the product in question. Even after time and expenses, regulatory approval by the FDA may not be obtained for any products we develop. In addition, delays or rejections may be encountered based upon changes in FDA policy during the period of product development and FDA review. Any regulatory approval may impose limitations in the indicated use for the product. Even if regulatory approval is obtained, a marketed product, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections. Subsequent discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

*Foreign Regulatory Approval.* Even if required FDA approval has been obtained with respect to a product, foreign regulatory approval of a product must also be obtained prior to marketing the product internationally. Foreign approval procedures vary from country to country and the time required for approval may delay or prevent marketing. In certain instances, we or our collaborative partners may seek approval to market and sell some of our products outside of the United States before submitting an application for approval to the FDA. The clinical testing requirements and the time required to obtain foreign regulatory approvals may differ from that required for FDA approval. Although there is now a centralized European Union approval mechanism for new pharmaceutical products in place, each European Union country may nonetheless impose its own procedures and requirements, many of which are time consuming and expensive, and some European Union countries require price approval as part of the regulatory process. Thus, there can be substantial delays in obtaining required approval from both the FDA and foreign regulatory authorities after the relevant applications are filed.

*Changes in Requirements.* The regulatory requirements applicable to any product may be modified in the future. We cannot determine what effect changes in regulations or statutes or legal interpretations may have on our business in the future. Changes could require changes to manufacturing methods, expanded or different labeling, the recall, replacement or discontinuation of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Any changes or new legislation could have a material adverse effect on our ability to develop and sell products and, therefore, generate revenue and cash flow.

The products under development by us may not meet all of the applicable regulatory requirements needed to receive regulatory marketing approval. Even after we expend substantial resources on research, clinical development and the preparation and processing of regulatory applications, we may not be able to obtain regulatory approval for any of our products. Moreover, regulatory approval for marketing a proposed pharmaceutical product in any jurisdiction may not result in similar approval in other jurisdictions. Our failure to obtain and maintain regulatory approvals for products under development would have a material adverse effect on our ability to develop and sell products and, therefore, generate revenue and cash flow.

***We may not be successful in receiving orphan drug status for certain of our products or, if that status is obtained, fully enjoying the benefits of orphan drug status.***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition. A disease or condition that affects populations of fewer than 200,000 people in the U.S. generally constitutes a rare disease or condition. We may not be successful in receiving orphan drug status for certain of our products. Orphan drug designation must be requested before submitting a new drug application. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are publicized by the FDA. Under current law, orphan drug status is conferred upon the first company to receive FDA approval to market the designated drug for the designated indication. Orphan drug status also grants marketing exclusivity in the U.S. for a period of seven years following approval of the new drug application, subject to limitations. Orphan drug designation does not provide any advantage in, or shorten the duration of, the FDA regulatory approval process. Although obtaining FDA approval to market a product with orphan drug status can be advantageous, the scope of protection or the level of marketing exclusivity that is currently afforded by orphan drug status and marketing approval may not remain in effect in the future.

Our business strategy involves obtaining orphan drug designation for certain of the oncology products we have under development. Although clofarabine has received orphan drug designation with the FDA and EMEA, we do not know whether any of our other products will receive an orphan drug designation. Orphan drug designation does not prevent other manufacturers from attempting to develop similar drugs for the designated indication or from obtaining the approval of a new drug application for their drug prior to the approval of our new drug application. If another sponsor's new drug application for a competing drug in the same indication is approved first, that sponsor is entitled to exclusive marketing rights if that sponsor has received orphan drug designation for its drug. In that case, the FDA would refrain from approving an application by us to market our competing product for seven years, subject to limitations. Competing products may receive orphan drug designations and FDA marketing approval before the products under development by us.

New drug application approval for a drug with an orphan drug designation does not prevent the FDA from approving the same drug for a different indication, or a molecular variation of the same drug for the same indication.



Because doctors are not restricted by the FDA from prescribing an approved drug for uses not approved by the FDA, it is also possible that another company's drug could be prescribed for indications for which products developed by us have received orphan drug designation and new drug application approval, and the same is true with the EMEA in Europe. Prescribing of approved drugs for unapproved uses, commonly referred to as off label sales, could adversely affect the marketing potential of products that have received an orphan drug designation and new drug application approval. In addition, new drug application approval of a drug with an orphan drug designation does not provide any marketing exclusivity in foreign markets.

The possible amendment of the Orphan Drug Act by the United States Congress has been the subject of frequent discussion. Although no significant changes to the Orphan Drug Act have been made for a number of years, members of Congress have from time to time proposed legislation that would limit the application of the Orphan Drug Act. The precise scope of protection that may be afforded by orphan drug designation and marketing approval may be subject to change in the future.

***The use of our products may be limited or eliminated by professional guidelines which would decrease our sales of these products and, therefore, our revenue and cash flows.***

In addition to government agencies, private health/science foundations and organizations involved in various diseases may also publish guidelines or recommendations to the healthcare and patient communities. These private organizations may make recommendations that affect the usage of therapies, drugs or procedures, including products developed by us. These recommendations may relate to matters such as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that are followed by patients and healthcare providers and that result in, among other things, decreased use or elimination of products developed by us could have a material adverse effect on our revenue and cash flows. For example, if clofarabine is definitively determined in clinical trials to be an active agent to treat solid tumor cancer patients, but the required dose is high, private healthcare/science foundations could recommend various other regimens of treatment which may from time to time show activity at lower doses.

***Generic products which third parties may develop may render our products noncompetitive or obsolete.***

An increase in competition from generic pharmaceutical products could have a material adverse effect on our ability to generate revenue and cash flow. For example, many of the indications in which clofarabine and Modrenal®, our co-lead drugs, have demonstrated activity are areas of unmet clinical need, such as clofarabine's application to pediatric acute leukemias in which, initially, the drug will be used as a salvage therapy, after other regimens of treatment have failed. Our lead investigators, who have assisted with the development of Modrenal®, envision, initially, that Modrenal® would be used as second or third line therapy, only after patients with advanced post-menopausal breast cancer receive regimens of tamoxifen and/or aromatase inhibitors (or similar drug) treatments. If generic drug companies develop a compound which is more effective than either clofarabine or Modrenal® in these areas of unmet clinical need, or equally as effective but at lower doses, it could adversely affect our market and/or render our drugs obsolete.

***Because many of our competitors have substantially greater capabilities and resources than us, they may be able to develop products before us or develop more effective products or market them more effectively, which would adversely affect our ability to generate revenue and cash flow.***

Competition in our industry is intense. Potential competitors in the U.S. and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Potential competitors for certain indications of our lead drugs include, with respect to clofarabine, Schering AG, which markets fludarabine, and certain generic drug companies in Europe which could market fludarabine upon expiry of the patent protections held by Schering. Potential competitors with respect to Modrenal® include Astra-zeneca and Novartis, which market tamoxifen and other aromatase inhibitors, which could be used by clinicians as first and second line therapies in patients with hormone sensitive, advanced, post-menopausal breast cancer prior to a Modrenal® regimen of treatment. No assurance can be given that the ongoing business activities of our competitors will not have a material adverse effect on our business prospects and projections going forward.

Although we seek to limit potential sources of competition by developing products that are eligible for orphan drug designation and new drug application approval or other forms of protection, our competitors may develop similar technologies and products more rapidly than us or market them more effectively. Competing technologies and products may be more effective than any of those that are being or will be developed by us. The generic drug industry is intensely competitive and includes large brand name and multi-source pharmaceutical companies. Because generic drugs do not have patent protection or any other market exclusivity, our competitors may introduce competing generic products, which may be sold at lower prices or with more aggressive marketing. Conversely, as we introduce branded drugs into our product portfolio, we will face competition from manufacturers of generic drugs which may claim to offer equivalent therapeutic benefits at a lower price. The aggressive pricing activities of our generic competitors could have a material adverse effect on our operations, revenue and cash flow.

***If we are unable to respond to rapid technological change and evolving therapies, our technologies and products could become less competitive or obsolete and our revenues and results of operations will be adversely affected.***

The pharmaceutical industry is characterized by rapid and significant technological change. We expect that pharmaceutical technology will continue to develop rapidly, and our future success will depend on our ability to develop and maintain a competitive position. Technological development by others may result in products developed by us, branded or generic, becoming obsolete before they are marketed or before we recover a significant portion of the development and commercialization expenses incurred with respect to these products. Alternative therapies or new medical treatments could alter existing treatment regimes, and thereby reduce the need for one or more of the products developed by us, which would adversely affect our revenue and cash flow. See also Generic products which third parties may develop may render our products noncompetitive or obsolete above.

***We depend on others for clinical testing of our products which could delay our ability to develop products.***

We do not currently have any internal product testing capabilities. Our inability to retain third parties for the clinical testing of products on acceptable terms would adversely affect our ability to develop products. Any failures by third parties to adequately perform their responsibilities may delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position. Our dependence on third parties for the development of products may adversely affect our potential profit margins and our ability to develop and deliver products on a timely basis.

***We rely on a limited number of manufacturers to operate our business and our products have not been manufactured in significant quantities. If these manufacturers experience problems or favor our competitors, we could fail to obtain sufficient quantities of products we require to operate our business successfully.***

We have never manufactured any products in commercial quantities, and the products being developed by us may not be suitable for commercial manufacturing in a cost-effective manner. Manufacturers of products developed by us will be subject to current good manufacturing practices prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities. We may not be able to enter into or maintain relationships either domestically or abroad with manufacturers whose facilities and procedures comply or will continue to comply with current good manufacturing practices or applicable foreign requirements. Failure by a manufacturer of our products to comply with current good manufacturing practices or applicable foreign requirements could result in significant time delays or our inability to commercialize or continue to market a product and could have a material adverse effect on our sales of products and, therefore, our cash flow. In the U.S., failure to comply with current good manufacturing practices or other applicable legal requirements can lead to federal seizure of violative products, injunctive actions brought by the federal government, and potential criminal and civil liability on the part of a company and our officers and employees.

***We have limited sales and marketing capability, and may not be successful in selling or marketing our products.***

The creation of infrastructure to commercialize oncology products is a difficult, expensive and time-consuming process. We may not be able to establish direct or indirect sales and distribution capabilities outside of the UK or be successful in gaining market acceptance for proprietary products or for other products. We currently have very limited sales and marketing capabilities outside of the UK. We currently employ eight full-time sales employees and two full-time marketing employees. To market any products directly, we will need to develop a



more fulsome marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. To the extent that we enter into co-promotion or other licensing arrangements, any revenues to be received by us will be dependent on the efforts of third parties. The efforts of third parties may not be successful. Our failure to establish marketing and distribution capabilities or to enter into marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

***We are dependent on certain key personnel and the loss of one or more these individuals could disrupt our operations and adversely affect our financial results.***

We are highly dependent on our Chief Executive Officer to develop our lead drug. Dr. Wood has an employment agreement with us, dated December 31, 2002, for an initial term of one year which automatically extends for an additional one year periods until either party gives the other written notice of termination at least 90 days prior to the end of the current term. Dr. Wood is not near retirement age and he does not, to our knowledge, plan on leaving us in the near future. Dr. Wood is one of our founders and he is intimately familiar with the science that underlies our lead drugs and ancillary technologies. He also maintains a position on the clofarabine management team that is responsible for all drug development activities relating to that lead drug, and has been instrumental in the development and maintenance of our key relationships within the scientific research and medical communities, and those with our vendors, inventors, co-development partners and licensors. If Dr. Wood was no longer employed by us, the development of our drugs would be significantly delayed and otherwise would be adversely impacted, and we may be unable to maintain and develop these important relationships.

In addition, we will be required to hire additional qualified scientific and technical personnel, as well as personnel with expertise in clinical testing and government regulation to expand our research and development programs and pursue our product development and marketing plans. There is intense competition for qualified personnel in the areas of our activities, and there can be no assurance that we will be able to attract and retain the qualified personnel necessary for the development of its business. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and research institutions. The failure to attract and retain key scientific, marketing and technical personnel would have a material adverse effect on the development of our business and our ability to develop, market and sell our products. See also - We have limited sales and marketing capability, and may not be successful in selling or marketing our products above.

***Our management and internal systems might be inadequate to handle our potential growth.***

Our success will depend in significant part on the expansion of our operations and the effective management of growth. This growth has and will continue to place a significant strain on our management and information systems and resources and operational and financial systems and resources. To manage future growth, our management must continue to improve our operational and financial systems and expand, train, retain and manage our employee base. Our management may not be able to manage our growth effectively. If our systems, procedures, controls, and resources are inadequate to support our operations, our expansion would be halted or delayed and we could lose our opportunity to gain significant market share or the timing with which we would otherwise gain significant market share. Any inability to manage growth effectively may harm our ability to institute our business plan. The strain on our systems, procedures, controls and resources is further heightened by the fact that our executive office and operational development facilities are located in separate time zones (New York, New York and Edinburgh, Scotland, respectively).

***We depend on patent and proprietary rights to develop and protect our technologies and products, which rights may not offer us sufficient protection.***

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend on our ability to obtain and enforce protection for products that we develop under U.S. and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. Several of the original patents to Modrenal have expired in the U.S. and



foreign countries. Thus, we and our licensors are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal. We cannot guarantee that such applications will result in issued patents or that such patents if issued will provide adequate protection against competitors. Patents may not be issued from these applications and issued patents may not give us adequate protection or a competitive advantage. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain U.S. or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from Southern Research Institute. The current projected expiration date of the license is March 2021. These patents cover pharmaceutical compositions and methods of using clofarabine. We cannot guarantee that these patents would survive an attack on their validity or that they will provide a competitive advantage over our competitors. Moreover, we cannot guarantee that Southern Research Institute was the first to invent the subject matter of these patents. In addition, we are aware of a third party U.S. patent which is directed to the treatment of chronic myeloid leukemia, or CML, using specific doses of clofarabine. We believe that our development and marketing of clofarabine for treatment of acute leukemias will not infringe any of the claims of this U.S. patent. Further, we believe that our development and marketing of clofarabine for treatment of chronic lymphocytic leukemia will not infringe any of the claims of this U.S. patent. If this patent is asserted against us, even though we may be successful in defending against such an assertion, our defense would require substantial financial and human resources. In addition, we may need a license to this patent to use the claimed dose in the treatment of CML. However, we do not know if such a license is available at commercially reasonable terms, if at all.

We could incur substantial costs in defending infringement suits brought against us or any of our licensors or in asserting any infringement claims that we may have against others. We could also incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors or distributors. An adverse outcome in any litigation could have a material adverse effect on our ability to sell products or use patents in the future. In addition, we could be required to obtain licenses under patents or other proprietary rights of third parties. These licenses may not be made available on terms acceptable to us, or at all. If we are required to, and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more products.

We also rely upon trade secret protection for our confidential and proprietary information. Others may independently develop substantially equivalent proprietary information and techniques or gain access to our trade secrets or disclose our technology. We may not be able to meaningfully protect our trade secrets which could limit our ability to exclusively produce products.

We require our employees, consultants, members of the scientific advisory board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information.

***Our international operations subject us to social, political and economic risks of doing business in foreign countries.***

We have the right to manufacture, market and distribute our lead drugs, clofarabine and Modrenal®, in territories outside of the U.S. Specifically, we currently market Modrenal® in the United Kingdom and upon receiving European approval for clofarabine, we intend to market the drug throughout Europe. Further, nearly half of our employees are employed by Bioenvision Limited, our wholly-owned subsidiary with offices in Edinburgh, Scotland.

Because we have international operations in the conduct of our business, we are subject to the risks of conducting business in foreign countries, including:



## Edgar Filing: BIOENVISION INC - Form POS AM

difficulty in establishing or managing distribution relationships;

different standards for the development, use, packaging, pricing and marketing of our products and technologies;

our inability to locate qualified local employees, partners, distributors and suppliers;

the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and

general geopolitical risks, such as political and economic instability, changes in diplomatic and trade relations, and foreign currency risks.

We do not engage in forward currency transactions which means we are susceptible to fluctuations in the U.S. dollar against foreign currencies such as the pound sterling. Accordingly, as the value of the dollar becomes weaker against the pound sterling, ongoing services provided by our UK employees, Cancer Research Organizations and other service providers become more expensive to us. No assurance can be given that the U.S. dollar will not continue to weaken which could have a material adverse effect on the costs associated with our drug development activities.

***We cannot predict our future capital needs and we may not be able to secure additional financing which could affect our ability to operate as a going concern.***

As of March 31, 2005, we had stockholders' equity of approximately \$80,531,000 and net working capital of approximately \$68,795,000. 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. For example, we will need to employ a European sales force within the next twelve months to capitalize on the commercial potential for clofarabine and Modrenal® if and to the extent our lead drugs are at market in Europe by mid-2005. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders would result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or accounting methods, even though these actions would otherwise benefit our business.

If adequate financing is not available, we may be required to delay, scale back or eliminate some of our research and development programs, to relinquish rights to certain technologies or products, or to license third parties to commercialize technologies or products that we would otherwise seek to develop. Any inability to obtain additional financing, if required, would have a material adverse effect on our ability to continue our operations and implement our business plan.

***The prices we charge for our products and the level of third-party reimbursement may decrease and our revenues could decrease.***

Our ability to commercialize products successfully depends in part on the price we may be able to charge for our products and on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health insurers and other third-party payors. We believe that Government officials and private health insurers are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the pricing flexibility which distributors will have with respect to newly approved health care products as well as the reimbursement status for such approved healthcare products.

Third-party payors may attempt to control costs further by selecting exclusive providers of their pharmaceutical products. If third-party payors were to make this type of arrangement with one or more of our

competitors, they would not reimburse patients for purchasing our competing products. For example, if a third-party payor in the U.K. were to pay patients for regimens of aromatase inhibitor treatment but not treatments of Modrenal®, this would cause a decline in sales of Modrenal®. This lack of reimbursement would diminish the market for products developed by us and would have a material adverse effect on us.

***Our products may be subject to recall.***

Product recalls may be issued at our discretion or by the FDA, the FTC or other government agencies having regulatory authority for product sales. Product recalls, if any in the future, may harm our reputation and cause us to lose development opportunities, or customers or pay refunds. Products may need to be recalled due to disputed labeling claims, manufacturing issues, quality defects, or other reasons. We do not carry any insurance to cover the risk of potential product recall. Any product recall could have a material adverse effect on us, our prospects, our financial condition and results of operations.

***We may face exposure from product liability claims and product liability insurance may not be sufficient to cover the costs of our liability claims related to technologies or products.***

We face exposure to product liability claims if the use of our technologies or products or those we license from third parties is alleged to have resulted in adverse effects to users of such products. Product liability claims may be brought by clinical trial participants, although to date, no such claims have been brought against us. If any such claims were brought against us, the cost of defending such claims may adversely affect our business. Regulatory approval for commercial sale of our products does not mitigate product liability risks. Any precautions we take may not be sufficient to avoid significant product liability exposure. Although we have obtained product liability and clinical trial insurance on our technologies and products at levels with which management deems reasonable, no assurance can be given that this insurance will cover any particular claim or that we have obtained an appropriate level of liability insurance coverage for our development activities. We currently maintain three million dollars per year, claims made product liability insurance coverage which we believe is adequate. Existing coverage may not be adequate as we further develop our products. In the future, adequate insurance coverage or indemnification by collaborative partners may not be available in sufficient amounts, or at acceptable costs, if at all. To the extent that product liability insurance, if available, does not cover potential claims, we will be required to self-insure the risks associated with those claims. The successful assertion of any uninsured product liability or other claim against us could limit our ability to sell our products or could cause monetary damages. In addition, future product labeling may include disclosure of additional adverse effects, precautions and contra indications, which may adversely impact product sales. The pharmaceutical industry has experienced increasing difficulty in maintaining product liability insurance coverage at reasonable levels, and substantial increases in insurance premium costs, in many cases, have rendered coverage economically impractical.

***Complying with changing corporate governance regulations, including an evaluation of our internal controls, may adversely affect our business and operations.***

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity. As a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance, internal control and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, our reputation may be harmed and our operations and revenues may be adversely affected.

***We may need to improve our financial control procedures.***

We may need to add additional personnel in the area of financial management. In connection with its review of our consolidated financial statements as of and for the three and nine month periods ended March 31, 2004, Grant Thornton LLP, then our registered independent public accounting firm, advised the Audit Committee and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness, under standards established by the American Institute of Certified Public Accountants, including, inadequate staffing and supervision leading to the untimely identification and resolution of certain accounting matters, failure to perform timely reviews, substantiation and evaluation of certain general ledger account balances, lack of procedures or expertise needed to prepare all required disclosures and evidence that employees lack the qualifications and training to fulfill their assigned functions. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes the entity's internal control from reducing to an appropriately low level the risk that material misstatements in the financial statements will not be prevented or detected on a timely basis. In response to the observations made by Grant Thornton LLP, we undertook a re-evaluation of our internal controls and procedures relating to those observations and implemented such enhancements as the review suggested were appropriate. While we have taken measures designed to address the matters raised by Grant Thornton LLP, we may need to implement additional measures to further enhance our internal controls and procedures. Neither Grant Thornton LLP nor our current auditors have been asked to form a conclusion on those measures.

***We are exposed to potential risks from recent legislation requiring companies to evaluate their internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002.***

We are evaluating our internal controls systems in order to allow management to report on the effectiveness of our internal control over financial reporting and our registered independent public accounting firm to attest to this report, as required by Section 404 of the Sarbanes-Oxley Act. We are performing the system and process evaluation and testing, and implementing any necessary remediation, required in an effort to comply with the management report and public accounting firm attestation requirements and continue to incur additional expenses and devote significant management time towards completing actions required for management's evaluation. The evaluation and attestation processes required by Section 404 are new and neither public companies nor public accounting firms have significant experience in testing or complying with these requirements. While we have developed and are implementing plans to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since, like other public companies, we and our registered independent public accounting firm are undergoing the process for the first time in a regulatory environment where the standards to assess adequacy of compliance are under development. We cannot assure you that there may not be significant deficiencies or material weaknesses that would be required to be reported as a result of the process.

**Risks Related to the Offering and Ownership of our Common Stock**

***The price of our common stock is likely to be volatile and subject to wide fluctuations.***

The market price of the securities of biotechnology companies has been especially volatile. Thus, the market price of our common stock is likely to be subject to wide fluctuations. For the twelve month period ended June 30, 2005, our closing stock price has ranged from a high of \$11.74 to a low of \$5.17. If our revenues do not grow or grow more slowly than we anticipate, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our common stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in investor confidence or otherwise fails, the market price of our common stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, companies that have experienced volatility in the market price of their stock have been the subject of securities class action litigation. If we were to become the subject of securities class action litigation, it could result in substantial costs and a diversion of management's attention and resources.

***Future sales or the possibility of future sales of substantial amount of our common stock by the selling stockholders or by our officers and directors may cause the price of our common stock to decline.***

The resale of shares of our common stock by the selling stockholders pursuant to this prospectus could cause the market price of our common stock to decline. Even the prospect of such resales could depress the market price for our common stock. In addition, our officers, directors and employees, including the selling stockholders, and certain other stockholders hold significant numbers of additional shares of our common stock that are not covered by this registration statement. Some of those shares are freely tradable without restriction under the federal securities laws, and those that are not may be sold in the future pursuant to newly filed effective registration statements, in compliance with the requirements of Rule 144 under the Securities Act. Sales in the public market of substantial amounts of our common stock, whether by our officers, directors, employees or others, or the perception that such sales could occur, could materially adversely affect prevailing market prices for our common stock and our ability to raise additional capital through the sale of equity securities.

***Anti-takeover laws, our shareholder rights plan, and provisions of our certificate of incorporation may discourage, delay, or prevent a merger or acquisition that our stockholders may consider favorable.***

Section 203 of the Delaware General Corporation Law contains provisions that may delay or prevent a third party from acquiring control of us, even if doing so might be beneficial to our stockholders by providing them an opportunity to sell their shares at a premium to the then current market price. In general, Section 203 prohibits designated types of business combinations, including mergers, for a period of three years between us and any third party who owns 15% or more of our common stock. This provision does not apply if:

our board of directors approves the transaction before the third party acquires 15% of our common stock;

the third party acquires at least 85% of our common stock at the time its ownership exceeds the 15% level; or

our board of directors and two-thirds of the shares of our common stock not held by the third party vote in favor of the transaction.

We also adopted a shareholder rights plan on November 17, 2004 to deter hostile or coercive attempts to acquire us. Under the plan, if any person or group acquires more than 15% of our common stock without approval of the board of directors under specified circumstances, our other stockholders have the right to purchase shares of our common stock, or shares of the acquiring company, at a substantial discount to the public market price. This plan makes an acquisition much more costly to a potential acquirer, which may deter a potential acquisition.

Our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms fixed by the board of directors. Stockholder approval is not necessary to issue preferred stock in this manner. Thus, our board of directors can authorize and issue shares of preferred stock with voting or conversion rights that could adversely affect the voting or other rights of holders of our common stock and thereby reduce its value. These rights could have the effect of making it more difficult for a person or group to acquire control of us, as well as prevent or frustrate any attempt by stockholders to change our direction or management. While our board of directors has no current intention to issue any preferred stock, the issuance of these shares may deter potential acquirors.

***Our existing principal stockholders, executive officers and directors will continue to have substantial control over our company after this offering, which may prevent you or other stockholders from influencing significant corporate decisions.***

Our existing principal stockholders, executive officers and directors beneficially own, in the aggregate, approximately 52% of our outstanding common stock. As a result, these stockholders will, if they so choose, be able to substantially control all matters requiring stockholder approval. These matters include the election of directors and approval of significant corporate transactions, such as a merger, consolidation, takeover or other business combination involving us. Our existing principal stockholders, executive officers and directors may have



interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership could also adversely affect the market price of our common stock or reduce any premium over market price that an acquirer might otherwise pay.

*Certain events could result in a dilution of holders of our common stock.*

As of August 1, 2005, we had 40,569,567 shares of common stock outstanding, 2,250,000 shares of Series A Convertible Preferred Stock outstanding which are currently convertible into 4,500,000 shares of common stock and common stock equivalents, and warrants and stock options, convertible or exercisable into 11,472,413 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from \$0.74 to \$8.87 per share. We have also reserved for issuance an aggregate of 4,500,000 shares of common stock for a stock option plan for our employees. Historically, from time to time, we have awarded our common stock to our officers, in lieu of cash compensation, although we do not expect to do so in the future. As of August 1, 2005, we have the sale of shares of common stock underlying 4,500,000 options are registered under the Securities Act on Form S-8. The future resale of these shares underlying stock options will result in a dilution to your percentage ownership of our common stock and could adversely affect the market price of our common stock.

The terms of our Series A Convertible Preferred Stock include antidilution protection upon the occurrence of sales of our common stock below certain prices, stock splits, redemptions, mergers and other similar transactions. If one or more of these events occurs the number of shares of our common stock that may be acquired upon conversion or exercise would increase. If converted or exercised, these securities will result in a dilution to your percentage ownership of our common stock. The resale of many of the shares of common stock which underlie these options and warrants are registered under this prospectus and the sale of such shares may adversely affect the market price of our common stock.

## FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on current expectations, estimates, forecasts and projections about the industry in which we operate, management's beliefs and assumptions made by management. Such statements include, in particular, statements about our plans, strategies and prospects under the headings Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business. You can generally identify forward-looking statements by the use of words such as believes, expects, may, will, should, could, seeks, approximates, intends, plans, objectives, goals, projects, estimates, anticipates, continues to, designed to, foreseeable future, scheduled and similar. Because these statements reflect our current views concerning future events and are based on current assumptions, they involve risks, uncertainties and other factors which may lead to actual results or effects that are materially different from those anticipated or contemplated in the forward-looking statements. Some, but not all, of the factors that may cause these differences include, but are not limited to:

statements about our drug development and commercialization goals and expectations;

potential regulatory approvals;

our plans for and anticipated results of our clinical development activities;

the potential advantage of our drug candidates;

statements about our future capital requirements, the sufficiency of our capital resources to meet those requirements and the expected composition of our capital resources;

other statements that are not historical facts; and

those items discussed in the Risk Factors section of this prospectus.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on these forward-looking statements. All written and oral forward-looking statements attributable to us or persons acting on our behalf are qualified in their entirety by these cautionary statements. We undertake no obligation to publicly update any forward-looking statement to reflect new information, events or circumstances, whether anticipated or unanticipated, or to conform the statement to actual results or changes in our expectations. You should, however, review the factors, risks and other information we provide in the reports we file from time to time with the SEC.

**USE OF PROCEEDS**

The selling stockholders will receive the proceeds from the resale of the shares of common stock. We will not receive any proceeds from the resale of the shares of common stock by the selling stockholders. We may receive consideration upon the exercise of options and we will receive consideration upon the conversion of warrants which we will use for general corporate purposes.

The selling stockholders will not pay any of the expenses that are incurred in connection with the registration of the shares of common stock, but they will pay all commissions, discounts and any other compensation to any securities broker-dealers through whom they sell any of the shares of common stock.

**MARKET PRICE OF OUR COMMON STOCK**

The following represents the range of reported high and low bid quotations for our common stock on a quarterly basis since July 1, 2000 as reported on the OTC Bulletin Board. Throughout this period and up to September 5, 2003, our trading symbol was BIOV. Our trading symbol was changed to BIV on September 8, 2003 upon commencement of listing our shares of common stock on the American Stock Exchange. The quotations also reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

|                                        | <b>High</b> | <b>Low</b> |
|----------------------------------------|-------------|------------|
| <b>Fiscal year ended June 30, 2003</b> |             |            |
| First Quarter                          | \$2.55      | \$1.35     |
| Second Quarter                         | 2.25        | 1.10       |
| Third Quarter                          | 1.55        | 0.39       |
| Fourth Quarter                         | 2.89        | 0.77       |
| <b>Fiscal year ended June 30, 2004</b> |             |            |
| First Quarter                          | \$5.20      | \$1.70     |
| Second Quarter                         | 5.40        | 3.13       |
| Third Quarter                          | 10.25       | 3.74       |
| Fourth Quarter                         | 12.00       | 8.00       |
| <b>Fiscal year ended June 30, 2005</b> |             |            |
| First Quarter                          | \$9.24      | \$5.90     |
| Second Quarter                         | 11.74       | 6.86       |
| Third Quarter                          | 9.18        | 5.17       |
| Fourth Quarter                         | 7.50        | 5.30       |

The last reported sale price of our common stock on the Nasdaq National Market on August 1, 2005 was \$7.65.

As of August 1, 2005, there were approximately 157 holders of record of our common stock.

**DIVIDEND POLICY**

We have never declared or paid cash dividends on our capital stock, and our board of directors does not intend to declare or pay any dividends on the common stock in the foreseeable future. However, we are required to accrue for and pay a dividend of 5%, subject to certain adjustments, on our cumulative Series A Convertible Participating Preferred Stock. Our earnings, if any, are expected to be retained for use in expanding our business. The declaration and payment in the future of any cash or stock dividends on the common stock will be at the discretion of the board of directors and will depend upon a variety of factors, including our ability to service our outstanding indebtedness and to pay our dividend obligations on securities ranking senior to the common stock, our future earnings, if any, capital requirements, financial condition and such other factors as our board of directors may consider to be relevant from time to time.

**SELLING STOCKHOLDERS**

As discussed elsewhere in this prospectus, the selling stockholders are individuals or entities who or which either hold shares of our common stock or may acquire the same upon the conversion of preferred shares or upon the exercise of certain options or warrants and, as discussed under the caption Plan of Distribution below, may include certain of their pledgees, donees, transferees or other successors-in-interest who receive shares as a gift, pledge, partnership distribution or other non-sale related transfer. The following table sets forth, as of the date of this prospectus:

the name of each selling stockholder;

the number of shares of common stock beneficially owned by each selling stockholder;

the number of shares of common stock that may be sold in this offering; and

the number and percentage of shares of common stock that will be beneficially owned by each selling stockholder following the offering to which this prospectus relates.

The information with respect to ownership after the offering assumes the sale of all of the shares offered and no purchases of additional shares. The selling stockholders may offer all or part of the shares covered by this prospectus at any time or from time to time.

For purposes of the table below, the number of shares beneficially owned are those beneficially owned as determined under the rules of the SEC. Such information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power and any shares for which the person has the right to acquire such power within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. Percentages in the table below are based on 40,569,567 shares of our common stock outstanding as of August 1, 2005.

| <u>Name</u>                                      | <u>Shares Owned Prior to the Offering</u> |                | <u>Number of Shares which may be Sold in this Offering</u> | <u>Shares Owned After the Offering</u> |                |
|--------------------------------------------------|-------------------------------------------|----------------|------------------------------------------------------------|----------------------------------------|----------------|
|                                                  | <u>Number</u>                             | <u>Percent</u> |                                                            | <u>Number</u>                          | <u>Percent</u> |
| Perseus-Soros BioPharmaceutical Fund, LP (1)     | 7,950,053                                 | 16.51%         | 7,950,053                                                  | --                                     | --             |
| Special Situations Private Equity Fund, L.P. (3) | 250,000                                   | *              | 250,000                                                    | --                                     | --             |
| SDS Merchant Fund, LP (4)                        | 144,999                                   | *              | 48,333                                                     | 96,666                                 | *              |
| SDS Merchant Fund, LP (5)                        | 354,999                                   | *              | 118,333                                                    | 236,666                                | *              |
| SDS Merchant Fund, LP (6)                        | 380,001                                   | *              | 166,667                                                    | 213,334                                | *              |
| Orion Biomedical Offshore Fund, LP (7)           | 133,875                                   | *              | 44,625                                                     | 89,250                                 | *              |
| Orion Biomedical Fund, LP (8)                    | 616,125                                   | 1.52%          | 205,375                                                    | 410,750                                | 1.01%          |
| Beaver Ltd. (9)                                  | 75,000                                    | *              | 25,000                                                     | 50,000                                 | *              |
| CKH Invest Aps. (10)                             | 50,001                                    | *              | 16,667                                                     | 33,334                                 | *              |
| Merlin Nexus I LP (11)                           | 673,617                                   | 1.66%          | 406,949                                                    | 266,668                                | *              |
| Alexandra Global Master Fund, ltd.(12)           | 666                                       | *              | 666                                                        | --                                     | --             |
| DWS Investment GmbH (13)                         | 1,360,600                                 | 3.35%          | 493,934                                                    | 866,666                                | 2.14%          |
| Michael Sistenich (14)                           | 125,001                                   | *              | 41,667                                                     | 83,334                                 | *              |
| Global Biotechnology Fund (15)                   | 209,369                                   | *              | 76,037                                                     | 133,332                                | *              |
| Oklahoma Medical Research Foundation (16)        | 44,166                                    | *              | 44,166                                                     | --                                     | --             |
| Robert A. Floyd (16)                             | 66,666                                    | *              | 66,666                                                     | --                                     | --             |
| Raymond A. Schinazi (16)                         | 66,666                                    | *              | 66,666                                                     | --                                     | --             |
| Christopher B. Wood (17)                         | 4,136,987                                 | 9.74%          | 2,254,905                                                  | 1,882,082                              | 4.43%          |
| Julie Wood (17)                                  | 318,750                                   | *              | 318,750                                                    | --                                     | --             |
| Stuart Smith (18)                                | 700,000                                   | 1.72%          | 700,000                                                    | --                                     | --             |
| Thomas Nelson (19)                               | 341,787                                   | *              | 258,351                                                    | 83,436                                 | *              |
| Kevin Leech (20)                                 | 1,813,912                                 | 4.47%          | 413,912                                                    | 1,400,000                              | 3.45%          |
| Bioaccelerate, Inc. (21)                         | 1,162,100                                 | 2.86%          | 434,828                                                    | 727,272                                | 1.79%          |
| Sterling Securities Ltd. (21)                    | 74,045                                    | *              | 74,045                                                     | --                                     | --             |



Edgar Filing: BIOENVISION INC - Form POS AM

| <u>Name</u>                                     | <u>Shares Owned Prior to the Offering</u> |                | <u>Number of Shares which may be Sold in this Offering</u> | <u>Shares Owned After the Offering</u> |                |
|-------------------------------------------------|-------------------------------------------|----------------|------------------------------------------------------------|----------------------------------------|----------------|
|                                                 | <u>Number</u>                             | <u>Percent</u> |                                                            | <u>Number</u>                          | <u>Percent</u> |
| Carpe DM, Inc. (21)                             | 59,058                                    | *              | 59,058                                                     | --                                     | --             |
| Michelle Tidball (21)                           | 254,114                                   | *              | 254,114                                                    | --                                     | --             |
| Weil Consulting Corporation (21)                | 75,000                                    | *              | 75,000                                                     | --                                     | --             |
| Kingsley Securities Ltd. (21)                   | 102,679                                   | *              | 102,679                                                    | --                                     | --             |
| Fontenelle LLC (21)                             | 50,000                                    | *              | 50,000                                                     | --                                     | --             |
| George Margetts (22)                            | 100,000                                   | *              | 100,000                                                    | --                                     | --             |
| Nagy Habib (23)                                 | 41,881                                    | *              | 41,881                                                     | --                                     | --             |
| NAB Holdings Ltd. (21) (24)                     | 451,913                                   | 1.11%          | 451,913                                                    | --                                     | --             |
| SCO Capital Partners LLC (25), (27)             | 7,009,946                                 | 16.51%         | 7,009,946                                                  | --                                     | --             |
| SCO Financial Group LLC (25), (27)              | 100,000                                   | *              | 100,000                                                    | --                                     | --             |
| SCO Securities LLC (25), (27)                   | 260,290                                   | *              | 260,290                                                    | --                                     | --             |
| Daniel DiPietro (29)                            | 50,000                                    | *              | 50,000                                                     | --                                     | --             |
| Jeremy Kaplan                                   | 10,000                                    | *              | 10,000                                                     | --                                     | --             |
| Joshua Golumb                                   | 10,000                                    | *              | 10,000                                                     | --                                     | --             |
| The Sophie C. Rouhandeh Trust(25)               | 150,000                                   | *              | 150,000                                                    | --                                     | --             |
| The Chloe H. Rouhandeh Trust (25)               | 150,000                                   | *              | 150,000                                                    | --                                     | --             |
| Jeffrey B. Davis (26), (27), (29)               | 749,243                                   | 1.84%          | 250,000                                                    | 499,243                                | 1.22%          |
| Edward W. Kelly (27), (28)                      | 356,013                                   | *              | 200,000                                                    | 156,013                                | *              |
| RRD International, Inc. (30)                    | 130,277                                   | *              | 130,277                                                    | --                                     | --             |
| RLB Capital, Inc. (31)                          | 100,000                                   | *              | 100,000                                                    | --                                     | --             |
| Stamford Capital (32)                           | 54,722                                    | *              | 54,722                                                     | --                                     | --             |
| Palladin Opportunity Fund LLC                   | 13,632                                    | *              | 13,632                                                     | --                                     | --             |
| SDS Capital Group SPC, Ltd. (33)                | 159,802                                   | *              | 159,802                                                    | --                                     | --             |
| Baystar Capital II, L.P. (34)                   | 60,000                                    | *              | 60,000                                                     | --                                     | --             |
| North Sound Legacy Fund, LLC (35)               | 1,440                                     | *              | 1,440                                                      | --                                     | --             |
| North Sound Legacy Institutional Fund, LLC (36) | 15,840                                    | *              | 15,840                                                     | --                                     | --             |
| North Sound Legacy International Fund, LLC (37) | 30,720                                    | *              | 30,720                                                     | --                                     | --             |
| Vertical Ventures, LLC (38)                     | 115,200                                   | *              | 115,200                                                    | --                                     | --             |
| Iroquois Capital LP (39)                        | 76,800                                    | *              | 76,800                                                     | --                                     | --             |
| Alpha Capital AG (40)                           | 96,000                                    | *              | 96,000                                                     | --                                     | --             |
| Millenium Partners LP (41)                      | 120,000                                   | *              | 120,000                                                    | --                                     | --             |
| Jennison Health Sciences Fund (42)              | 288,000                                   | *              | 288,000                                                    | --                                     | --             |
| BioPharmaceutical Portfolio (43)                | 30,240                                    | *              | 30,240                                                     | --                                     | --             |
| MP BioPharmaceutical Partners, L.P. (44)        | 16,680                                    | *              | 16,680                                                     | --                                     | --             |
| MP BioPharmaceutical Fund Ltd. (45)             | 68,880                                    | *              | 68,880                                                     | --                                     | --             |
| MP BioPharm Market-Neutral, L.P. (46)           | 4,200                                     | *              | 4,200                                                      | --                                     | --             |
| Silveroak Investments, Inc. (47)                | 48,000                                    | *              | 48,000                                                     | --                                     | --             |
| SF Capital Partners Ltd. (48)                   | 288,000                                   | *              | 288,000                                                    | --                                     | --             |
| Perceptive Lifesciences Master Fund, Ltd. (49)  | 216,000                                   | *              | 216,000                                                    | --                                     | --             |
| Cranshire Capital, L.P. (50)                    | 48,000                                    | *              | 48,000                                                     | --                                     | --             |
| Quogue Capital LLC (51)                         | 14,000                                    | *              | 14,000                                                     | --                                     | --             |
| Meditor Master Curra Fund Limited (52)          | 192,000                                   | *              | 192,000                                                    | --                                     | --             |
| Atlas Equity I, Ltd. (53)                       | 103,333                                   | *              | 103,333                                                    | --                                     | --             |
| Steve Oliviera (54)                             | 24,000                                    | *              | 24,000                                                     | --                                     | --             |
| SRG Capital LLC (55)                            | 24,000                                    | *              | 24,000                                                     | --                                     | --             |
| StoneStreet LP (56)                             | 60,000                                    | *              | 60,000                                                     | --                                     | --             |
| DKR Soundshore Oasis Holding Company, Ltd. (57) | 48,000                                    | *              | 48,000                                                     | --                                     | --             |
| Total                                           | 34,311,788                                |                | 27,083,742                                                 | 7,228,046                              |                |

\* Represents less than 1% of our outstanding shares of common stock.

(1) Includes 2,250,000 shares of Series A Preferred Stock currently convertible into 4,500,000 shares of common stock and a warrant to purchase 3,000,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Also includes 375,044

## Edgar Filing: BIOENVISION INC - Form POS AM

common shares and a warrant to purchase 75,009 shares of common stock exercisable at \$7.50 for five years from May 13, 2004. Perseus-Soros Partners, LLC is the general partner of the Perseus-Soros BioPharmaceutical Fund, LP. Perseus BioTech Fund Partners, LLC and SFM Participation, L.P. are the managing members of Perseus-Soros Partners, LLC. Perseuspur, LLC is the managing member of Perseus BioTech Fund Partners, LLC. Frank Pearl is the sole member of Perseuspur, LLC and in such capacity may be deemed a beneficial owner of securities held for the account of the Perseus-Soros BioPharmaceutical Fund, LP. SFM AH, LLC is the general partner of SFM Participation, L.P. The sole managing member of SFM AH, LLC is Soros Fund Management LLC. George Soros is the Chairman of Soros Fund Management LLC and in such capacity may be deemed a beneficial owner of securities held for the account of the Perseus-Soros BioPharmaceutical Fund, LP. The address of Perseus-Soros BioPharmaceutical Fund, LP is 888 Seventh Avenue, 30th Floor, New York, New York 10106.



(2) Intentionally omitted.

- (13) Includes 1,350,500 shares of common stock resulting from converting their Series A Preferred Stock, the purchase of an additional 50,501 shares of common stock in the March 2004 financing and exercising a warrant on March 17, 2004. Also a warrant to purchase 10,100 shares of common stock exercisable at \$7.50 for five years from May 13, 2004.
- (14) Includes 125,001 shares of common stock.
- (15) Includes 209,369 shares of common stock.
- (16) Under the terms of an amendment to a license agreement with Oklahoma Medical Research Foundation, we issued 200,000 shares of common stock, (all of which have been sold) and a five-year warrant to purchase an additional 200,000 shares of common stock. Such warrant to purchase 200,000 shares of common stock is exercisable at \$2.33 per share for five years from May 14, 2002. On February 17, 2004, Oklahoma Medical Research Foundation did a non-sale transfer of its warrant to purchase 66,666 shares of common stock to Dr. Robert A. Floyd and its warrant to purchase 66,666 shares of common stock to Dr. Raymond A. Schinazi. On April 12, 2004, Oklahoma Medical Research Foundation converted its warrant into common shares and has 44,166 of such shares remaining.
- (17) Dr. Wood is Chairman and Chief Executive Officer of the Company. Excludes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest.
- (18) Includes options to acquire 225,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (19) Includes 341,787 shares of common stock.
- (20) These shares are owned of record by Phoenix Ventures Limited, a Channel Islands (Jersey) corporation, which, to our knowledge, is wholly-owned by Kevin Leech.
- (21) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors. On October 8, 2003, certain options originally issued to Bioaccelerate, Inc. were transferred as follows:
  - (i) NAB Holdings Ltd. received options to purchase 500,000 shares of common stock, 350,000 of which were transferred to Michelle Tidball on December 9, 2003; on February 20, 2004, they did a cashless exercise of their remaining option to purchase 150,000 shares of common stock and received 123,666 shares of common stock ;
  - (ii) Sterling Securities Ltd. received options to purchase 100,000 shares of common stock;
  - (v) Kingsley Securities Ltd. received options to purchase 124,544 shares of common stock and on February 20, 2004, they did a cashless exercise of this option and received 102,679 shares of common stock; and
  - (vi) Fontenelle LLC received options to purchase 50,000 shares of common stock, which it exercised in November 2003 for 50,000 shares of common stock.

Further, on November 25, 2003, the following recipients of such options executed a cashless exercise of such options and received the following shares of the Company's common stock:

- (i) Sterling Securities Ltd. received 74,045 shares of common stock;

- (ii) Carpe DM, Inc. received 59,058 shares of common stock; and
  - (iii) Michelle Tidball received 73,811 shares of common stock. On December 16, 2003, Ms. Tidball executed a cashless exercise of 350,000 options transferred to her by NAB Holdings Inc. and received 255,303 shares of the Company's common stock, which includes 75,000 shares issued to Weil Consulting Corporation. Barbara Platts, in her capacity as Managing Director of Bioaccelerate, Inc., has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.
- (22) Includes an option to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
  - (23) Includes 41,881 common shares.
  - (24) Includes an option to purchase 450,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001. On December 16, 2003, NAB Holdings Ltd. exercised these options and received 328,247 shares of common stock pursuant to a cashless exercise.
  - (25) Includes a warrant to purchase 1,200,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 issued to SCO Capital, LLC; a warrant to purchase 688,333 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 issued to SCO Capital, LLC; a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 issued to SCO Securities, LLC; a warrant to purchase 150,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 held by the Sophie C. Rouhandeh Trust; and a warrant to purchase 150,000 shares of common stock at \$1.25 per share for five years from November 16, 2001 held by the Chloe H. Rouhandeh Trust. Steven H. Rouhandeh, in his capacity as President of SCO Capital Partners, LLC and trustee of the trusts, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof. Excludes a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 which were originally held by SCO Financial Group, LLC, but transferred to (i) Daniel DiPietro (50,000), (ii) Jeremy Kaplan (10,000), and (iii) Joshua Golumb (10,000). SCO Financial Group, LLC served as a financial advisor to the Company through May 2004 and SCO Capital Partners, LLC extended a \$1 million secured credit facility to the Company in November 2001. SCO Securities, LLC, a related entity, served as placement agent to the Company in connection with the Company's May 2002 and March and May 2004 financings. As placement agent in connection with the March and May 2004 financing, SCO Securities, LLC received a warrant to purchase 204,452 shares of common stock exercisable at \$6.25 per share for five years from March 22, 2004 and a warrant to purchase 55,838 shares of common stock exercisable at \$6.25 per share for five years from May 13, 2004.
  - (26) Includes a warrant to purchase 250,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002. Mr. Davis is the President of SCO Financial Group LLC, an affiliate of SCO Capital Partners LLC. Mr. Davis disclaims beneficial ownership of all shares of common stock deemed beneficially owned by SCO Capital Partners LLC.
  - (27) Indicates the selling stockholder was a former stockholder of Pathagon.
  - (28) Mr. Kelly has executed a consulting agreement with us pursuant to which we issued to him 200,000 shares of common stock which vested over an eighteen month period.
  - (29) Indicates the selling stockholder is a current employee of SCO Financial Group LLC.
  - (30) Includes 130,277 shares of common stock resulting from the cashless exercise of a warrant to purchase 175,000 shares of common stock on July 21, 2004.

- (31) Includes a warrant to purchase 60,000 shares of common stock exercisable at \$1.25 per share for three years from March 8, 2004 and 40,000 common shares issued pursuant to an exercise of 40,000 warrants.
- (32) Includes a warrant to purchase 40,000 shares of common stock exercisable at \$1.80 per share at anytime from March 4, 2004 through February 23, 2007 and 14,722 common shares issued pursuant to a cashless exercise of 20,000 warrants.
- (33) Includes 133,168 shares of common stock and warrant to purchase 26,634 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (34) Includes 50,000 shares of common stock and warrant to purchase 10,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (35) Includes 1,200 shares of common stock and warrant to purchase 240 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (36) Includes 13,200 shares of common stock and warrant to purchase 2,640 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (37) Includes 25,600 shares of common stock and warrant to purchase 5,120 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (38) Includes 96,000 shares of common stock and warrant to purchase 19,200 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (39) Includes 64,000 shares of common stock and warrant to purchase 12,800 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (40) Includes 80,000 shares of common stock and warrant to purchase 16,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (41) Includes 100,000 shares of common stock and warrant to purchase 20,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (42) Includes 240,000 shares of common stock and warrant to purchase 48,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (43) Includes 25,200 shares of common stock and warrant to purchase 5,040 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (44) Includes 13,900 shares of common stock and warrant to purchase 2,780 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (45) Includes 57,400 shares of common stock and warrant to purchase 11,480 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (46) Includes 3,500 shares of common stock and warrant to purchase 700 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (47) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (48) Includes 240,000 shares of common stock and warrant to purchase 48,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.

- (49) Includes 216,000 shares of common stock.
- (50) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (51) Includes a warrant to purchase 14,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (52) Includes 160,000 shares of common stock and warrant to purchase 32,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (53) Includes 103,333 shares of common stock.
- (54) Includes 20,000 shares of common stock and warrant to purchase 4,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (55) Includes 20,000 shares of common stock and warrant to purchase 4,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (56) Includes 50,000 shares of common stock and warrant to purchase 10,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (57) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.

## DESCRIPTION OF OUR CAPITAL STOCK

The following summarizes the material provisions of our certificate of incorporation and by-laws that relate to our capital stock. Copies of those documents are incorporated by reference as exhibits to the registration statement that includes this prospectus. See [Where You Can Find More Information](#).

### Description of Common Stock

*Number of Authorized and Outstanding Shares.* Our Certificate of Incorporation authorizes the issuance of 70,000,000 shares of common stock, \$.001 par value per share, of which 40,569,567 shares were outstanding on August 1, 2005. All of the outstanding shares of common stock are fully paid and non-assessable.

*Voting Rights.* Holders of shares of common stock are entitled to one vote for each share on all matters to be voted on by the stockholders. Holders of common stock have no cumulative voting rights. Accordingly, the holders of a simple majority of the outstanding common stock and Series A convertible preferred stock, voting together as a class at a stockholders meeting at which a quorum is present, can elect all of the directors nominated for election at the meeting.

*Other.* Holders of common stock have no preemptive rights to purchase our common stock. There are no conversion rights or redemption or sinking fund provisions with respect to the common stock.

*Transfer Agent.* Shares of common stock are registered at the transfer agent and are transferable at such office by the registered holder (or duly authorized attorney) upon surrender of the common stock certificate, properly endorsed. No transfer shall be registered unless we are satisfied that such transfer will not result in a violation of any applicable federal or state securities laws. The transfer agent for our common stock is American Stock Transfer & Trust Company, 59 Maiden Lane, New York, New York 10038, Attn: Susan Silber.

### Description of Preferred Stock

*Number of Authorized and Outstanding Shares.* Our Certificate of Incorporation authorizes the issuance of up to 20,000,000 shares of preferred stock, par value \$.001 per share, in one or more series with such limitations and restrictions as may be determined in the sole discretion of our board of directors, with no further authorization by stockholders required for the creation and issuance thereof. We have designated 5,920,000 shares of our preferred stock as Series A convertible preferred stock, of which 2,250,000 shares were issued and outstanding as of August 1, 2005.

*Voting Rights.* The holders of the Series A convertible preferred stock vote as a single class with the common stock, on an as-converted basis, on all matters upon which the holders of the common stock are entitled to vote.

*Conversion.* Each outstanding share of Series A convertible preferred stock may currently be converted into two shares of common stock. The shares of Series A convertible preferred stock shall be automatically convertible into shares of common stock if the market price of the common stock after one year from the date of issuance is \$10.00 or more for 30 consecutive trading days and the trading volume is at least 150,000 shares per trading day during such 30-day period.

*Liquidation Preference and Dividends.* Holders of Series A convertible preferred stock have a liquidation preference over holders of common stock of \$3.00 per share. Holders of the Series A convertible preferred stock are entitled to an annual 5% dividend which may be paid in cash or additional shares of common stock in our sole discretion.

Our charter also authorizes our board of directors to increase the number of shares of preferred stock we may issue without approval of common stockholders. Preferred stock may be issued in one or more series, the terms of which may be determined without further action by common stockholders. These terms may include preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends, qualifications or terms or



conditions of redemption. The issuance of any preferred stock could materially adversely affect the rights of holders of our common stock, and therefore could reduce its value. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The power of the board of directors to issue preferred stock could make it more difficult, delay, discourage, prevent or make it more costly to acquire or effect a change in control, thereby preserving the current stockholders' control.

#### **Stockholder Rights Plan**

Under our stockholder rights plan, if a person or group acquires 15% or more of our common stock, all rightsholders, except the acquiror, will be entitled to acquire at the then exercise price of a right that number of shares of our common stock which at the time will have a market value of two times the exercise price of the right. In addition, under certain circumstances, all rightsholders, other than the acquiror, will be entitled to receive at the then exercise price of a right that number of shares of common stock of the acquiring company which at the time will have a market value of two times the exercise price of the right. The initial exercise price of a right is \$70. Such rights provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock and may have the effect of delaying or preventing a change in control. The issuance of preferred stock also could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of our common stock.

#### **Warrants**

As of August 1, 2005, there were outstanding warrants to purchase an aggregate of 7,166,147 shares of our common stock, exercisable at prices ranging from \$1.25 to \$8.25 per share. The weighted average exercise price of the warrants is \$2.33.

#### **Stock Options**

As of August 1, 2005, there were outstanding options to purchase an aggregate of 4,283,166 shares of our common stock, exercisable at prices ranging from \$0.735 to \$8.87 per share, of which, options to purchase 2,801,356 shares were exercisable. The weighted average exercise price of the options is \$3.15.

#### **Delaware Law and Certain By-Law Provisions**

Certain provisions of our by-laws are intended to strengthen our board of directors' position in the event of a hostile takeover attempt. These by-law provisions have the following effects:

- they provide that only business brought before the annual meeting by our board of directors or by a stockholder who complies with the procedures set forth in the by-laws may be transacted at an annual meeting of stockholders; and
- they establish a procedure for our board of directors to fix the record date whenever stockholder action by written consent is undertaken.

Furthermore, our Company is subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, the statute prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a business combination includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is a person who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation's voting stock.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

### AND RESULTS OF OPERATIONS

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

#### Overview and Company Status

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. On December 29, 2004, the FDA approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who have received two or more prior regimens. We believe clofarabine is the first new medicine initially approved in the United States for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for certain cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is selling clofarabine under the brand name Clolar in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL and acute myelogenous leukemia, or AML, with the European Medicines Evaluation Agency, or EMEA. The Company anticipates an opinion from the EMEA in Q3 calendar 2005.

We are selling our second product, Modrenal®, in the United Kingdom, through our sales force of eight sales specialists. Modrenal® is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and we have initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden.

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

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this emerging stage. Our management believes that we have the opportunity to become a leading oncology-focused pharmaceutical company in the next four years if we successfully bring clofarabine to market and if mutual recognition is granted for Modrenal® in the largest European commercial markets.

We anticipate that revenues derived from our two lead drugs, clofarabine and Modrenal® will permit us to further develop the other products currently in our product pipeline. In addition to clofarabine and Modrenal®, we are performing initial development work on Velostan, initially for the treatment of bladder cancer, and Virostat for the treatment of Hepatitis C. The work to date on these compounds has been limited because of the need to concentrate on clofarabine and Modrenal® but management believe these compounds have potential value. With Velostan the Company has been developing a process for the separation of optical isomers of the compound, and with Virostat the Company has commenced a phase II clinical trial in patients with hepatitis C viral infection. We have had discussions with potential product co-development partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans. In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. In May 2003, we entered into a License and Sub-License Agreement with Dechra Pharmaceuticals, plc ( Dechra ), pursuant to which we sub-licensed the marketing and development rights to Vetoryl® trilostane, solely with respect to animal health applications, in the United States and Canada, to Dechra. We received \$1.25 million 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® technology and we have had discussions



with potential product licensing partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans.

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

- satisfy our future capital requirements for the implementation of our business plan;
- commercialize our existing products;
- complete development of products presently in our pipeline and obtain necessary regulatory approvals for use;
- implement and successfully execute our business and marketing strategy to commercialize products;
- establish and maintain our client base;
- continue to develop new products and upgrade our existing products;
- continue to establish and maintain relationships with manufacturers for our products;
- respond to industry and competitive developments; and
- attract, retain, and motivate qualified personnel.

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

#### **Summary of Significant Accounting Policies**

Financial Reporting Release No. 60, which was released by the SEC, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of the consolidated financial statements. In addition, Financial Reporting Release No. 61 was released by the SEC, which requires all companies to include a discussion to address, among other things, liquidity, off-balance sheet arrangements, contractual obligations and commercial commitments. The following discussion is intended to supplement the summary of significant accounting policies as described in Note 1 of the Notes To Consolidated Financial Statements for the year ended June 30, 2004 included under Item 7 in this annual report on Form 10-KSB, which are presented beginning at page F-1. These policies were selected because they represent the more significant accounting policies and methods that are broadly applied in the preparation of the consolidated financial statements.

*Revenue Recognition* - Revenue under research contracts is recorded as earned under the contracts, as services are provided. In accordance with SEC Staff Accounting Bulletin No. 104, upfront nonrefundable fees associated with license and development agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the period of involvement. If the estimated service period is subsequently modified, the period over which the up-front fee is recognized would be modified accordingly on a prospective basis. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved.

*Stock Based Compensation* - In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation, we apply Accounting Principles Board Opinion 25 and related interpretations in accounting for our stock option plan and, accordingly, we do not recognize compensation expense for employee stock options granted with exercise prices equal to or greater than fair market value. Non-employee stock-based compensation arrangements are accounted for in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Under EITF No. 96-18, as amended, where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument.

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

***Three and Nine Months Ended March 31, 2005 Compared to Three and Nine Months Ended March 31, 2004***

**Results of Operations**

The Company recorded revenues for the three months ended March 31, 2005 and 2004 of approximately \$1,399,000 and \$846,000, respectively, representing an increase of approximately \$553,000. This amount was primarily due to an increase in license and royalty revenue due to increased milestone payments and royalties received from certain of our co-development partners, in the amount of \$354,000.

For the nine months ended March 31, 2005 and 2004, the Company recorded revenues of \$3,660,000 and \$1,758,000, representing an increase of approximately \$1,902,000. This increase primarily was due to an increase in license and royalty revenue from milestone payments and royalties received from certain of our co-development partners in the amount of approximately \$799,000 and an increase in research and development contract revenue due to increased sales in the Named Patient Program and increased clofarabine research and development expenses for which we receive 50% reimbursement from our co-development partner, in the amount of approximately \$739,000.

The cost of products sold for the three and nine months ended March 31, 2005 were approximately \$99,000 and \$229,000, respectively. The cost of products sold reflects the direct costs associated with our sales of Modrenal@.

Research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$2,137,000 and \$994,000, respectively, representing an increase of approximately \$1,143,000. Research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$5,986,000 and \$2,545,000, respectively, representing an increase of approximately \$3,441,000.

Our research and development costs include costs associated with six projects, five of which the Company currently devotes time and resource. Clofarabine research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$1,668,000 and \$962,000, respectively, representing an increase of approximately \$706,000. Clofarabine research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$4,661,000 and \$1,612,000, respectively, representing an increase of approximately \$3,049,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials of clofarabine being conducted in Europe.

Modrenal® research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$447,000 and \$(13,000), respectively, representing an increase of \$460,000. Modrenal® research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$1,267,000 and \$744,000, respectively, representing an increase of \$523,000. The increase primarily reflects costs associated with ongoing clinical trials.

Velostan research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$15,000 and \$39,000, respectively, representing a decrease of \$24,000. Velostan research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$32,000 and \$152,000, respectively, representing a decrease of \$120,000. The decrease primarily reflects the Company's primary focus on clofarabine and Modrenal® during these periods.

Virostat research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$7,000 and \$0, respectively, representing an increase of \$7,000. Virostat research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$13,000 and \$31,000, respectively, representing a decrease of \$18,000. The decrease primarily reflects the Company's primary focus on clofarabine and Modrenal® during these periods.

OLIGON research and development costs for the three months ended March 31, 2005 and 2004 were approximately \$0 and \$6,000, respectively, representing a decrease of \$6,000. OLIGON research and development costs for the nine months ended March 31, 2005 and 2004 were approximately \$13,000 and \$6,000, respectively, representing an increase of \$7,000. The increase primarily reflects pre-development costs incurred in connection with continuing co-partnering discussions.

There were no research and development costs associated with Gene Therapy for the three and nine months ended March 31, 2005 and 2004 due to the Company's focus on clofarabine and Modrenal® during these periods.

The clinical trials and development strategy for the clofarabine and Modrenal® projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) clofarabine research and development costs have been approximately \$10,279,000; (ii) Modrenal® research and development costs have been approximately \$5,664,000; (iii) Velostan research and development costs have been approximately \$333,000; (iv) Virostat research and development costs have been approximately \$71,000; (v) OLIGON research and development costs have been approximately \$23,000; 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, 2005 and 2004 were approximately \$2,074,000 and \$3,722,000, respectively, representing a decrease of \$1,648,000. Of this amount \$2,594,000 is related to a decrease in costs associated with the variable accounting treatment of options issued to an officer of the Company, substantially offset by an increase in payroll due to the significant increase in headcount in both the New York and Edinburgh offices of \$387,000, an increase in sales and marketing costs of \$308,000 related to the Company's deployment of a sales and marketing force in the UK in early 2005, and an increase in royalty expense of \$205,000. Selling, general and administrative expenses for the nine months ended March 31, 2005 and 2004 were approximately \$6,885,000 and \$7,079,000, respectively, representing a decrease of \$194,000. Of this amount \$3,028,000 is related to a decrease in costs associated with the variable accounting treatment of options issued to an officer of the Company, substantially offset by an increase in payroll due to the significant increase in



headcount in both the New York and Edinburgh offices of \$873,000, an increase in consulting fees due to the Company's expansion of regulatory and investor relations initiatives in the amount of \$1,192,000, an increase in sales and marketing costs of \$322,000 related to the Company's deployment of a sales and marketing force in the UK and an increase in royalty expense of \$205,000.

Depreciation and amortization expense for the three months ended March 31, 2005 and 2004 were approximately \$347,000 and \$343,000, respectively, representing an increase of \$4,000. Depreciation and amortization expense for the nine months ended March 31, 2005 and 2004 were \$1,028,000 and \$1,023,000, respectively, representing an increase of \$5,000. This increase primarily reflects the increase in our net asset base.

### **Liquidity and Capital Resources**

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

On March 31, 2005, we had cash and cash equivalents of approximately \$70,335,000 and working capital of \$68,795,000. Management believes the Company has sufficient cash and cash equivalents and working capital to continue currently planned operations over the next 12 months. Although we do not currently plan to acquire or obtain licenses for new technologies, if any such opportunity arises and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

On February 8, 2005, we completed a secondary public offering in which we sold 7,500,000 common shares at \$8.00 per share, with net proceeds to the Company of approximately \$55.6 million, after deducting underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds for further development of our lead products, for sales and marketing expenses related to the commercial launch of our lead products, for working capital and other general corporate purposes.

On March 22, 2004, we consummated a private placement transaction, pursuant to which we raised \$12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of \$7.50 per share. We recorded proceeds of \$11,792,801 net of all legal, professional and financing fees incurred in connection with the offering. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations to our holders of Series A Convertible Preferred Stock which hold preemptive rights for equity offerings. We raised an additional \$3.2 million (net of all legal, professional and financial services incurred) from the second closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of \$7.50 per share.

On May 7, 2002 we authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock may be converted into shares of common stock at an initial conversion price of \$1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A Convertible Preferred Stock also received, in respect of each share of Series A Convertible Preferred Stock purchased in a private placement which took place in May 2002, one warrant to purchase one share of our common stock at an initial exercise price of \$2.00 subject to adjustment. We sold an aggregate of 5,916,666 shares of Series A Convertible Preferred Stock in the May 2002 private placement for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock, resulting in aggregate gross proceeds of approximately \$17,750,000. A portion of the proceeds were used to repay in full the Jano Holdings and SCO Capital obligations upon which such facilities were terminated as well as to repay fees amounting to \$1,610,000 related to the transaction.

The Company received a nonrefundable upfront payment of \$1.35 million when it entered into the co-development agreement with Genzyme and received an additional \$3.5 million 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 FDA, the Company received an additional (i) \$2 million in April 2004 and (ii) \$2 million in September 2004. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related royalty period, through

## Edgar Filing: BIOENVISION INC - Form POS AM

March 2021. For the three months ended March 31, 2005 and 2004, the Company recognized revenues of approximately \$110,000 and \$22,000, respectively, in connection with the milestone payments received to date. For the nine months ended March 31, 2005 and 2004, the Company recognized revenues of approximately \$329,000, and \$51,000, respectively, in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Genzyme. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with research and development costs including approximately (i) \$55,000 and \$11,000 for the three months ended March 31, 2005 and 2004, respectively, and (ii) \$165,000 and \$26,000 for the nine months ended March 31, 2005 and 2004, respectively related to such charges.

The Company received a nonrefundable upfront payment of \$1.25 million 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 royalty period, currently through September 2022. The Company recognized revenues of approximately \$15,000 and \$29,000 in connection with the upfront payment from Dechra for the three months ended March 31, 2005 and 2004, respectively. The Company recognized revenues of approximately \$72,000 and \$87,000 in connection with the upfront payment from Dechra for the nine months ended March 31, 2005 and 2004, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made 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 and \$6,000 for the three months ended March 31, 2005 and 2004, respectively. Research and Development costs related to this agreement include approximately \$14,000 and \$18,000 for the nine months ended March 31, 2005 and 2004, respectively.

The Company has the following commitments as of March 31, 2005:

### Payments Due in

|                                 | Total   | 2005    | 2006   | 2007   |
|---------------------------------|---------|---------|--------|--------|
| Employee Contracts              | 474,539 | 474,539 | -      | -      |
| Occupancy Lease and Automobiles | 278,673 | 205,569 | 62,919 | 10,185 |
| Total                           | 753,212 | 680,108 | 62,919 | 10,185 |
|                                 |         |         |        |        |

In October 2004, the Company executed a Sublease Agreement pursuant to which we sublease 5,549 square feet of commercial space at 345 Park Avenue, 41st Floor, New York, NY 10154, which is the location of the Company's principal executive offices. Subject to the terms and conditions of the Sublease Agreement, the lease expires on December 31, 2009.

### Subsequent Events

On April 4, 2005, Bioenvision, Inc. notified Grant Thornton LLP ("GT") of GT's dismissal in connection with its decision to engage new auditors as its independent registered public accounting firm. On that date, Bioenvision appointed Deloitte & Touche LLP ("D&T") as its new independent registered public accounting firm for the fiscal year ending June 30, 2005. The decision to engage D&T was made by the Audit Committee of Bioenvision's Board of Directors on April 4, 2005. The appointment was effective as of such date.



On May 23, 2005, management and the audit committee of the Company concluded that financial statements included in its annual report on Form 10-KSB for the fiscal year ended June 30, 2004, should not be relied upon because of a requirement to correct the Company's tax accounting related to the acquisition of Pathagon, Inc. in February 2002 which was identified during the review process of the financial statements to be included in the Company's quarterly report on Form 10-QSB for the quarter ended March 31, 2005. Accordingly, the Company restated its financial statements included in its annual report on Form 10-KSB for the year ended June 30, 2004 (the "10-KSB/A"). The Company's 10-KSB/A was filed on June 29, 2005.

On May 24, 2005, the Company received a notice from the Nasdaq staff indicating that the Company is not in compliance with Nasdaq's requirements for the continued listing due to its failure to timely file its Form 10-QSB for the period ended March 31, 2005, as required under Marketplace Rule 4310(c)(14) and that therefore its common stock is subject to delisting from The Nasdaq Stock Market. The notice does not by itself result in immediate delisting of the common stock, although Nasdaq stated that unless the Company requests a hearing on Nasdaq's delisting notice, the Company's securities will be delisted from The Nasdaq Stock Market at the opening of business on June 2, 2005. The Company made a timely request for a hearing with the Nasdaq Listing Qualifications Panel to review the Nasdaq staff's determination which will stay the delisting pending the hearing and a determination by the Nasdaq Listing Qualifications Panel. On June 30, 2005, Bioenvision, Inc. announced that the Nasdaq Listings Qualifications Panel approved its request for continued listing on the Nasdaq National Market and that the fifth character "E" will be removed from Bioenvision's trading symbol effective on the opening of trading on Friday, July 1, 2005.

*Year Ended June 30, 2004 Compared to Year Ended June 30, 2003*

**Results of Operations**

We reported revenues of approximately \$3,102,000 and \$505,000 for the years ended June 30, 2004 and 2003, respectively. Revenues reflect recognition of consideration received pursuant to our agreements with co-development and sub-licensing partners in connection with our platform of drugs and technologies. Of the revenues recorded for the year ended June 30, 2004, approximately \$2,100,000 was recognized from ILEX, pursuant to the Co-Development Agreement, and approximately \$600,000 was recognized from Stegram Pharmaceuticals under the Stegram Co-Development Agreement.

## Edgar Filing: BIOENVISION INC - Form POS AM

Research and development costs for the years ended June 30, 2004 and 2003 were approximately \$4,883,000 and \$1,689,000 and respectively, representing an increase of \$3,194,000.

Our research and development costs include costs associated with six projects of which the Company devotes significant time and resource. Clofarabine research and development costs for the year ended June 30, 2004 and 2003 were approximately \$2,651,000 and \$871,000, respectively, representing an increase of approximately \$1,780,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials being conducted in Europe.

Modrenal® research and development costs for the year ended June 30, 2004 and 2003 were approximately \$2,026,000 and \$913,000, respectively, representing an increase of \$1,113,000. The increase primarily reflects increased development activities associated with the Modrenal® development plan, including costs associated with the U.S. prostate cancer trial which is ongoing.

Gossypol research and development costs were approximately \$152,000 and \$30,000, respectively, representing an increase of \$122,000. The increase primarily reflects preparation of a protocol and other preparatory activities in advance of the Phase I Clinical Trial intended to be commenced in Q3 of calendar 2004.

Gene Therapy research and development costs for the year ended June 30, 2004 and 2003 were approximately \$0 and (\$130,000), respectively. The 2003 amount primarily reflects a reversal of an accrued expense in the year ended 2002 of \$200,000 which was determined to be less than originally estimated by the Company in the year ended June 30, 2003.

The clinical trials and development strategy for the clofarabine and Modrenal® projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of these four projects is as follows: (i) clofarabine research and development costs have been approximately \$5.6 million; (ii) Modrenal® research and development costs have been approximately \$4.4 million; (iii) Gossypol research and development costs have been approximately \$302,000; and (iv) Gene Therapy research and development costs have been approximately \$450,000. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, clofarabine and Modrenal®, over the next two years.

Selling, general and administrative expenses for the year ended June 30, 2004 and 2003 were approximately \$9,082,000 and \$4,567,000, respectively, representing an increase of \$4,515,000. Of this amount, approximately \$2,400,000 of this increase was due to the re-pricing of 380,000 options granted to an employee pursuant to the terms of his Employment Agreement (see Note 7 to the Financial Statements); approximately \$1,000,000 of the increase was due to an increase in sales and marketing expenses related to pre-marketing activities with clofarabine and marketing costs associated with Modrenal® and approximately \$1,100,000 of the increase was due to increases in our consulting and legal expenses as the result of our recent growth.

We reported interest and finance charges of \$0 for the year ended June 30, 2004, representing a decrease of \$325,000 from the year ended June 30, 2003. This decrease reflects the retirement of our credit facility in May 2002 and the fact that we carried no long term debt during the year ended June 30, 2004.

Depreciation and amortization expense totaled approximately \$1,348,000 for the year ended June 30, 2004, representing an increase of \$3,100 from the year ended June 30, 2003. The increase is primarily due to the amortization of certain intangible assets we acquired in the Pathagon transaction which we acquired during the year ended June 30, 2002.



*Year Ended June 30, 2003 Compared to Year Ended June 30, 2002*

We reported revenues of approximately \$505,000 and \$803,000 for the years ended June 30, 2003 and 2002, respectively. Revenues reflect recognition of consideration received pursuant to our agreements with co-development and sub-licensing partners in connection with our platform of drugs and technologies. Of the revenues recorded for the year ended June 30, 2003, approximately \$370,000 was recognized from ILEX pursuant to the Co-Development Agreement and \$100,000 was recognized as royalty revenue from Edwards Lifesciences.

Research and development costs for the years ended June 30, 2003 and 2002 were approximately \$1,689,000 and \$1,912,000, respectively, representing a decrease of \$223,000.

Our research and development costs include costs associated with six projects of which the Company devotes significant time and resource. Clofarabine research and development costs for the year ended June 30, 2003 and 2002 were approximately \$871,000 and \$596,000, respectively, representing an increase of \$275,000. The increase primarily reflects the costs associated with our having commenced clinical trials in Europe to develop clofarabine.

Modrenal® research and development costs for the year ended June 30, 2003 and 2002 were approximately \$913,000 and \$923,000, respectively, representing a decrease of \$10,000.

Gossypol research and development costs were approximately \$30,000 and \$90,000, respectively, representing a decrease of \$60,000. The decrease primarily reflects a decrease in the amount of resource devoted by the Company to this compound while the Company focused on developing its lead drugs.

Gene Therapy research and development costs for the year ended June 30, 2003 were approximately \$(130,000) and \$303,000, respectively, representing a decrease of \$433,000. The decrease primarily reflects an accrued expense in the year ended 2002 of \$200,000 which was determined to be less than originally estimated by the Company in the year ended June 30, 2003.

The clinical trials and development strategy for the clofarabine and Modrenal® projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Estimated total costs to date for each of these four projects is as follows: (i) clofarabine research and development costs have been approximately \$3.0 million; (ii) Modrenal® research and development costs have been approximately \$2.35 million; (iii) Gossypol research and development costs have been approximately \$150,000; and (iv) Gene Therapy research and development costs have been approximately \$450,000. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, clofarabine and Modrenal®, over the next two years.

Administrative expenses for the year ended June 30, 2003 and 2002 were approximately \$4,567,000 and \$2,128,000, respectively, representing an increase of \$2,439,000. Of this amount, approximately \$1,600,000 of this increase was due to the expansion of the internal management team from one full time employee to eight full time employees; approximately \$150,000 of this increase was due to lease expenses and office supplies /equipment for the newly opened New York and Edinburgh, Scotland offices, both of which we opened during the year; approximately \$300,000 of the increase was due to an increase in investor and public relations expenses related to pre-marketing activities with clofarabine and marketing costs associated with Modrenal® approximately \$200,000 of the increase was related to increases in related travel expense to successfully manage our drug development activities; and approximately \$150,000 of the increase was due to increases in our consulting and legal expenses as the result of our recent growth.

We reported interest and finance charges of \$325,000 for the year ended June 30, 2003, representing a decrease of \$1,848,000 from the year ended June 30, 2002. This decrease reflects the retirement of our credit facility in May 2002 and the fact that we carried no long term debt during the year ended June 30, 2003.

Depreciation and amortization expense totaled approximately \$1,345,000 for the year ended June 30, 2003, representing an increase of \$766,000 from the year ended June 30, 2002. The increase is primarily due to the amortization of certain intangible assets we acquired in the Pathagon transaction which we consummated in February 2002.

### **Liquidity and Capital Resources**

We anticipate that we may continue to incur significant operating losses for the fiscal year ended June 30, 2005. There can be no assurance as to whether or when we will generate material revenues or achieve profitable operations.

The Company received a nonrefundable upfront payment of \$1.35 million when it entered into the co-development agreement with ILEX and received an additional \$3.5 million in December 2003 when it converted ILEX's option to market clofarabine in the U.S. into a sublicense. The Company received an additional \$2 million in April 2004 upon ILEX's filing the New Drug Application for clofarabine with FDA and the Company expects to receive an additional \$2 million from ILEX in October 2004 in connection with ILEX having completed such NDA filing. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. 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 the



## Edgar Filing: BIOENVISION INC - Form POS AM

years ended June 30, 2004 and 2003, respectively, the Company recognized revenues of approximately \$161,000 and \$370,000 in connection with the upfront and milestone payments received to date.

Deferred costs included royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with ILEX. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis, concurrent with revenue that is recognized in connection with the ILEX agreement. Research and Development costs include approximately \$81,000 and \$207,000 for the years ended June 30, 2004 and 2003, respectively, related to such charges.

The Company received a nonrefundable upfront payment of \$1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, through May 2014. The Company recognized revenues of approximately \$114,000 and \$12,000 in connection with the upfront payment from Dechra for the years ended June 30, 2004 and 2003, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Stegram 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 include approximately \$23,000 and \$2,000 for the years ended June 30, 2004 and 2003, respectively.

On May 7, 2002 we authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock may be converted into shares of common stock at an initial conversion price of \$1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A Convertible Preferred Stock also received, in respect of each share of Series A Convertible Preferred Stock purchased in a private placement which took place in May 2002, one warrant to purchase one share of our common stock at an initial exercise price of \$2.00 subject to adjustment.

Through May 16, 2002 we have sold an aggregate of 5,916,666 shares of Series A Convertible Preferred Stock in the May 2002 private placement for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock, resulting in aggregate gross proceeds of approximately \$17,750,000. A portion of the proceeds were used to repay in full the Jano Holdings and SCO Capital obligations upon which such facilities were terminated as well as to repay fees amounting to \$1,610,000 related to the transaction.

On March 22, 2004, we consummated a private placement transaction, pursuant to which we raised \$12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of \$7.50 per share. We recorded proceeds of \$11,792,801 net of all legal, professional and financing fees incurred in connection with the offering. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations to our holders of Series A Convertible Preferred Stock which hold preemptive rights for equity offerings. We raised an additional \$3.2 (net of all legal, professional and financial services incurred) million from the second closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of \$7.50 per share.

On June 30, 2004, we have cash and cash equivalents of approximately \$19,166,000 and working capital of \$18,828,000 which management believes will be sufficient to continue currently planned operations over the next 12 months. We can not ensure additional funds will not be raised during the next twelve months because of the significant scale up of our operating activities, including clofarabine development and the launch of Modrenal®. However, if required or desirable, there can be no assurance that suitable debt or equity financing will be available for the Company. Further, although we do not currently plan to acquire or obtain licenses for new technologies, if any such opportunity arises and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

## Edgar Filing: BIOENVISION INC - Form POS AM

We anticipate that we may continue to incur significant operating losses for the fiscal year ended June 30, 2005. There can be no assurance as to whether or where we will generate material revenues or achieve profitable operations.

The Company has the following commitments as of June 30, 2004:

### Payments Due in

|                                 | Total   | 2005    | 2006   | 2007   |
|---------------------------------|---------|---------|--------|--------|
| Employee Contracts              | 474,539 | 474,539 | -      | -      |
| Occupancy Lease and Automobiles | 278,673 | 205,569 | 62,919 | 10,185 |
| Total                           | 753,212 | 680,108 | 62,919 | 10,185 |

The Company has a commitment under its operating lease with the New York office. The Company leases 3,229 square feet under a lease that expires on September 30, 2005. The Company leases approximately 1,000 square feet in Edinburgh, Scotland under lease agreement for its subsidiary, Bioenvision, Ltd. which expire on August 31, 2004.



### **Subsequent Events**

In July 2004, the Company filed for approval of clofarabine in Europe for the treatment of relapsed or refractory acute leukemia in children. The EMEA accepted and validated the application and has commenced a marketing authorization review for clofarabine.

In July 2004, the Company hired a new employee to serve in the capacity as Vice President, Corporate Compliance and Associate General Counsel of the Company.

In July 2004, the Company commenced enrollment of patients in a Phase II clinical study of Modrenal® in androgen independent prostate cancer.

In August 2004, shares of the Company's common stock commenced trading on the NASDAQ National Market.

In August 2004, the Company commenced enrollment of patients in its Pivotal Phase II study to evaluate the use of clofarabine as first-line therapy for the treatment of adults with Acute Myeloid Leukemia.

### **Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, "Share Based Payment", requiring all share-based payments to employees, including grants of employee stock options, to be recognized as compensation expense in the consolidated financial statements based upon their fair values. As amended by the SEC on April 14, 2005, this standard is effective for the quarter beginning July 1, 2005 and includes two transition methods. Upon adoption, we will be required to use either the modified retrospective transition method or the modified prospective transition method. Under the modified retrospective transition method, the previously reported amounts are restated for all periods presented to reflect the SFAS 123 amounts in the income statement. Under the modified prospective transition method, awards that are granted, modified or settled after the date of adoption should be measured and accounted for in accordance with SFAS 123R. Unvested equity-classified awards that were granted prior to the effective date should continue to be accounted for in accordance with SFAS 123 except that amounts must be recognized in the income statement. We are currently evaluating the impact of this standard and its transitional alternatives.

In December 2004, the FASB issued SFAS 153 "Exchange of Non-monetary assets". This statement was a result of a joint effort by the FASB and the International Accounting Standards Board ("IASB") to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. One such difference was the exception from fair value measurement in APB Opinion No. 29, "Accounting for Non-Monetary Transactions", for non-monetary exchanges of similar productive assets. SFAS 153 replaces this exception with a general exception from fair value measurement for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. This statement is effective for non-monetary assets exchanges occurring in fiscal periods beginning after June 15, 2005.

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs". SFAS 151 amends Accounting Research Bulletin ("ARB") No. 43, Chapter 4. This statement clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS 151 is the result of a broader effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on the results of operations or financial position of the company.

**BUSINESS****Overview**

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. The FDA recently approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL. We believe clofarabine is the first new medicine initially approved in the United States for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for all cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is marketing clofarabine under the brand name Clolar in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL with the European Medicines Evaluation Agency, or EMEA. If approved, we anticipate commencing sales in Europe during the second half of calendar 2005 through a dedicated European sales force.

We are selling our second product, Modrenal, in the United Kingdom, through our sales force of eight sales specialists. Modrenal is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and we have initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden. In addition to clofarabine and Modrenal, we are currently developing Virostat for Hepatitis C.

**Products and pipeline**

| Candidate            | Indication                                          | Status                                       | U.S. rights              | Ex-U.S. rights |             |
|----------------------|-----------------------------------------------------|----------------------------------------------|--------------------------|----------------|-------------|
| Clofarabine (Clolar) | Relapsed or Refractory Acute Lymphoblastic Leukemia | Marketed in U.S. (pediatric);                | Genzyme                  | Bioenvision    |             |
|                      |                                                     | Filed in E.U. (pediatric)                    |                          |                |             |
|                      | Acute Myelogenous Leukemia                          | Phase II in E.U. (adult)                     | Genzyme                  | Bioenvision    |             |
|                      |                                                     | Refractory Chronic Lymphocytic Leukemia      | Phase II in U.S. (adult) | Genzyme        | Bioenvision |
|                      | Solid Tumors                                        | Non-Cancer                                   | Phase I (Intravenous)    | Genzyme        | Bioenvision |
|                      |                                                     |                                              | Phase I (Oral)           | Genzyme        | Bioenvision |
|                      |                                                     |                                              | Developmental            | Bioenvision    | Bioenvision |
| Modrenal             | Breast Cancer                                       | Marketed in U.K.;                            | Bioenvision              | Bioenvision    |             |
|                      |                                                     | Phase IV in U.K.;                            |                          |                |             |
| Virostat             | Prostate Cancer<br>Hepatitis C                      | Phase II in E.U.                             | Bioenvision              | Bioenvision    |             |
|                      |                                                     | Phase II in U.S.                             |                          |                |             |
|                      |                                                     | Investigator                                 |                          |                |             |
|                      |                                                     | Sponsored Phase II in Europe and Middle East |                          |                |             |

1. This trial is a pilot study and is not a pivotal regulatory study.



## Our Products

### *Clofarabine (Clolar)*

On December 28, 2004, clofarabine was approved by the FDA after a fast track review for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two prior regimens. Genzyme currently maintains rights to market the drug for all cancer indications in the U.S. and Canada and we will receive a royalty on these sales. Genzyme is marketing clofarabine under the brand name Clolar. We also submitted a Marketing Authorization Application, or MAA, the European equivalent of a U.S. new drug application, or NDA, with the EMEA in July 2004 for European approval of clofarabine in relapsed or refractory pediatric acute leukemia. We expect an opinion from the EMEA in mid-2005. Clofarabine received Orphan Drug designation in the U.S. and in Europe, which provides ten years of marketing exclusivity in Europe and seven years of marketing exclusivity in the U.S. Further, in July 2004, the FDA granted a six-month extension of the marketing exclusivity for clofarabine in pediatric ALL under the federal Best Pharmaceuticals for Children Act.

Pediatric leukemia is the most prevalent form of cancer among children up to age 19 in the U.S. It is estimated that approximately 3,400 children were diagnosed with leukemias in the U.S. in 2004, with ALL accounting for over 75% of the incidence rate. Although survival rates for childhood leukemia have improved significantly since the early 1970s, approximately 20% of pediatric patients with ALL and 60% of pediatric patients with AML do not achieve long-term survival and we believe there is a medical need for new agents to treat this population of patients. Clofarabine is approved for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two prior regimens. The adult leukemia market represents a potentially significantly larger commercial opportunity with over 11,500 patients with AML and over 8,000 patients with chronic lymphocytic leukemia, or CLL, diagnosed each year within the U.S. Based on population and incidence rates data, we believe that the E.U. patient population with pediatric leukemias and adult AML and CLL approximates that of the U.S.

Clofarabine is a purine nucleoside analog, which is a small molecule, that we are developing with Genzyme, our co-development partner, for the treatment of acute and chronic leukemias, lymphomas and solid tumors. Clofarabine attacks cancer cells by damaging DNA in cancer cells, preventing DNA repair by damaged cancer cells, damaging the cancer cell's important control structures, and initiating the process of programmed cell death, or apoptosis, in cancer cells. Clofarabine appears to combine many of the favorable properties of the two most commonly used purine nucleoside analog drugs, fludarabine and cladribine, but appears to have greater potency at damaging the DNA of leukemia cells and a broader range of clinical activity.

In the U.S., pivotal Phase II clinical trials were conducted for the treatment of relapsed or refractory acute leukemia in children and an NDA was filed by Genzyme with the FDA in March 2004, based upon the interim results of 70 patients enrolled in these two trials. In August of 2004, clinical data on an additional cohort of 14 patients were submitted to the FDA and of the aggregate ALL group of 49 patients, a 31% overall response rate was achieved, and of the aggregate AML group of 35 patients, a 26% overall response rate was achieved.

In Europe, we facilitated an investigator sponsored trial, or an IST, of clofarabine as first line therapy for older adult patients with AML who were unsuitable for intensive chemotherapy. The IST was closed to recruitment in August 2004 because a 67% overall response rate was achieved. This response rate was more than three times greater than the expected response rate under the current standard of care for this patient population and the investigator determined that these positive results warranted accelerated initiation of the pivotal Phase II regulatory study of clofarabine as a first-line treatment for older adult patients newly diagnosed with AML. We expect to complete the Phase II trial in mid-2005 and anticipate that it will form the basis for an E.U. regulatory submission for approval in this indication.

On December 1, 2004 the FDA's Oncologic Drug Advisory Committee, or ODAC, convened to determine if clinical data from Phase II trials in relapsed and refractory pediatric ALL and AML demonstrated a durable clinical response that would predicate a clinical benefit in future clinical administration. The panel voted in favor of the approval of clofarabine for pediatric ALL under its accelerated approval pathway and voted against immediate use in pediatric AML, requesting additional information. In connection with the approval that was granted by the FDA, Genzyme is required to conduct further control studies of clofarabine to verify and describe its clinical benefit.



Clofarabine is currently being evaluated in an IST Phase II clinical trial for refractory CLL in the U.S. In addition, in 2005 we intend to investigate clofarabine in European Phase II clinical trials for CLL and indolent lymphoma. In pre-clinical studies, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the lung, colon, kidney, breast, pancreas and prostate, as well as its action against leukemia cells. The initial data from the Phase I clinical trials indicate activity for clofarabine in certain solid tumor types. We believe this level of activity against solid tumors distinguishes clofarabine from other purine nucleoside analogs. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon, pancreatic, lung, breast and prostate cancer. Currently, we anticipate the initial Phase I clinical trials for clofarabine, using both the oral and intravenous formulations, in solid tumors will be completed by end of calendar 2005.

Pursuant to the terms of our co-development agreement with Genzyme, the successor-in-interest to ILEX Oncology, Inc., both parties are required to share promptly all information, including clinical data, generated under the co-development program and Genzyme is obligated to pay all of the U.S. and Canadian research and development costs and 50% of all approved ex-U.S. and Canada research and development costs (except for Japan and Southeast Asia). If additional resources are required above the agreed upon costs, we may elect to pay these additional costs and certain of these payments will be credited against future royalty payments to Genzyme at the rate of \$1.50 for every \$1.00 of additional expenditures. Under the co-development agreement with Genzyme, we receive royalties on Genzyme's annual net sales on a sliding scale based on the level of annual net sales. Similarly, we pay a royalty to Genzyme and Southern Research Institute, the inventor of clofarabine, on our European annual net sales.

Pursuant to the terms of our co-development agreement with Southern Research Institute, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications except for U.S. and Canadian cancer indications and except for any indications in Japan and Southeast Asia. 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 expect to expire in 2021. In addition, we hold an exclusive option from Southern Research Institute to market and distribute clofarabine in Japan and Southeast Asia for all human applications. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in Japan and Southeast Asia.

### ***Modrenal***

We currently market Modrenal (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 eight sales specialists and two marketing executives selling and marketing Modrenal in the U.K.

Modrenal's licensed indication enables us to promote Modrenal for use immediately after relapse to initial hormone therapy such as tamoxifen or one of a class of drugs known as aromatase inhibitors. However, we are initially positioning Modrenal as a third or fourth line treatment option in post-menopausal advanced breast cancer. In the five largest E.U. countries (France, Germany, Italy, Spain and the U.K.), we believe approximately 520,000 women are currently living with post-menopausal advanced breast cancer of which over a third require third or fourth line agents following prior treatment failure.

Modrenal has been extensively studied in clinical trials in the U.S., Europe and Australia, and an analysis, known as a meta-analysis, of a series of these clinical studies, that included 714 patients with post-menopausal advanced breast cancer who received Modrenal has been conducted. Overall, a clinical benefit rate of 35% was achieved in patients with both hormone-sensitive and hormone-insensitive breast cancers. Generally, a clinical benefit is achieved when a patient's disease disappears, is decreased by greater than fifty percent or is stabilized for at least six months. In a sub-set analysis of these clinical trial data, a clinical benefit rate of 46% was achieved for 351 patients with hormone-sensitive breast cancer who had responded to one or more prior hormonal therapies and were given Modrenal upon relapse of the cancer. In one of the studies which was conducted in Australia, a clinical benefit rate of 55% was achieved for 64 patients who received Modrenal having previously responded to tamoxifen and subsequently relapsed. We believe these data compare favorably to currently marketed aromatase inhibitors and other agents given as second line or subsequent therapies. Furthermore, Modrenal has an acceptable side-effect profile. On the basis of these data, Modrenal was granted a product license in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.



We began marketing Modrenal in May 2003 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. We also intend to seek regulatory approval for Modrenal in the U.S. as a therapy for hormone-sensitive breast cancers and hormone independent prostate cancers, but this strategy is dependent upon the results of the ongoing clinical trials and the resource capability of the Company. Our ongoing clinical trials in breast cancer target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as tamoxifen or any of the aromatase inhibitors. In addition, there is an ongoing Phase II clinical trial of Modrenal in the U.S. that is focused on patients who have androgen independent prostate cancer and have a rising prostate specific antigen, or PSA, level.

In mid-2005 we began enrollment in a U.K., Phase IV study in post-menopausal advanced breast cancer, a Phase II study in pre-menopausal breast cancer and a Phase II study in neo-adjuvant, pre-operative breast cancer. In Europe, we have initiated the filing process for mutual recognition for approval of Modrenal on a country-by-country basis. Each such approval, if granted, would be based upon Modrenal's approval in the U.K. for post-menopausal advanced breast cancer following relapse to initial hormone therapy. The Company anticipates such approvals would be granted, on a country-by-country basis, within nine to 12 months following each such filing, but grant of any such approval is entirely within the control of the individual regulatory authorities.

We have the exclusive right to market and distribute Modrenal throughout the world for all human applications, except for South Africa and Japan where the drug is marketed for the treatment of low-renin hypertension. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the marketing of Modrenal. Given that we have new patent applications filed, which are subject to issuance, we expect the last of our underlying patents to expire in 2020.

#### **Other Products and Technologies**

##### ***Virostat***

Virostat is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. Virostat, especially when irradiated by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Investigator sponsored Phase II clinical trials have been initiated in Europe and the Middle East to study Virostat's use in treating Hepatitis C.

Blood transfusions are required to treat a variety of medical conditions and, to meet that need, over 90 million blood donations occur each year. Of these, approximately 39 million donations occur in North America, Western Europe and Japan. We licensed from Oklahoma Medical Research Foundation the rights to use a range of thiazine dyes, including Virostat, for their use in *in vitro* and *in vivo* inactivation of pathogens in biological fluids.

##### ***Velostan***

Velostan is a cytostatic drug we are investigating in Europe for bladder cancer. Velostan is the first compound in a group of chemically related compounds that are believed to work by blocking cell division and reversing the malignant process in the cancer cell. We believe the optical isomer we have developed is more active and less toxic than its parent compound.

#### **OLIGON® Technology**

With the acquisition of Pathagon in February 2002, we acquired patents, technology and technology patents relating to OLIGON® anti-infective technology, and have licensed rights from Oklahoma Medical Research Foundation to the use of thiazine dyes, including methylene blue, for other anti-infective uses.

The OLIGON® technology is based on the antimicrobial properties of silver ions. The broad spectrum activity of silver ions against bacteria, including antibiotic-resistant strains, has been known for decades. OLIGON® materials have application in a wide range of devices and products, including vascular access devices, urology catheters, pulmonary artery catheters and thoracic devices, renal dialysis catheters, orthopedic devices and several other medical and consumer product applications. One application of the OLIGON® technology has been licensed to a





third party, which is currently marketing the technology in its line of short-term vascular access catheters. Six U.S. patents for the OLIGON® technology have been granted and additional patents have been filed. In addition, patents have been filed in Europe, Canada and Japan.

The OLIGON® technology specifically targets hospital-acquired infections which are occurring on an ever-increasing rate. Hospital-acquired infections were the eleventh leading cause of death in 2000 and related treatment costs to the health care industry exceeded \$5.5 billion. Infection rates are comparable in Europe and even higher in developing countries. According to the U.S. Center for Disease Control, the U.S. healthcare system spends an estimated \$5 billion per year treating hospital-acquired infections resulting from medical devices, approximately 87% of which is spent just on the treatment of infections caused by infected catheters. OLIGON® devices will be marketed as next generation products into large existing markets.

#### ***Gene Therapy Technology***

Our product portfolio also includes a variety of gene therapy products which, we believe, may offer advancements in the field of cancer treatment and may have additional applications in certain non-cancer diseases such as diabetes, cystic fibrosis and other auto-immune disorders. Pursuant to a co-development agreement with the Royal Free and University College Medical School and a Canadian biotechnology company, we are developing gene vector technologies which, based on pre-clinical research and early Phase I clinical trials, we believe have potential in a wide array of clinical conditions. To date, the technology has undergone small-scale clinical testing with the albumin and thrombopoietin genes. The results showed the technology is capable of producing a prolonged elevation in serum albumin levels in cancer and cirrhosis patients with hypo-albuminemia, a serious physiological disorder. We believe this has considerable market potential since low albumin levels are considered to be very dangerous consequences of many diseases, including cirrhosis and liver cancer.

#### ***Animal Health Products***

We also have one animal health product, Veteryl®, at market in the United Kingdom for the treatment of Cushing's disease in dogs. In November 2001, we granted to Arnolds Ltd., a major distributor of animal products in the United Kingdom, the right to market the drug for a six-month trial period, after which time, if the results were satisfactory to Arnolds, we would enter into a licensing arrangement whereby Arnolds would pay royalties to us on sales from April 2002 onward. During the trial period, Arnolds posted more than \$400,000 of sales of the drug. Arnolds has licensed the drug from us for sale in the United Kingdom market in consideration of a payment of a 5% royalty on sales. Separately, in May 2003, we granted to Dechra Pharmaceuticals, PLC, an affiliate of Arnolds Ltd., the exclusive right to market the drug in the United States for \$5.5 million of total consideration (including milestone payments) and a royalty of 2%-4% of annual net sales.

#### **Patents and Proprietary Rights**

Our success will depend, in part, upon our ability to obtain and enforce protection for our products under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Our policy is to file patent applications in the United States and/or foreign jurisdictions to protect technology, inventions and improvements to our inventions that are considered important to the development of our business. Also, we will rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop a competitive position.

Through our current license agreements, we have acquired the right to utilize the technology covered by several issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. We evaluate the desirability of seeking patent or other forms of protection for our products in foreign markets based on the expected costs and relative benefits of attaining this protection. There can be no assurance that any patents will be issued from any applications or that any issued patents will afford adequate protection to us. Further, there can be no assurance that any issued patents will not be challenged, invalidated, infringed or circumvented or that any rights granted thereunder will provide competitive advantages to us. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. There can be no assurance that patents now in



existence or hereafter issued to others will not adversely affect the development or commercialization of our products or that our planned activities will not infringe patents owned by others.

As a result of the licenses described above, we are the exclusive licensee or sublicensee of three United States patents expiring in 2005, 2008 and 2014 relating to compounds, pharmaceutical compositions and methods of use encompassing clofarabine. We have also filed two United States patent applications relating to the use of clofarabine in autoimmune diseases. Although the composition of matter patents to trilostane have expired, we are the exclusive licensee of several United States and foreign patent applications relating to the use of trilostane alone or in combination with anticancer agents and the exclusive licensee to a manufacturing process patent for trilostane.

We could incur substantial costs in defending ourselves in infringement suits brought against us or any of our licensors or in asserting any infringement claims that we may have against others. We could also incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors or distributors. An adverse outcome in any litigation could have a material adverse effect on our business and prospects. In addition, we could be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any of these licenses would be made available on terms acceptable to us, or at all. If we are required to, and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more of our products.

We also rely upon trade secret protection for our confidential and proprietary information. There can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose this technology or that we can meaningfully protect our trade secrets.

It is our policy to require our employees, consultants and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

### **Sales and Marketing**

Currently we have an arrangement in place with Genzyme for the co-development and marketing of one of our lead products, clofarabine, and another arrangement with Edwards Lifesciences for the marketing of short-term vascular access catheters using the OLIGON® technology. We have also engaged in our own marketing and sales efforts in connection with the marketing and sale of Modrenal® in the United Kingdom. If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of five other key regions within the E.U. However, in order to market any of our products effectively, we would need to establish a much more integrated marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces.

Our marketing policy is to generate awareness of our products and target the two key audiences for our products - doctors and patients. Medical education is also a priority, with the use of peer-opinion leaders, clinical trials at major centers, satellite symposia and conferences, product advertising in specific scientific journals and trained sales personnel. Patient education is carefully controlled and is important to our marketing approach.

### **Manufacturing**

We do not have and do not intend to establish any internal product testing, manufacturing or distribution capabilities. Our strategy is to enter into collaborative arrangements with other companies for the clinical testing, manufacture and distribution of the products. Manufacturers of our products will be subject to Good Manufacturing Practices prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities, which may change from time to time.



## Research and Development

In developing new products, we consider a variety of factors including: (i) existing or potential marketing opportunities for these products; (ii) our capability to arrange for these products to be manufactured on a commercial scale; (iii) whether or not these products complement our existing products; (iv) the opportunities to leverage these products with the development of additional products; and (v) the ability to develop co-marketing relationships with pharmaceutical and/or other companies with respect to the products. We intend to fund future research and development activities at a number of medical and scientific centers in Europe and the United States. Costs related to these activities are expected to include: clinical trial expenses; drug production costs; salaries and benefits of scientific, clinical and other personnel; patent protection costs; analytical and other testing costs; professional fees; and insurance and other administrative expenses. We have spent approximately \$4,883,000 and \$1,689,000 on research and development activities for the fiscal years ended June 30, 2004 and 2003 respectively.

## Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our drug delivery products.

The process required by the FDA under the new drug provisions of the Federal Food, Drug and Cosmetics Act before our products may be marketed in the United States generally involves the following:

- pre-clinical laboratory and animal tests;

- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use;

- submission to the FDA of a new drug application; and

- FDA review and approval of the new drug application.

The testing and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approval will be granted on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. There is no certainty that pre-clinical trials will result in the submission of an IND or that submission of an IND will result in FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional



review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Human clinical trials are typically conducted in three sequential phases which may overlap:

PHASE I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion;

PHASE II: Studies are conducted in a limited patient population to identify possible short term adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage;

PHASE III: Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites. Phase III or IIb/III trials are often referred to as pivotal trials, as they are used for the final approval of a product.

In the case of products for life-threatening diseases such as cancer, the initial human testing is often conducted in patients with disease rather than in healthy volunteers. Since these patients already have the targeted disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials and so these trials are frequently referred to as Phase I/II trials. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore, we, the FDA, the institutional review board or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application for approval of the marketing and commercial shipment of the product. The FDA may deny a new drug application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if the additional data is submitted, the FDA may ultimately decide that the new drug application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards for production and distribution is not maintained or if safety problems occur after the product reaches the market. In addition, the FDA requires surveillance programs to monitor approved products which have been commercialized, and the agency has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs.

The FDA has a Fast Track program intended to facilitate the development and expedite the review of drugs that demonstrate the potential to address unmet medical needs for treatment of serious or life-threatening conditions. Under this program, if the FDA determines from a preliminary evaluation of clinical data that a fast track product may be effective, the FDA can review portions of a new drug application for a Fast Track product before the entire application is complete, and undertakes to complete its review process within six months of the filing of the new drug application. The FDA approval of a Fast Track product can include restrictions on the product's use or distribution such as permitting use only for specified medical procedures or limiting distribution to physicians or facilities with special training or expertise. The FDA may grant conditional approval of a product with Fast Track status and require additional clinical studies following approval.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data from pre-clinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after the FDA approves a product, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.



Any products manufactured or distributed under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon manufacturers and their third party manufacturers.

We are subject to numerous other federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

We also are subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products which we sell outside the United States. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Whether or not we obtain FDA approval, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for these approvals may differ substantially from that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country. For clinical trials conducted outside the United States, the clinical stages generally are comparable to the phases of clinical development established by the FDA.

### **Competition**

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including a number of large pharmaceutical companies as well as several specialized biotechnology companies, are developing cancer drugs similar to ours. There are products on the market that will compete directly with the products that we are seeking to develop. In addition, colleges, universities, government agencies and other public and private research institutions will continue to conduct research and are becoming more active in seeking patent protection and licensing arrangements to collect license fees, milestone payments and royalties in exchange for license rights to technologies that they have developed, some of which may directly compete with our technologies. These companies and institutions also compete with us in recruiting qualified scientific personnel. Many of our competitors have substantially greater financial, research and development, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in preclinical testing, human clinical trials and regulatory approval procedures. Our competitors may develop safer or more effective products than ours, obtain patent protection or intellectual property rights that limit our ability to commercialize products, or commercialize products more quickly than we can.

We expect technology developments in our industry to continue to occur at a rapid pace. Commercial developments by our competitors may render some or all of our potential products obsolete or non-competitive, which would materially harm our business and financial condition.

### **Employees**

As of August 1, 2005, we had 27 full-time employees based in New York, New York, and Edinburgh, Scotland. Of these, 3 are in management, 4 are in legal/accounting, 10 are in sales/marketing, 5 are in administration and 5 are in research and development. We believe our relationships with our employees are satisfactory.

### **Description of Property**

As of the date of this report we do not own any interest in real property. We currently lease 3,229 square feet of office space at our principal executive offices at 345 Park Avenue, 41st Floor, New York, New York 10154 for approximately \$26,351 per month. These facilities are the center for all of our administrative functions in the



United States. Also, we rent on a month-to-month basis approximately 2,437 square feet of office space in Edinburgh, Scotland for approximately £14,400 per month. To date, most of our drug development programs have been conducted at scientific institutions around the world. It is our policy to continue development at leading scientific institutions in the United States and Europe. We do not plan to conduct laboratory research in any of our facilities in the near future, rather, we will conduct research through collaborative arrangements with Southern Research Institute, M.D. Anderson and others.

#### **Legal Proceedings**

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd., which we refer to as the Tessman Defendants, in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously.

#### **Corporate Information**

We were incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed our name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in January 1999. Our principal executive offices are located at 345 Park Avenue, 41st Floor, New York, New York 10154. Our telephone number is (212) 750-6700 and our fax number is (212) 750-6777. Our website is [www.bioenvision.com](http://www.bioenvision.com). Information included or referred to on our website is not incorporated by reference in or otherwise a part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

#### **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our excess cash is invested in high quality money market instruments. These instruments have various short-term maturities. We hold no derivative financial instruments and we do not currently engage in hedging activities. 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. We do not have any outstanding debt.

**MANAGEMENT****Directors**

The following table sets forth information as to our directors as of August 1, 2005, together with their positions and ages.

| <b>Name of Director</b>   | <b>Age</b> | <b>Position</b>                                   |
|---------------------------|------------|---------------------------------------------------|
| Christopher B. Wood, M.D. | 59         | Chairman of the Board and Chief Executive Officer |
| Michael Kauffman, M.D.    | 42         | Director                                          |
| Thomas Scott Nelson, C.A. | 66         | Director                                          |
| Steve A. Elms             | 41         | Director                                          |
| Andrew Schiff, M.D.       | 39         | Director                                          |

Set forth below is the name, principal occupation for the last five years, selected biographical information and the period of service as director of each of the directors.

**Christopher B. Wood, M.D.** has served as our chairman of the board of directors and chief executive officer since January 1999. From January 1997 to December 1998, Dr. Wood was chairman of the board of Eurobiotech, Inc., a Delaware company. From March 1994 to January 1997, Dr. Wood was a specialist surgeon in the National Health Service in the United Kingdom. From April 1979 to March 1991, Dr. Wood was a specialist surgeon at The Royal Postgraduate Medical School, London, England. Dr. Wood holds an M.D. from the University of Wales School of Medicine and the Fellowship of the Royal College of Surgeons of Edinburgh.

**Michael Kauffman M.D., Ph.D.** was named a director in January 2004. Dr. Kauffman is currently the president and chief executive officer of Predix Pharmaceuticals. Prior to that he was the vice president, medicine, and Proteasome Inhibitor (VELCADE ) Program Leader at Millennium Pharmaceuticals Inc. Prior to that, Dr. Kauffman held senior positions at Millennium Predictive Medicine, Inc., as cofounder and vice president of Medicine, and at Biogen Corporation. Dr. Kauffman received his M.D. and Ph.D. (molecular biology and biochemistry) at Johns Hopkins and his postdoctoral training at Harvard University. He is board certified in internal medicine, and comes with over 10 years of experience in drug discovery and development.

**Thomas Scott Nelson, C.A.** was named a director in May 1998. Mr. Nelson served as our chief financial officer from May 1998 to September 2002. From 1996 to 1999, Mr. Nelson served as the director of finance of the management board of the Royal & Sun Alliance Insurance Group. From 1991 to 1996, Mr. Nelson served as group finance director of the main board of Sun Alliance Insurance Group. He has served as chairman of the United Kingdom insurance industry committee on European regulatory, fiscal and accounting issues. He has also worked with Deloitte in Paris and as a consultant with PA Consultants Management. Mr. Nelson is a member of the Institute of Chartered Accountants of Scotland and a fellow of the Institute of Cost and Management Accountants. Mr. Nelson holds a B.A. degree from Cambridge University.

**Steven A. Elms** was named a director in May 2002. Mr. Elms has served as a Managing Director of the Perseus-Soros Management, LLC, an affiliate of the Perseus-Soros BioPharmaceutical Fund, LP since June 2000. For five years prior to joining Perseus-Soros, Mr. Elms was a principal in the Life Science Investment Banking group of Hambrecht & Quist (now J.P. Morgan H&Q). Mr. Elms also serves as a director of Adams Respiratory Therapeutics, Inc.

**Andrew Schiff, M.D.** was named a director in May 2002. Dr. Schiff has served as a Managing Director of Perseus-Soros Management, LLC, an affiliate of the Perseus-Soros Biopharmaceutical Fund, LP since September of 1999. Over the last 10 years, Schiff has practiced internal medicine at The New York Presbyterian Hospital where he maintains his position as a Clinical Assistant Professor of Medicine. Dr. Schiff also serves as a director of Adams Respiratory Therapeutics, Inc.



### Committees of the Board of Directors

The board of directors currently has two standing committees: the Audit Committee and the Compensation Committee. The board of directors does not have a standing Nominating Committee.

The audit committee is comprised of Mr. Elms and Drs. Schiff and Kauffman; with Mr. Elms serving as chairman of the audit committee. All audit committee members are independent, as defined in Rule 4200(a)(15) of the National Association of Securities Dealers listing standards. All members of the audit committee are financially literate and the board of directors has determined that Dr. Kauffman (i) is an audit committee financial expert and (ii) is independent, as that term is used in Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act. The Audit Committee recommends the independent accountants appointed by the board of directors to audit our the financial statements, which includes an inspection of our books and accounts, and reviews with such accountants the scope of their audit and their report thereon, including any questions and recommendations that may arise relating to such audit and report or our internal accounting and auditing system procedures.

The Compensation Committee is comprised of Mr. Elms and Drs. Schiff and Kauffman; with Dr. Kauffman serving as chairman of the Compensation Committee. The function of the Compensation Committee is to review and approve the compensation of executive officers and establish targets and incentive awards under our incentive compensation plans.

During the fiscal year ended June 30, 2004, (i) the board of directors held 6 meetings; (ii) the Audit Committee held 4 meetings and (iii) the compensation committee held one meeting. During the fiscal year ended June 30, 2004, each director attended at least 75% of the meetings of the board of directors and 100% of the total number of meetings of committees on which he served.

### Compensation of Directors

Our policy is that non-management directors are entitled to receive a director's fee of \$2,000 per meeting for attendance at meetings of the board of directors that they attend in person, \$1,000 per meeting for attendance at meetings of committees the board of directors that they attend in person, and \$250 for each board or committee meeting they attend by teleconference, in addition, they are reimbursed for actual expenses incurred in respect of such attendance. We do not separately compensate employees for serving as directors. We do not provide additional compensation for committee participation or special assignments of the board of directors.

In connection with joining our board of directors, on January 20, 2004, Dr. Michael Kauffman was granted an option to purchase 25,000 shares of our common stock at an exercise price of \$4.55 (the fair market value of our common stock, on the date of the grant), 12,500 of which vest on January 20, 2005 with the remaining 12,500 vesting on January 20, 2006.

### EXECUTIVE AND SENIOR OFFICERS

Set forth below is the name, age as of August 1, 2005, principal occupation for the last five years, selected biographical information and the period of service as an executive officer of each of the executive officers.

**Christopher B. Wood, M.D.**, age 59, has served as our chairman of the board of directors and chief executive officer since January 1999. From January 1997 to December 1998, Dr. Wood was chairman of Eurobiotech, Inc., a Delaware company. From March 1994 to January 1997, Dr. Wood was a specialist surgeon in the National Health Service, United Kingdom. From April 1979 to March 1991, Dr. Wood was a specialist surgeon at The Royal Postgraduate Medical School, London, England. Dr. Wood holds an M.D. from the University of Wales School of Medicine and the Fellowship of the Royal College of Surgeons of Edinburgh.

**David P. Luci, C.P.A., Esq.**, age 38, has served as our chief financial officer, general counsel and corporate secretary since July 2004, after serving as director of finance, general counsel and corporate secretary since July 2002. From September 1994 to July 2002, Mr. Luci served as a corporate associate at Paul, Hastings, Janofsky & Walker LLP (New York office). Prior to that, Mr. Luci served as a senior auditor at Ernst & Young LLP (New York



office). Mr. Luci is a certified public accountant. He holds a Bachelor of Science in Business Administration with a concentration in accounting from Bucknell University and a J.D. from Albany Law School of Union University.

**Hugh S. Griffith**, age 37, has served as Chief Operating Officer of Bioenvision, Ltd., our wholly-owned sales and marketing subsidiary, since July 2004 after serving as Commercial Director (Europe) since October 2002. Mr Griffith served as Executive Commercial Director of QuantaNova Ltd. from January 2002 to September 2002. From October 1995 to December 2001, Mr Griffith held several senior commercial positions at Abbott Laboratories, including Senior Business Unit Manager, Business Development Manager and Area Sales Manager. From April 1992 to October 1995 Mr Griffith served with Parke-Davis, Warner Lambert. Mr. Griffith holds a Masters of Business Administration from Cardiff Business School, University of Wales; a Diploma of Marketing; and a Bachelor of Science with Honours in Biology from the University of Stirling in Scotland.

**Ian Abercrombie**, age 44, has served as Sales Manager (Europe) since January 2003. Mr Abercrombie joined us from his position of European Sales and Marketing Director with Biolitec Pharma which he held from February of 2002 through January of 2003. From 1995 through January of 2002, Mr. Abercrombie was with Johnson & Johnson. Mr. Abercrombie holds a Bachelor of Science in Marketing from the University of Stirling in Scotland.

**Kristen M. Dunker, Esq.**, age 31, has served as Vice President, Corporate Compliance and Associate General Counsel since June 2004. From September 1999 to June 2004, Ms. Dunker served as a corporate associate at Paul, Hastings, Janofsky & Walker LLP. Ms. Dunker holds a Bachelor of Science in Business Administration from Bucknell University and a J.D. from the University of Denver College of Law.

**Robert Sterling**, age 42, has served as Vice President, Product Development since July, 2004, after serving as Vice President, Veterinary Affairs since July 2002. He is responsible for development of our anti-viral, anti-microbial and veterinary businesses. Before joining us, Mr. Sterling worked for nine years at Hoechst Roussel Vet, where he held various marketing and sales positions. Mr. Sterling holds a B.S. degree from Penn State University.

**Andrew Saunders, M.D.**, age 40, has served as Medical Director at Bioenvision since May, 2005. Dr. Saunders joined us from Global Drug Development at Hoffman-La-Roche where he was Clinical Science Leader for MabThera oncology with global medical and scientific responsibility for the MabThera development programme. From 2000 to 2002, Dr. Sanders held the position of European Clinical Research Physician in oncology with Eli Lilly & Company. Dr. Saunders holds a Degree in Medicine (1989) from Trinity College Dublin, Republic of Ireland including primary degree qualifications as follows: Batchelor of Medicine; Batchelor of Surgery; Batchelor of Obstetrics; Batchelor of Arts. Dr. Saunders underwent post-graduate training in general medicine and haematology and his Post-Graduate qualifications include: MRCP (Member of Royal College of United Kingdom) in 1996; and MFPM (Member of Faculty Pharmaceutical Medicine) in 2000.



**EXECUTIVE COMPENSATION**

The following table sets forth the compensation paid and awarded to all individuals serving as (a) our chief executive officer, (b) each of our four other most highly compensated executive officers (other than our chief executive officer) at the end of our fiscal year ended June 30, 2005 whose total annual salary and bonus exceeded \$100,000 for these periods, and (c) up to two additional individuals, if any, for whom disclosure would have been provided pursuant to (b) except that the individual(s) were not serving as our executive officers at the end of our fiscal year ended June 30, 2005 (each a Named Executive Officer):

| Name &<br>Principal Position                                                          | Summary Compensation Table |             |           |           | Long term compensation Awards Payouts    |                 |                            |
|---------------------------------------------------------------------------------------|----------------------------|-------------|-----------|-----------|------------------------------------------|-----------------|----------------------------|
|                                                                                       | Year                       | Salary      | Bonus     | Other     | Securities<br>underlying<br>options/SARs | LTIP<br>payouts | All other<br>compen-sation |
|                                                                                       |                            | \$          | \$        | \$        |                                          | \$              | \$                         |
| Christopher B. Wood, MD, Chairman and Chief Executive Officer                         | 2005                       | 300,000     | 129,000   | 30,000(1) | 195,000(2)                               | -               | -                          |
|                                                                                       | 2004                       | 225,000     | -         | -         | -                                        | -               | -                          |
|                                                                                       | 2003                       | 225,000     | -         | -         | 500,000(3)                               | -               | -                          |
| David P. Luci, Esq., Chief Financial Officer, General Counsel and Corporate Secretary | 2005                       | 275,000     | 86,000(4) | -         | 160,000                                  | -               | -                          |
|                                                                                       | 2004                       | 220,000     | 20,000(5) | -         | 185,000(6)                               | -               | -                          |
|                                                                                       | 2003                       | 205,200     | 25,000(7) | -         | 500,000(8)                               | -               | -                          |
| Hugh S. Griffith, Chief Operating Officer (Europe)                                    | 2005                       | 250,000     | 86,000    | 46,090(9) | 160,000                                  | -               | -                          |
|                                                                                       | 2004                       | 216,000     | -         | 36,400    | 175,000(10)                              | -               | -                          |
|                                                                                       | 2003                       | 216,000     | 20,000    | 14,400    | 300,000(11)                              | -               | -                          |
| Andrew Saunders, MD                                                                   | 2005                       | 231,250(12) | -         | -         | 50,000(13)                               | -               | -                          |
|                                                                                       | 2004                       | -           | -         | -         | -                                        | -               | -                          |
|                                                                                       | 2003                       | -           | -         | -         | -                                        | -               | -                          |
| Kristen M. Dunker, Esq.                                                               | 2005                       | 170,000     | 50,000    | -         | 36,250(14)                               | -               | -                          |
|                                                                                       | 2004                       | 135,000     | -         | -         | 140,000(15)                              | -               | -                          |
|                                                                                       | 2003                       | -           | -         | -         | -                                        | -               | -                          |

- 
- (1) Dr. Wood receives a Company sponsored contribution to his pension plan in the amount of \$30,000 per annum.
  - (2) On January 6, 2005, Dr. Wood was granted options to purchase 195,000 shares of our common stock at \$8.17 per share. Of these options, options to purchase 48,750 shares of our common stock vested immediately and options to purchase 48,750 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of the grant date.
  - (3) On December 31, 2002, Dr. Wood was granted options to purchase 500,000 shares of our common stock at \$1.45 per share. Of these options, options to purchase 166,666 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of the grant date.
  - (4) Excludes \$872,000 which constitutes the value of the equity component of Mr. Luci's annual bonus (options to purchase 160,000 shares of our common stock granted on January 6, 2005).
  - (5) Excludes \$370,000 which constitutes the value of the equity component of Mr. Luci's annual bonus (options to purchase 185,000 shares of our common stock granted on January 20, 2004).
  - (6) On January 20, 2004, Mr. Luci was granted options to purchase 185,000 shares of our common stock at a then-current fair market value. Of these options, options to purchase 61,666 shares of our common stock

- vest and become exercisable, subject to certain circumstances, on the first anniversary of the grant date and options to purchase 61,667 shares of our common stock vest and become exercisable, on each of the second and third anniversaries of the grant date.
- (7) The annual bonus of \$57,000 was prorated for the portion of calendar year 2002 within which Mr. Luci was employed by us.
- (8) On July 22, 2002, Mr. Luci was granted options to purchase 380,000 shares of our common stock. On March 31, 2003, in connection with the execution of an employment agreement between us and Mr. Luci, these options were cancelled and we issued options to purchase 500,000 shares of common stock at \$0.735 per share. Of these options, options to purchase 170,000 shares of our common stock are immediately exercisable and, subject to certain circumstances, options to purchase 110,000 shares of common stock vest and become exercisable on each of the first, second and third anniversaries of March 31, 2003, the grant date.
- (9) Mr. Griffith receives a Company sponsored contribution to his pension plan of \$25,000 per annum and is reimbursed for his car lease in the amount of \$21,090 per annum.
- (10) On January 20, 2004, Mr. Griffith was granted options to purchase 175,000 shares of our common stock at \$4.05 per share. Of these options, options to purchase 58,333 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of the grant date.
- (11) On October 22, 2003, Mr. Griffith was granted options to purchase 300,000 shares of our common stock at \$1.45 per share. Of these options, options to purchase 100,000 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of October 22, 2002, the grant date.
- (12) Dr. Saunders base salary is 125,000 GBP, which converts to \$231,250 at an exchange rate of 1.85.
- (13) On March 16, 2005, Dr. Saunders was granted options to purchase 50,000 shares of our common stock at \$5.44 per share. Of these options, options to purchase 12,500 shares of our common stock vest and become exercisable, subject to certain circumstances, on June 30, 2005 and options to purchase 12,500 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of the grant date.
- (14) On January 6, 2005, Ms. Dunker was granted options to purchase 36,250 shares of our common stock at \$8.17 per share. Of these options, options to purchase 9,063 shares of our common stock vested immediately and options to purchase 9,063 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of the grant date.
- (15) On June 22, 2004, Ms. Dunker was granted options to purchase 140,000 shares of our common stock at \$8.25 per share. Of these options, options to purchase 30,000 shares of our common stock vested immediately and options to purchase 55,000 shares of our common stock vest and become exercisable on each of the first and second anniversaries of the grant date.

## EMPLOYMENT AGREEMENTS

We have entered into employment agreements with certain of our principal executive officers. Pursuant to these agreements, our executive officers agree to devote all or a substantial portion of their business and professional time efforts to our business as executive officers. The employment agreements provide for certain compensation packages, which include bonuses and other incentive compensation. The agreements also contain covenants restricting the employees from competing with us and our business and prohibiting them from disclosing confidential information about us and our business.

On September 1, 1999, we entered into an employment agreement with Christopher B. Wood, M.D. under which he serves as our chairman and Chief Executive Officer. The initial term of Dr. Wood's employment agreement is two years with automatic one-year extensions thereafter unless either party gives written notice to the contrary. On December 31, 2002, we entered into a new employment agreement with Dr. Wood, under which he continues to serve as our chairman and Chief Executive Officer. Under this contract, the term is one year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. Dr. Wood's new employment agreement provides for an initial base salary of \$225,000, a bonus as determined by the board of directors, health insurance and other benefits currently or in the future provided to our key employees. If Dr. Wood's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to his then current annual base salary and any and all unvested options will vest and immediately become exercisable.

On October 23, 2002, we entered into an employment agreement with Hugh S. Griffith, pursuant to which he agrees to serve as our Commercial Director (Europe). The initial term of Mr. Griffith's employment agreement is one-year, with automatic six month extensions thereafter unless either party provides written notice to the contrary. If Mr. Griffith's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 0.5 multiplied by the sum of his then current annual base salary plus a payment equal to six (6) months of his then current base salary in complete satisfaction of our obligation to provide no less than six (6) months prior written notice as set forth in the employment agreement.

On January 6, 2003, we entered into an employment agreement with Ian Abercrombie, pursuant to which he agrees to serve as our Sales Manager (Europe). The initial term of Mr. Abercrombie's employment agreement is one-year, with automatic six month extensions thereafter unless either party provides written notice to the contrary. If Mr. Abercrombie's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a payment equal to six (6) months of his then current base salary in complete satisfaction of our obligation to provide no less than six (6) months prior written notice as set forth in the employment agreement.

On March 31, 2003, we entered into an employment agreement with David P. Luci, pursuant to which he serves as our Director of Finance, General Counsel and Corporate Secretary. The initial term of Mr. Luci's employment agreement is one-year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. If Mr. Luci's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 1.5 multiplied by the sum of (i) his then current annual base salary plus (ii) his then average annual bonus for the preceding two years and any and all unvested options will vest and immediately become exercisable.

**STOCK OPTIONS AND LONG TERM INCENTIVE PLANS****Option/SAR Grants in Last Fiscal Year**

The following table sets forth information concerning option/SAR grants in our fiscal year ended June 30, 2005 to each Named Executive Officer:

| Name                    | Number of securities underlying options/SARs granted (#) | Percent of total options/SARs granted to employees in fiscal year | Exercise or base price (\$/share) | Expiration Date | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(1) |           |
|-------------------------|----------------------------------------------------------|-------------------------------------------------------------------|-----------------------------------|-----------------|---------------------------------------------------------------------------------------------------|-----------|
|                         |                                                          |                                                                   |                                   |                 | 5%(\$)                                                                                            | 10% (\$)  |
| Christopher B. Wood, MD | 195,000                                                  | 24.63%                                                            | \$8.17                            | 1/6/15(2)       | 664,950                                                                                           | 1,920,750 |
| David P. Luci, Esq.     | 160,000                                                  | 20.2%                                                             | \$8.17                            | 1/6/15(2)       | 545,600                                                                                           | 1,576,000 |
| Hugh S. Griffith        | 160,000                                                  | 20.2%                                                             | \$8.17                            | 1/6/15(2)       | 545,600                                                                                           | 1,576,000 |
| Andrew Saunders, MD     | 50,000                                                   | 6.3%                                                              | \$5.44                            | 3/16/15(3)      | 313,000                                                                                           | 647,500   |
| Kristen M. Dunker, Esq. | 36,250                                                   | 4.6%                                                              | \$8.17                            | 1/6/15(2)       | 123,613                                                                                           | 357,063   |

- (1) The dollar amounts under these columns are the result of calculations at rates set by the Securities and Exchange Commission and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying common stock. The potential realizable values are calculated using the closing price of \$7.28 per share of our common stock as quoted on the Nasdaq National Market on the last day of the fiscal year, or June 30, 2005, and assuming that the market price appreciates from this price at the indicated rate for the entire term of each option and that each option is exercised and sold on the last day of its term at the assumed appreciated price.
- (2) Options vest 25% on the grant date and 25% on each of the first, second and third anniversaries of the grant date.
- (3) Options vest 25% on June 30, 2005 and 25% on each of the first, second and third anniversaries of the grant date, March 16, 2005.
- During our fiscal year ended June 30, 2005, Mr. Luci exercised options to purchase 390,000 shares of our common stock and paid the Company the aggregate exercise price of \$286,650. There were no other options exercised in our fiscal year ended June 30, 2005 by the named executive officers.

**Option Exercises and Year-End Option Values**

The following table provides information regarding the exercise of stock options during the fiscal year ended June 30, 2005 and the number and value of unexercised options to purchase our common stock held as of June 30, 2005 by our named executive officers. As permitted by the rules of the Securities and Exchange Commission, we have calculated the value of the unexercised in-the-money options at fiscal year end on the basis of the closing price of \$7.28 per share of our common stock as quoted on the Nasdaq National Market on the last day of the fiscal year, or June 30, 2005, less the applicable exercise price multiplied by the number of shares which may be acquired on exercise. We have calculated the value realized of exercised options based on the difference between the per share option exercise price and the fair market value per share of our common stock on the date of exercise, multiplied by the number of shares for which the option was exercised.

**Aggregated Option/SAR Exercises in Last Fiscal Year and Fiscal Year End 2005 Option/SAR Values**

| Name                    | Shares<br>acquired on<br>exercise (#) | Value<br>Realized (\$) | Number of Securities underlying<br>unexercised options/SARs at Fiscal<br>Year End (#) |               | Value of Unexercised<br>In-the-Money Options/SARs at<br>Fiscal Year End(1) (\$) |               |
|-------------------------|---------------------------------------|------------------------|---------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------|---------------|
|                         |                                       |                        | Exercisable                                                                           | Unexercisable | Exercisable                                                                     | Unexercisable |
|                         |                                       |                        | Christopher B. Wood, MD                                                               | 0             | 0                                                                               | 1,882,083     |
| David P. Luci, Esq.     | 33,946                                | \$344,552              | 101,666.67                                                                            | 353,333.33    | \$199,183                                                                       | \$1,118,317   |
|                         | 246,054                               | \$2,010,261            |                                                                                       |               |                                                                                 |               |
|                         | 110,000                               | \$701,800              |                                                                                       |               |                                                                                 |               |
| Hugh S. Griffith        | 0                                     | 0                      | 298,333.33                                                                            | 336,666.67    | \$1,354,417                                                                     | \$1,121,333   |
| Andrew Saunders, MD     | 0                                     | 0                      | 12,500                                                                                | 37,500        | \$23,000                                                                        | \$69,000      |
| Kristen M. Dunker, Esq. | 0                                     | 0                      | 94,062.5                                                                              | 82,187.5      | 0                                                                               | 0             |

**Ten Year Option/SAR Repricings**

| Name                                                                                        | Date    | Number of<br>Securities<br>underlying<br>options/SARs<br>repriced or<br>amended (#) | Market Price of<br>Stock at time of<br>Repricing or<br>Amendment (\$) | Exercise Price<br>at time of<br>Repricing or<br>Amendment (\$) | New<br>Exercise<br>Price (\$) | Length of Original<br>Option Term remaining<br>at date of repricing or<br>amendment |
|---------------------------------------------------------------------------------------------|---------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------|
| David P. Luci, Esq., Chief<br>Financial Officer, General<br>Counsel, Corporate<br>Secretary | 3/31/03 | 380,000                                                                             | \$0.735                                                               | \$1.95                                                         | \$0.735                       | 9.25 years                                                                          |

**Equity Compensation Plan Information**

The following table provides information about the securities authorized for issuance under the Company's equity compensation plans as of June 30, 2005:

| Plan category                                                 | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| (a)                                                           | (b)                                                                                         | (c)                                                                         |                                                                                                                                             |
| Equity compensation plans approved by security holders        | 3,006,500                                                                                   | \$3.10                                                                      | 1,493,500                                                                                                                                   |
| Equity compensation plans not approved by security holders(1) |                                                                                             |                                                                             |                                                                                                                                             |
| Total                                                         | 3,006,500                                                                                   | \$3.10                                                                      | 1,493,500                                                                                                                                   |

(1) We have no equity compensation plans not approved by security holders.

**Stock Option Plan**

Our Board of Directors has adopted, and our stockholders have approved our 2003 Stock Incentive Plan, as amended. The plan was adopted to recognize the contributions made by our employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve our ability to attract, retain and motivate individuals upon whom our growth and financial success depends.

The key provisions of the plan are as follows:

*Eligibility and Administration.*

The plan authorizes the Board of Directors or the compensation committee (the Administrator), to (i)select the participants who are to be granted options, restricted shares or performance units, (ii)determine the number of shares of Common Stock to be granted to each participant, (iii)designate options, to the extent the award consists of options, as incentive stock options or nonstatutory stock options, (iv)determine the vesting schedule and performance criteria, if any, for restricted shares and performance units and (v)determine to what extent the awards may be transferable. As of the date hereof, there are approximately 7 employees who are currently eligible to participate in the plan under the Company's policies. All directors and consultants are currently eligible to participate in the plan. The Administrator's interpretations and construction of the plan are final and binding on the Company.

*Shares Available for Issuance Under the Plan*

The stock subject to options granted under the plan are shares of the Company's authorized but unissued or reacquired shares of Common Stock. On August 1, 2005, the closing price of the common stock on the Nasdaq National Market of the Common Stock was \$7.65 per share. There are 4,500,000 shares reserved for grants of options under the plan. On the same date, there were 40,569,567 shares of Common Stock outstanding.

*Grant, Exercise and other Terms of Awards.*

Options issued under the plan are designated as either incentive stock options or nonstatutory stock options. Incentive stock options are options meeting the requirements of Section 422 of the Code, and nonstatutory options are options not intended to so qualify.

The exercise price of options granted under the plan may not be less than 100% of the fair market value of the Common Stock of the Company (as defined by the plan) on the date of the grant. With respect to any participant who owns stock representing more than 10% of the voting rights of the outstanding Common Stock of the Company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value of the Common Stock on the grant date, and the maximum term of any such incentive stock option must not exceed five years.

Options, restricted shares and performance units are evidenced by written award agreements in a form approved by the Administrator from time to time and no award is effective until the applicable award agreement has been executed by both parties thereto. Options granted under the plan may become exercisable in cumulative increments over a period of months or years, or otherwise, as determined by the Administrator. The purchase price of options shall be paid in cash; provided, however, that if the applicable award agreement so provides, or the Administrator, in its sole discretion otherwise approves thereof, the purchase price may be paid in shares of Common Stock having a fair market value on the exercise date equal to the exercise price or in any combination of cash and shares of Common Stock, as long as the sum of the cash so paid and the fair market value of the shares so surrendered equals the aggregate purchase price. In addition, the Administrator may permit deferred compensation elections by certain directors and executive officers. The award agreement evidencing the restricted shares and/or performance units shall set forth the terms upon which the Common Stock subject to any awards or the achievement of any cash bonus may be earned.

No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Administrator) from the date of the grant, and no incentive stock options granted under the Amended Award Plan to a participant who owns more than ten percent of the total combined voting power of all classes of outstanding stock of the Company shall be exercisable after the expiration of five years (or less, in the discretion of the Administrator) from the date of the grant. The aggregate fair market value (as of the respective date or dates of grant) of the shares of Common Stock underlying the incentive stock options that are exercisable for the first time by a participant during any calendar year under the plan and all other similar plans maintained by the Company may not exceed \$100,000. If a participant ceases to be an employee of the Company for any reason other than his or her death, Disability or Retirement (as such terms are defined in the plan), such participant shall have the right, subject to certain restrictions, to exercise that option at any time within ninety days (or less, in the discretion of the Administrator) after cessation of employment, but, except as otherwise provided in the applicable award agreement, only to the extent that, at the date of cessation of employment, the participant's right to exercise such option had vested and had not been previously exercised. The Administrator, in its sole discretion, may provide that the option shall cease to be exercisable on the date of such cessation if such cessation arises by reason of termination for Cause (as such term is defined in the Amended Award Plan) or if the participant becomes an employee, director or consultant of an entity that the Administrator determines is in direct competition with the Company.

In the event a participant dies before such participant has fully exercised his or her option, then the option may be exercised at any time within twelve months after the participant's death by the executor or administrator of his or her estate or by any person who has acquired the option directly from the participant by bequest or inheritance, but except as otherwise provided on the applicable award agreement, only to the extent that, at the date of death, the participant's right to exercise such option had vested pursuant to the terms of the applicable award agreement and had not been forfeited or previously exercised.

In the event a participant ceases to be an employee of the Company by reason of Disability, such participant shall have the right, subject to certain restrictions, to exercise the option at any time within twelve months (or such shorter period as the Administrator may determine) after such cessation of employment, but only to the extent that, at the date of cessation of employment, the participant's right to exercise such option had previously vested pursuant to the terms of the applicable award agreement and had not previously been exercised.

In the event a participant ceases to be an employee of the Company by reason of Retirement, such participant shall have the right, subject to certain restrictions, to exercise the option at any time within ninety days (or such longer or shorter period as the Administrator may determine) after cessation of employment, but only to the extent that, at the date of cessation of employment, the participant's right to exercise such option had vested pursuant to the terms of the applicable award agreement and had not previously been exercised.

*Adjustment of Awards Upon Certain Events.*

If the Company merges with another corporation and the Company is the surviving corporation in such merger and under the terms of such merger the shares of Common Stock outstanding immediately prior to the merger remain outstanding and unchanged, each outstanding award shall continue to apply to the shares subject thereto and will also pertain and apply to any additional securities and other property, if any, to which a holder of the number of shares subject to the option would have been entitled as a result of the merger.

In the event all or substantially all of the assets of the Company are sold, the Company engages in a merger where the Company does not survive or the Company is consolidated with another corporation, each participant shall receive immediately before the effective date of such sale, merger or consolidation restricted shares and the value of any performance units to which the participant is then entitled (regardless of any vesting condition) and each outstanding option will become exercisable (without regard to the vesting provisions thereof) for a period of at least 30 days ending five days prior to the effective date of the transaction. Notwithstanding the foregoing, the surviving corporation may, in its sole discretion, (i) (a) grant to participants with options, options to purchase shares of the surviving corporation upon substantially the same terms as the options granted under the plan, (b) tender to all participants with restricted shares, an award of restricted shares of the surviving or acquiring corporation, and (c) tender to all participants with performance units, an award of performance units of the surviving or acquiring corporation, or (ii) (a) permit participants with restricted shares to receive unrestricted shares immediately prior to the effective date of any transaction, (b) permit participants with performance units to receive cash with respect to the value of any performance units immediately before the effective date of the transaction and (c) provide participants with options the choice of exercising the option prior to the consummation of the transaction or receiving a replacement option.

Notwithstanding anything to the contrary and except as otherwise expressly provided in the applicable award agreement, the vesting or similar installment provisions relating to the exercisability of any award, option or replacement option tendered as described in the previous sentence shall be accelerated, and the participant with restricted shares or performance units shall become fully vested, and the participant with options shall have the right, for a period of at least 30 days, to exercise such options; provided that such accelerations of vesting and exercisability shall occur only in the event that the participant's employment with or services for the Company should terminate within two years following a Change of Control (as defined in the plan), unless such employment or services are terminated by the Company for Cause (as defined in the plan) or by the participant voluntarily without Good Reason (as defined in the plan), or such employment or services are terminated due to the death or Disability of the participant. Notwithstanding the foregoing, no incentive stock option shall become exercisable pursuant to the foregoing without the participant's consent, if the result would be to cause such option not to be treated as an incentive stock option.

The number of shares of Common Stock covered by the plan, the number of shares of Common Stock covered by each outstanding option, restricted share and performance unit and the exercise price of any options shall be proportionately adjusted for any increase or decrease in the number of issued shares of Common Stock resulting from a subdivision or consolidation of such shares or a stock split or the payment of a stock dividend (but only of Common Stock) or any other increase or decrease in the number of issued shares effected without receipt of consideration by the Company.

*Transfer of Awards.*

Unless an award is designated transferable by the Administrator upon grant, during the lifetime of the participant who has been granted an award, the award shall be shall not be assignable or transferable. No incentive stock option may be designated as transferable. In the event of the participant's death, any nontransferable award shall be transferable by the participant's will or the laws of descent and distribution.





*Amendment and Termination.*

The plan will continue in effect until terminated by the Board of Directors or until expiration of the plan on November 17, 2013. The Board may suspend or discontinue the plan or revise or amend it.

**COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION**

During the fiscal year ended June 30, 2005, the compensation committee of the board of directors was comprised of Mr. Elms and Drs. Schiff and Kauffman; with Dr. Kauffman serving as chairman of the Compensation Committee. None of the committee's members was employed by us as an officer or employee during the fiscal year ended June 30, 2005. No committee member had any interlocking relationships requiring disclosure under applicable rules and regulations.

For a description of certain relationships and transactions with members of the board of directors or their affiliates, see *Certain Relationships and Related Transactions* beginning on page 71.

**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information regarding the beneficial ownership of common stock, as of August 1, 2005 by (i) each person whom we know to beneficially own 5% or more of the common stock, (ii) each of our directors, (iii) each person listed on the Summary Compensation Table set forth under Executive Compensation and (iv) all of our directors and executive officers. The number of shares of common stock beneficially owned by each stockholder is determined in accordance with the rules of the Commission and does not necessarily indicate beneficial ownership for any other purpose. Under these rules, beneficial ownership includes those shares of common stock over which the stockholder exercises sole or shared voting or investment power. The percentage ownership of the common stock, however, is based on the assumption, expressly required by the rules of the Commission, that only the person or entity whose ownership is being reported has converted or exercised common stock equivalents into shares of common stock; that is, shares underlying common stock equivalents are not included in calculations in the table below for any other purpose, including for the purpose of calculating the number of shares outstanding generally. Except as otherwise noted below, the address for each person listed on the table is c/o Bioenvision, Inc., 345 Park Avenue, 41st Floor, New York, New York 10154.

| NAME                                                                                                          | BENEFICIAL OWNERSHIP<br>OF STOCK | CURRENT PERCENTAGE OF<br>CLASS (1) |
|---------------------------------------------------------------------------------------------------------------|----------------------------------|------------------------------------|
| Perseus-Soros Biopharmaceutical<br>Fund, LP (2)<br>888 Seventh Avenue, 30th Floor<br>New York, New York 10106 | 7,950,053                        | 16.51%                             |
| SCO Capital Partners LLC (3)<br>1285 Avenue of the Americas, 35th Floor<br>New York, New York 10019           | 7,670,236                        | 17.90%                             |
| Cumberland Associates LLC(4)<br>1114 Avenue of the Americas<br>New York, NY 10036                             | 2,163,406                        | 5.3%                               |
| Christopher B. Wood, M.D. (5)                                                                                 | 4,136,987                        | 9.74%                              |
| David P. Luci (6)                                                                                             | 470,720                          | *                                  |
| Hugh Griffith (7)                                                                                             | 298,333                          | *                                  |
| Thomas Scott Nelson                                                                                           | 341,787                          | *                                  |
| Andrew Saunders(8)                                                                                            | 12,500                           | *                                  |
| Kristen Dunker(9)                                                                                             | 94,063                           | *                                  |
| Steven A. Elms<br>888 Seventh Avenue, 29th Floor<br>New York, New York 10106                                  | 0                                | *                                  |

Edgar Filing: BIOENVISION INC - Form POS AM

| NAME                                                                                 | BENEFICIAL OWNERSHIP OF STOCK | CURRENT PERCENTAGE OF CLASS (1) |
|--------------------------------------------------------------------------------------|-------------------------------|---------------------------------|
| Andrew N. Schiff, M.D.<br>888 Seventh Avenue, 29th Floor<br>New York, New York 10106 | 0                             | *                               |
| Michael Kauffman M.D., Ph.D(10).                                                     | 14,375                        | *                               |
| All Executive Officers and Directors as a group (11)                                 | 5,358,765                     | 12.47%                          |

\* Represents holdings of less than one percent (1%).

(1) Based on a total of 40,569,567 shares of common stock outstanding as of August 1, 2005.

(2) Includes 2,250,000 shares of Series A Preferred Stock currently convertible into 4,500,000 shares of common stock and a warrant to purchase 3,000,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Also includes 375,044 common shares and a warrant to purchase 75,009 shares of common stock exercisable at \$7.50 for five years from May 13, 2004. Perseus-Soros Partners, LLC is the general partner of the Perseus-Soros BioPharmaceutical Fund, LP. Perseus BioTech Fund Partners, LLC and SFM Participation, L.P. are the managing members of Perseus-Soros Partners, LLC. Perseuspur, LLC is the managing member of Perseus BioTech Fund Partners, LLC. Frank Pearl is the sole member of Perseuspur, LLC and in such capacity may be deemed a beneficial owner of securities held for the account of the Perseus-Soros BioPharmaceutical Fund, LP. SFM AH, LLC is the general partner of SFM Participation, L.P. The sole managing member of SFM AH, LLC is Soros Fund Management LLC. George Soros is the Chairman of Soros Fund Management LLC and in such capacity may be deemed a beneficial owner of securities held for the account of the Perseus-Soros BioPharmaceutical Fund, LP.

(3) Includes a warrant to purchase 1,200,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 issued to SCO Capital, LLC; a warrant to purchase 688,333 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 issued to SCO Capital, LLC; a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 issued to SCO Securities, LLC; a warrant to purchase 150,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 held by the Sophie C. Rouhandeh Trust; and a warrant to purchase 150,000 shares of common stock at \$1.25 per share for five years from November 16, 2001 held by the Chloe H. Rouhandeh Trust. Steven H. Rouhandeh, in his capacity as President of SCO Capital Partners, LLC and trustee of the trusts, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof. Excludes a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 which were originally held by SCO Financial Group, LLC, but transferred to (i) Daniel DiPietro (50,000), (ii) Jeremy Kaplan (10,000), and (iii) Joshua Golumb (10,000). SCO Financial Group, LLC served as a financial advisor to us through May 2004 and SCO Capital Partners, LLC extended a \$1 million secured credit facility to us in November 2001. SCO Securities, LLC, a related entity, served as placement agent to us in connection with our May 2002 and March and May 2004 financings. As placement agent in connection with the March and May 2004 financing, SCO Securities, LLC received a warrant to purchase 204,452 shares of common stock exercisable at \$6.25 per share for five years from March 22, 2004 and a warrant to purchase 55,838 shares of common stock exercisable at \$6.25 per share for five years from May 13, 2004.

(4) Based upon its Schedule 13G filed on July 14, 2005, Cumberland Associates owns 2,163,406 shares of common stock.

- (5) Dr. Wood is our chairman and Chief Executive Officer. Excludes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest. Includes options to acquire 1,500,000 shares of common stock which are exercisable at \$1.25 per share, options to acquire 333,333 shares of common stock which are exercisable at \$1.45 per share and options to acquire and options to acquire 48,750 shares of our common stock which are exercisable at \$8.17 per share.

(6)

Includes options to acquire 61,666 shares of common stock which are exercisable at \$4.05 per share and 40,000 options which are exercisable at \$8.17 per share.

(7)

Includes options to acquire 200,000 shares of the common stock which are exercisable at \$1.45 per share, options to acquire 58,333 shares of common stock at \$4.05 per share and options to acquire 40,000 shares of common stock at \$8.17 per share.

- (8) Includes options to acquire 12,500 shares of common stock at \$5.44 per share.  
(9) Includes options to acquire 85,000 shares of common stock at \$8.25 per share and 9,063 shares of common stock at \$8.17 per share.  
(10) Includes options to acquire 12,500 shares of common stock at \$4.55 and options to acquire 1,875 shares of common stock at \$8.17 per share.  
(11) Includes options to acquire 2,403,020 shares of common stock.

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

In May 2002, we completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock. In March and May of 2004, we completed a private placement pursuant to which we issued an aggregate of 2,602,898 shares of our common stock and warrants to purchase an aggregate of 780,870 shares of common stock. An affiliate of SCO Capital Partners LLC, one of our stockholders, served as our financial advisor in connection with these financings and earned a placement fee of approximately \$1,200,000 in connection with the May 2002 private placement and warrants to purchase 260,291 shares of common stock for \$6.25 per share for the March and May 2004 financings.

## PLAN OF DISTRIBUTION

The shares covered by this prospectus may be offered and sold from time to time by the selling stockholders. The term selling stockholders includes pledgees, donees, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholders as a pledge, gift, partnership distribution or other non-sale related transfer. The number of shares beneficially owned by each selling stockholder will decrease as and when it effects any such transfers. The plan of distribution for the selling stockholders' shares sold hereunder will otherwise remain unchanged, except that the transferees, pledgees, donees or other successors will be selling stockholders hereunder. To the extent required, we may amend and/or supplement this prospectus from time to time to describe a specific plan of distribution.

The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The selling stockholders may offer their shares from time to time pursuant to one or more of the following methods:

- on Nasdaq or on any other market on which our common stock may from time to time be trading;
- one or more block trades in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker or dealer as principal and resale by the broker or dealer for its account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- in public or privately-negotiated transactions;
- through the writing of options on the shares;
- through underwriters, brokers or dealers (who may act as agents or principals) or directly to one or more purchasers;
- an exchange distribution in accordance with the rules of an exchange;
- through agents; or
- through market sales, both long or short, to the extent permitted under the federal securities laws; or in any combination of these methods.

The sale price to the public may be:

- the market price prevailing at the time of sale;
- a price related to the prevailing market price;
- at negotiated prices; or
- any other prices as the selling stockholder may determine from time to time.

In connection with distributions of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume;

sell the shares short and redeliver the shares to close out such short positions;

enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to them of shares offered by this prospectus, which they may in turn resell; and

pledge shares to a broker-dealer or other financial institution, which, upon a default, they may in turn resell.

In addition to the foregoing methods, the selling stockholders may offer their shares from time to time in transactions involving principals or brokers not otherwise contemplated above, in a combination of such methods as described above or any other lawful methods.

Sales through brokers may be made by any method of trading authorized by any stock exchange or market on which the shares may be listed or quoted, including block trading in negotiated transactions. Without limiting the foregoing, such brokers may act as dealers by purchasing any or all of the shares covered by this prospectus, either as agents for others or as principals for their own accounts, and reselling such shares pursuant to this prospectus. A selling stockholder may effect such transactions directly, or indirectly through underwriters, broker-dealers or agents acting on their behalf. In effecting sales, brokers and dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate.

Upon our being notified by the selling stockholders that any material arrangement has been entered into with a broker-dealer for the sale of shares offered hereby through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing:

the names of the selling stockholder(s) and of the participating broker-dealer(s), identifying them as underwriters, as required;

the number of shares involved;

the price at which such shares were sold;

the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable; and

other facts material to the transaction.

The shares may also be sold pursuant to Rule 144 under the securities act, which permits limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the availability of certain current public information concerning the issuer, the resale occurring following the required holding period under 144 and the number of shares during any three-month period not exceeding certain limitations. The selling stockholders have the sole and absolute discretion not to accept any purchase offer or make any sale of their shares if they deem the purchase price to be unsatisfactory at any particular time.

The selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom these broker-dealers may act as agents or to whom they sell as principal or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares will do so for their own account and at their own risk. It is possible that the selling stockholders will attempt to sell shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then market price. The selling stockholders cannot assure that all or any of the shares offered by this prospectus will be issued to, or sold by, the selling stockholders if they do not exercise or convert the common stock

equivalents that they own. The selling stockholders and any brokers, dealers or agents, upon effecting the sale of any of the shares offered by this prospectus, may be deemed underwriters as that term is defined under the securities act or the exchange act, or the rules and regulations under those acts. In that event, any commissions received by the broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the securities act.

The selling stockholders, alternatively, may sell all or any part of the shares offered by this prospectus through an underwriter. To our knowledge, none of the selling stockholders have entered into any agreement with a prospective underwriter and there can be no assurance that any such agreement will be entered into. If the selling stockholders enter into such an agreement or agreements, then we will set forth in a post-effective amendment to this prospectus the following information:

- the number of shares being offered;
- the terms of the offering, including the name of any selling stockholder, underwriter, broker, dealer or agent;
- the purchase price paid by any underwriter;
- any discount, commission and other underwriter compensation;
- any discount, commission or concession allowed or reallocated or paid to any dealer;
- the proposed selling price to the public; and
- other facts material to the transaction.

We will also file such agreement or agreements. In addition, if we are notified by the selling stockholders that a donee, pledgee, transferee or other successor-in-interest intends to sell more than 500 shares, a supplement to this prospectus will be filed.

The selling stockholders and any other persons participating in the sale or distribution of the shares will be subject to applicable provisions of the exchange act and the rules and regulations under the exchange act, including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of purchases and sales of any of the shares by, the selling stockholders or any other such person. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to the same securities for a specified period of time prior to the commencement of the distribution, subject to specified exceptions or exemptions. All of these limitations may affect the marketability of the shares.

We have agreed to pay all costs and expenses incurred in connection with the registration of the shares offered by this prospectus, except that the selling stockholder will be responsible for all selling commissions, transfer taxes and related charges in connection with the offer and sale of the shares and the fees of the selling stockholder's counsel.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus forms a part continuously effective until the earlier of the date that the shares covered by this prospectus may be sold pursuant to Rule 144(k) of the securities act and the date that all of the shares registered for sale under this prospectus have been sold.

We have agreed to indemnify the selling stockholders, or their respective transferees or assignees, against certain liabilities, including liabilities under the securities act, or to contribute to payments that the selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may be required to make in respect of those liabilities.



## MATERIAL UNITED STATES FEDERAL TAX CONSEQUENCES

### FOR NON-UNITED STATES STOCKHOLDERS

The following is a summary of the material U.S. federal income tax considerations with respect to the ownership and disposition of our common stock by a non-U.S. holder (as defined below) as of the date hereof. This summary deals only with non-U.S. holders that hold our common stock as a capital asset.

For purposes of this summary, a non-U.S. holder means a beneficial owner of our common stock that is not treated as a partnership for U.S. federal income tax purposes and is not any of the following for U.S. federal income tax purposes: (i) a citizen or resident of the U.S., (ii) a corporation, including any entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the U.S., any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (iv) a trust if (1) its administration is subject to the primary supervision of a court within the U.S. and one or more U.S. persons have the authority to control all of its substantial decisions, or (2) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This summary is based upon provisions of the Internal Revenue Code of 1986, as amended, and regulations, rulings and judicial decisions as of the date hereof. Those authorities may be changed, perhaps retroactively, or be subject to differing interpretations, so as to result in U.S. federal tax considerations different from those summarized below. This summary does not represent a detailed description of the U.S. federal tax considerations to you in light of your particular circumstances. In addition, it does not represent a description of the U.S. federal tax considerations to you if you are subject to special treatment under the U.S. federal tax laws (including if you are a U.S. expatriate, controlled foreign corporation or passive foreign investment company), and it generally does not address any U.S. taxes other than the federal income tax. We cannot assure you that a change in law will not alter significantly the tax considerations that we describe in this summary.

If an entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partnership holding our common stock, or a partner in such a partnership, you should consult your tax advisors.

**If you are considering the purchase of our common stock, you should consult your own tax advisors concerning the particular U.S. federal tax consequences to you of the ownership and disposition of the common stock, as well as the consequences to you arising under the laws of any other taxing jurisdiction, including any state, local or foreign tax consequences.**

### Dividends

We have never declared or paid any cash dividends on our common stock and do not currently anticipate paying any cash dividends on our common stock. If we were to pay dividends in the future on our common stock, they would be subject to U.S. federal income tax in the manner described below.

Dividends paid to a non-U.S. holder of our common stock generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. However, dividends that are effectively connected with the conduct of a trade or business by a non-U.S. holder within the U.S. and, where an income tax treaty applies, are attributable to a U.S. permanent establishment of the non-U.S. holder, are not subject to this withholding tax, but instead are subject to U.S. federal income tax on a net income basis at applicable individual or corporate rates. Certain certification and disclosure requirements must be complied with in order for effectively connected dividends to be exempt from this withholding tax. Any such effectively connected dividends received by a foreign corporation may be subject to an additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

A non-U.S. holder of our common stock who is entitled to and wishes to claim the benefits of an applicable treaty rate (and avoid backup withholding as discussed below) for dividends, will be required to (i) complete Internal Revenue Service, or IRS, Form W-8BEN (or successor form) and make certain certifications, under penalty of perjury, to establish its status as a non-U.S. person and its entitlement to treaty benefits (which may also require,



in certain circumstances, the provision of a U.S. taxpayer identification number) or (ii) if the common stock is held through certain foreign intermediaries, satisfy the relevant certification requirements of applicable U.S. Treasury regulations. Special certification and other requirements apply to certain non-U.S. holders that are entities rather than individuals.

A non-U.S. holder of our common stock eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

#### **Gain on disposition of common stock**

A non-U.S. holder generally will not be subject to U.S. federal income tax with respect to gain recognized on a sale or other disposition of our common stock unless (i) the gain is effectively connected with a trade or business of the non-U.S. holder in the U.S. and, where a tax treaty applies, is attributable to a U.S. permanent establishment of the non-U.S. holder (in which case, for a non-U.S. holder that is a foreign corporation, the branch profits tax described above may also apply), (ii) in the case of a non-U.S. holder who is an individual, such holder is present in the U.S. for 183 or more days in the taxable year of the sale or other disposition and certain other conditions are met, or (iii) we are or have been a U.S. real property holding corporation for U.S. federal income tax purposes.

We believe we have not been and currently are not, and we do not anticipate becoming, a U.S. real property holding corporation for U.S. federal income tax purposes.

#### **Federal estate tax**

Common stock held by an individual non-U.S. holder at the time of death will be included in such holder's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

#### **Information reporting and backup withholding**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to such holder and the tax withheld (if any) with respect to such dividends, regardless of whether withholding was required. Copies of the information returns reporting such dividends and any withholding may also be made available to the tax authorities in the country in which the non-U.S. holder resides under the provisions of an applicable income tax treaty. In addition, dividends paid to a non-U.S. holder generally will be subject to backup withholding unless applicable certification requirements are met.

Payment of the proceeds of a sale of our common stock within the U.S. or conducted through certain U.S.-related financial intermediaries is subject to information reporting and, depending on the circumstances, backup withholding unless the beneficial owner certifies under penalties of perjury that it is not a U.S. person (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or the holder otherwise establishes an exemption.

Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against such holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

**LEGAL MATTERS**

Certain legal matters have been passed upon for us by Paul, Hastings, Janofsky & Walker LLP, New York, New York.

**EXPERTS**

We changed independent registered public accounting firms in April 2005, from Grant Thornton LLP to Deloitte & Touche LLP. Information regarding the change in independent accountants was reported in our Current Report on Form 8-K dated April 4, 2005. There were no disagreements or reportable events requiring disclosure under Item 304(b) of Regulation S-K.

Our consolidated financial statements at and for the years ended June 30, 2004 and 2003, included in this prospectus and registration statement, have been audited by Grant Thornton LLP, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein and are included in reliance upon the reports of such firm given on the authority of said firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. These filings are not deemed to be incorporated by reference into this prospectus or the registration statement of which it forms a part. You may read and copy any documents filed by us at the Public Reference Section of the SEC, 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our filings with the SEC are also available to the public through the SEC's website at <http://www.sec.gov>.

We have filed with the SEC a registration statement on Form S-1 under the Securities Act for the registration of the common stock offered by this prospectus. This prospectus, which is a part of the registration statement, does not contain all of the information included in the registration statement. Any statement made in this prospectus concerning the contents of any contract, agreement or other document is not necessarily complete. For further information regarding our company and the common stock offered by this prospectus, please refer to the registration statement, including the exhibits and schedules thereto. If we have filed any contract, agreement or other document as an exhibit to the registration statement, you should read the exhibit for a more complete understanding of the documents of matter involved.

**BIOENVISION, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**Unaudited Interim Consolidated Financial Statements:**

|                                                                                                                               |     |
|-------------------------------------------------------------------------------------------------------------------------------|-----|
| Consolidated Balance Sheets (Unaudited) as of March 31, 2005 and June 30, 2004 as restated                                    | F-2 |
| Consolidated Statements of Operations (Unaudited) for the period ended March 31, 2005 and June 30, 2004 as restated           | F-3 |
| Consolidated Statements of Stockholders' Equity (Unaudited) for the period ended March 31, 2005 and June 30, 2004 as restated | F-4 |
| Consolidated Statements of Cash Flows (Unaudited) for the period ended March 31, 2005 and June 30, 2004 as restated           | F-5 |
| Notes to Consolidated Financial Statements (Unaudited) as restated                                                            | F-6 |

**Audited Consolidated Financial Statements:**

|                                                                                                              |      |
|--------------------------------------------------------------------------------------------------------------|------|
| Report of Independent Registered Public Accounting Firm                                                      | F-16 |
| Consolidated Balance Sheets as of June 30, 2004 and 2003 as restated                                         | F-17 |
| Consolidated Statements of Operations for Years ended June 30, 2004 and 2003 as restated                     | F-18 |
| Consolidated Statements of Stockholders' Equity (Deficit) for Years ended June 30, 2004 and 2003 as restated | F-19 |
| Consolidated Statements of Cash Flows for years ended June 30, 2003 and 2002 as restated                     | F-20 |
| Notes to Consolidated Financial Statements as restated                                                       | F-21 |

Bioenvision, Inc. and Subsidiaries

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**ASSETS**

Current assets

Cash and cash equivalents

Restricted cash

Deferred costs

Accounts receivable

Inventory

Other current assets

Total current assets

Property and equipment, net

Intangible assets, net

Goodwill

Security deposits

Deferred costs

Total assets

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities

Accounts payable

Accrued expenses

Accrued dividends payable

Deferred revenue

Total current liabilities

Deferred revenue

Total liabilities

Commitments and contingencies

Stockholders' equity

Preferred stock - \$0.001 par value; 20,000,000 shares authorized;

2,250,000 and 3,341,666 shares issued and outstanding at March 31, 2005 and June 30, 2004 (liquidation preference \$6,750,000 and \$10,024,998, respectively)

Common stock - par value \$0.001; 70,000,000 shares authorized;

40,448,948 and 28,316,163 shares issued and outstanding at March 31, 2005 and June 30, 2004, respectively

Additional paid-in capital

Deferred compensation

Accumulated deficit

Accumulated other comprehensive income

Stockholders' equity

Total liabilities and stockholders' equity

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

F-2

---

Bioenvision, Inc. and Subsidiaries

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)**

|                                                                                                                                                                                                                                                                                                            | Three months ended<br><u>March 31,</u><br><u>2005</u> |               | Nine months ended<br><u>March 31,</u><br><u>2005</u> |               |             |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|---------------|------------------------------------------------------|---------------|-------------|
|                                                                                                                                                                                                                                                                                                            | <u>2004</u>                                           | <u>2004</u>   | <u>2005</u>                                          | <u>2004</u>   | <u>2004</u> |
|                                                                                                                                                                                                                                                                                                            | (Restated                                             | Note I)       | (Restated                                            | Note I)       | Note I)     |
| Revenue                                                                                                                                                                                                                                                                                                    |                                                       |               |                                                      |               |             |
| Licensing and royalty revenue                                                                                                                                                                                                                                                                              | \$430,411                                             | \$76,452      | \$1,012,068                                          | \$212,988     |             |
| Product sales                                                                                                                                                                                                                                                                                              | 149,364                                               | -             | 364,495                                              | -             |             |
| Research and development contract revenue                                                                                                                                                                                                                                                                  | 819,194                                               | 770,042       | 2,283,657                                            | 1,545,042     |             |
| Total revenue                                                                                                                                                                                                                                                                                              | 1,398,969                                             | 846,494       | 3,660,220                                            | 1,758,030     |             |
| Costs and expenses                                                                                                                                                                                                                                                                                         |                                                       |               |                                                      |               |             |
| Cost of products sold                                                                                                                                                                                                                                                                                      | 99,061                                                | -             | 229,417                                              | -             |             |
| Research and development                                                                                                                                                                                                                                                                                   | 2,136,849                                             | 994,307       | 5,986,496                                            | 2,545,128     |             |
| Selling, general and administrative<br>(includes stock based compensation income (expense) of<br>\$713,116 and \$(2,526,943) for the three months ended<br>March 31, 2005 and 2004, respectively, and \$(687,290)<br>and \$(3,625,535) for the nine months ended March 31,<br>2005 and 2004, respectively) | 2,074,430                                             | 3,721,937     | 6,885,382                                            | 7,079,367     |             |
| Depreciation and amortization                                                                                                                                                                                                                                                                              | 346,504                                               | 343,456       | 1,028,197                                            | 1,023,325     |             |
| Total costs and expenses                                                                                                                                                                                                                                                                                   | 4,656,844                                             | 5,059,700     | 14,129,492                                           | 10,647,820    |             |
| Loss from operations                                                                                                                                                                                                                                                                                       | (3,257,875)                                           | (4,213,206)   | (10,469,272)                                         | (8,889,790)   |             |
| Interest income                                                                                                                                                                                                                                                                                            | 185,465                                               | 14,576        | 297,479                                              | 49,465        |             |
| Net loss before income tax benefit                                                                                                                                                                                                                                                                         | (3,072,410)                                           | (4,198,630)   | (10,171,793)                                         | (8,840,325)   |             |
| Income tax benefit                                                                                                                                                                                                                                                                                         | -                                                     | 506,087       | -                                                    | 1,065,575     |             |
| Net loss                                                                                                                                                                                                                                                                                                   | (3,072,410)                                           | (3,692,543)   | (10,171,793)                                         | (7,774,750)   |             |
| Cumulative preferred stock dividend                                                                                                                                                                                                                                                                        | (83,219)                                              | (175,704)     | (319,935)                                            | (587,971)     |             |
| Net loss available to common stockholders                                                                                                                                                                                                                                                                  | \$(3,155,629)                                         | \$(3,868,247) | \$(10,491,728)                                       | \$(8,362,721) |             |
| Basic and diluted net loss per share of common stock                                                                                                                                                                                                                                                       | \$(0.08)                                              | \$(0.19)      | \$(0.33)                                             | \$(0.46)      |             |
| Weighted average shares used in computing basic and<br>diluted net loss per share                                                                                                                                                                                                                          | 37,602,163                                            | 19,912,396    | 31,907,864                                           | 18,122,445    |             |

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



F-3

---

Bioenvision, Inc. and Subsidiaries

**CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**

(unaudited)

|                                                                          | Preferred Stock |         | Common Stock |          | Additional<br>Paid In | Deferred     | Accumulated<br>Other<br>Comprehensive | Income (Loss) |
|--------------------------------------------------------------------------|-----------------|---------|--------------|----------|-----------------------|--------------|---------------------------------------|---------------|
|                                                                          | Shares          | \$      | Shares       | \$       | Capital               | Compensation | Deficit                               |               |
| Balance at July 1, 2003 (Restated Note I)                                | 5,916,966       | \$5,917 | 17,122,739   | \$17,123 | \$47,304,449          | \$-          | \$(26,156,098)                        | \$152,346     |
| Net loss for the period<br>(Restated Note I)                             |                 |         |              |          |                       |              | (10,651,267)                          |               |
| Cumulative preferred stock dividend for the period                       |                 |         |              |          |                       |              | (856,776)                             |               |
| Currency translation adjustment                                          |                 |         |              |          |                       |              |                                       | (12,748)      |
| Deferred compensation                                                    |                 |         |              |          |                       | (223,990)    |                                       |               |
| Shares issued in connection with private placement                       |                 |         | 2,602,898    | 2,603    | 16,265,495            |              |                                       |               |
| Costs related to March private placement financing                       |                 |         |              |          | (1,301,035)           |              |                                       |               |
| Preferred stock converted to common stock                                | (2,575,300)     | (2,575) | 5,150,000    | 5,150    | (2,575)               |              |                                       |               |
| Expense related to repricing of options                                  |                 |         |              |          | 2,381,066             |              |                                       |               |
| Cashless exercise of options to shares                                   |                 |         | 2,122,682    | 2,122    | (2,122)               |              |                                       |               |
| Warrants issued in connection with services                              |                 |         |              |          | 671,601               |              |                                       |               |
| Shares issued to consultants for services                                |                 |         | 14,510       | 15       | 305,972               |              |                                       |               |
| Shares issued to employee                                                |                 |         | 20,000       | 20       | 28,380                |              |                                       |               |
| Options issued in connection with services                               |                 |         |              |          | 93,987                |              |                                       |               |
| Options issued to employees                                              |                 |         |              |          | 262,601               |              |                                       |               |
| Shares issued from warrant conversions                                   |                 |         | 1,283,334    | 1,283    | 2,509,883             |              |                                       |               |
| Balance at June 30, 2004<br>(Restated Note I)                            | 3,341,666       | \$3,342 | 28,316,163   | \$28,316 | \$68,517,702          | \$(223,990)  | \$(37,664,141)                        | \$139,598     |
| Net loss for the period                                                  |                 |         |              |          |                       |              | (10,171,793)                          |               |
| Cumulative preferred stock dividend for the period                       |                 |         |              |          |                       |              | (319,935)                             |               |
| Currency translation adjustment                                          |                 |         |              |          |                       |              |                                       | (22,166)      |
| Deferred compensation                                                    |                 |         |              |          |                       | 65,710       |                                       |               |
| Warrants issued in connection with services                              |                 |         |              |          | 509,686               |              |                                       |               |
| Options issued in connection with services                               |                 |         |              |          | 46,369                |              |                                       |               |
| Preferred stock converted to common stock                                | (1,091,666)     | (1,092) | 2,183,332    | 2,183    | (1,092)               |              |                                       |               |
| Shares issued in connection with public offering net of related expenses |                 |         | 7,500,000    | 7,500    | 55,642,500            |              |                                       |               |
| Shares issued from warrant conversion                                    |                 |         | 1,598,411    | 1,598    | 3,277,365             |              |                                       |               |
| Cash exercise of options to shares                                       |                 |         | 575,833      | 576      | 626,898               |              |                                       |               |
| Cashless exercise of options to shares (non-employees)                   |                 |         | 212,709      | 213      | (213)                 |              |                                       |               |
| Shares issued in connection with services                                |                 |         | 62,500       | 63       | 496,188               |              |                                       |               |
| Expenses (income) related to repricing of options                        |                 |         |              |          | (430,725)             |              |                                       |               |
| Balance at March 31, 2005                                                | 2,250,000       | \$2,250 | 40,448,948   | \$40,449 | \$128,684,678         | \$(158,280)  | \$(48,155,869)                        | \$117,432     |

The accompanying notes are an integral part of this financial statement.

F-4

---

Bioenvision, Inc. and Subsidiaries

**CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS****(unaudited)**

|                                                                              | Nine months ended<br><u>March 31,</u><br><u>2005</u> | <u>2004</u><br><b>Restated</b> <b>Note 1</b> |
|------------------------------------------------------------------------------|------------------------------------------------------|----------------------------------------------|
| Cash flows from operating activities                                         |                                                      |                                              |
| Net loss                                                                     | \$(10,171,793)                                       | \$(7,774,750)                                |
| Adjustments to reconcile net loss to net cash used in operating activities   |                                                      |                                              |
| Depreciation and amortization                                                | 1,028,197                                            | 1,023,325                                    |
| Deferred tax benefit                                                         | -                                                    | (1,065,575)                                  |
| Stock based compensation                                                     | 687,290                                              | 3,625,535                                    |
| Changes in net deferred revenue and expenses                                 | (221,863)                                            | 2,655,463                                    |
| Changes in assets and liabilities                                            |                                                      |                                              |
| <i>Accounts payable</i>                                                      | 1,496,396                                            | 721,607                                      |
| <i>Inventory</i>                                                             | (433,335)                                            | -                                            |
| Other current assets                                                         | (329,104)                                            | (81,628)                                     |
| Security deposits                                                            | (132,686)                                            | 96,868                                       |
| Accounts receivable                                                          | 423,111                                              | (2,615,263)                                  |
| Accrued expenses                                                             | 390,003                                              | (237,353)                                    |
| Net cash used in operating activities                                        | (7,263,784)                                          | (3,651,771)                                  |
| Cash flows from investing activities                                         |                                                      |                                              |
| Purchase of intangible assets                                                | (241,998)                                            | (30,772)                                     |
| Capital expenditures                                                         | (236,793)                                            | (3,116)                                      |
| Net cash used in investing activities                                        | (478,791)                                            | (33,888)                                     |
| Cash flows from financing activities                                         |                                                      |                                              |
| Proceeds from issuance of common stock, net of related expenses              | 55,650,000                                           | 12,157,240                                   |
| Proceeds from exercise of options, warrants and other convertible securities | 3,906,436                                            | 1,157,546                                    |
| Dividends paid                                                               | (354,597)                                            | -                                            |
| Net cash provided by financing activities                                    | 59,201,839                                           | 13,314,786                                   |
| Net increase in cash and cash equivalents                                    | 51,459,264                                           | 9,629,127                                    |
| Cash and cash equivalents, beginning of period                               | 18,875,675                                           | 7,929,686                                    |
| <b><i>Cash and cash equivalents, end of period</i></b>                       | <b>\$70,334,939</b>                                  | <b>\$17,558,813</b>                          |

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

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

March 31, 2005

(Unaudited)

**NOTE A - Description of Business and Significant Accounting Policies**

*Description of Business*

Bioenvision, Inc. is a product-focused biopharmaceutical company with two approved cancer therapeutics. On December 29, 2004, the FDA approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who have received two or more prior regimens. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, the Company's co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for certain cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is selling clofarabine under the brand name Clolar in the U.S. In Europe, the Company has filed for approval of clofarabine in pediatric ALL and pediatric acute myelogenous leukemia, or AML, with the European Medicines Evaluation Agency, or EMEA.

The Company is currently selling its second product, Modrenal®, in the United Kingdom. Modrenal® is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and the Company has initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

In addition to clofarabine and Modrenal®, the Company is developing Velostan, initially for the treatment of bladder cancer, and Virostat, initially for the treatment of Hepatitis C.

*Significant Accounting Policies*

In addition to the accounting policies reported in Note 1 to the consolidated financial statements Organization and significant accounting policies in the Company's annual report on Form 10-KSB for the year ended June 30, 2004, we deem the following recent accounting policies to be important in understanding our operating results and financial condition.

Revenue Recognition

In accordance with SEC Staff Accounting Bulletin No. 104, upfront nonrefundable fees associated with research and development collaboration agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the estimated research and development period using the straight-line method. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis using the straight-line method. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved. Continuation of certain contracts and grants are dependent upon the Company and/or its co-development partners achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project.

Upfront nonrefundable fees associated with licensing arrangements are recorded as deferred revenue and recognized over the licensing arrangement using the straight line method, which approximates the life of the patent.

The Company currently sells its products to wholesale distributors and directly to hospitals, clinics, and retail pharmacies. Revenue from product sales is recognized when the risk of loss is passed to the customer, the sales price is fixed and determinable, and collectibility is reasonably assured.

The Company follows the guidance of Emerging Issues Task Force ( EITF ) 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent in the presentation of revenues and direct costs of revenues. This guidance requires the Company to assess whether it acts as a principal in the transaction or as an agent acting on behalf of

F-6

---

others. The Company records revenue transactions gross in its statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

In May 2003, the EITF reached a consensus on EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations because the Company had already followed a revenue recognition model consistent with EITF 00-21.

#### Credit Risk

Our accounts receivable are primarily due from wholesale distributors and our co-development partners. Based on our evaluation of the collectibility of these accounts receivable, we believe the exposure to credit risk is minimal and, as such, we feel that no allowance for doubtful accounts is necessary at March 31, 2005 and June 30, 2004.

#### Inventory

Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. The Company periodically reviews inventories and items considered outdated or obsolete are reduced to their estimated net realizable value. Inventories consisted of \$125,211 of raw material, \$218,160 of work-in-progress, and \$89,964 of finished goods at March 31, 2005.

#### Accounting for Stock-Based Compensation

At March 31, 2005, the Company has stock based compensation plans which are described more fully in the Company's annual report on Form 10-KSB for the year ended June 30, 2004. As permitted by Statement of Financial Accounting Standards ( SFAS ) No. 123, Accounting for Stock Based Compensation, and amended by SFAS 148, the Company accounts for stock based compensation arrangements in accordance with provisions of Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees. Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. Under APB Opinion No. 25, no stock-based employee compensation cost is reflected in reported net loss, when options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant.

The following table summarizes the pro forma effect of stock-based compensation as if the fair value method of accounting for stock options had been applied in measuring compensation cost. No tax benefits were attributed to the stock-based employee compensation expense during the three and nine months ended March 31, 2005 and 2004 because there is no incremental tax effect related to the additional expense incurred.

Edgar Filing: BIOENVISION INC - Form POS AM

|                                                                                                                 | Three months ended<br><u>March 31,</u><br><u>2005</u> |                              | Nine months ended<br><u>March 31,</u><br><u>2005</u> |                              |
|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|------------------------------|------------------------------------------------------|------------------------------|
|                                                                                                                 |                                                       | <u>2004</u><br>(As restated) |                                                      | <u>2004</u><br>(As restated) |
| Net loss available to common stockholders, as reported                                                          | \$ (3,155,629)                                        | \$(3,868,247)                | \$ (10,491,728)                                      | \$ (8,362,721)               |
| Add: Stock-based employee compensation expense (income) included in reported net loss                           | (628,508)                                             | 1,962,337                    | (365,016)                                            | 2,616,245                    |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards | (1,268,146)                                           | (194,060)                    | (1,859,343)                                          | (407,438)                    |
| Pro forma net loss                                                                                              | \$ (5,052,283)                                        | \$ (2,099,970)               | \$ (12,716,087)                                      | \$ (6,153,914)               |
| Loss per share                                                                                                  |                                                       |                              |                                                      |                              |
| Basic and diluted as reported                                                                                   | \$ (0.08)                                             | \$ (0.19)                    | \$ (0.33)                                            | \$ (0.46)                    |
| Basic and diluted pro forma                                                                                     | \$ (0.13)                                             | \$ (0.11)                    | \$ (0.40)                                            | \$ (0.34)                    |

The weighted-average assumptions used for the three and nine months ended March 31, 2005 were: risk-free interest rate of 3.40% and 3.36%, respectively; expected dividend yield of 0.0%, expected life of 3.95 and 3.88 years, respectively; and expected volatility of 80% for both periods. The weighted-average assumptions used for the three and nine months ended March 31, 2004 were: risk-free interest rate of 2.19% and 2.21%, respectively; expected dividend yield of 0.0%, expected life of 3.5 years and expected volatility of 80% for both periods.

During 2005, the Company corrected an error on the pro-forma stock based compensation disclosures required under SFAS 123 determined under fair value based method in the table above. The Company failed to add back to net loss the stock based compensation recorded by the Company in connection with the repricing of an officer's options and deduct the fair value of the award calculated under SFAS 123. This has decreased such amounts previously reported in the proforma net loss for the three month and nine month periods ended March 31, 2004 by \$1,909,000 and \$2,475,000, respectively.

In December 2004, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 123R, Share Based Payment , requiring all share-based payments to employees, including grants of employee stock options, to be recognized as compensation expense in the consolidated financial statements based upon their fair values. As amended by the SEC on April 14, 2005, this standard is effective for the quarter beginning July 1, 2005 and includes two transition methods. Upon adoption, we will be required to use either the modified retrospective transition method or the modified prospective transition method. Under the modified retrospective transition method, the previously reported amounts are restated for all periods presented to reflect the SFAS 123 amounts in the income statement. Under the modified prospective transition method, awards that are granted, modified or settled after the date of adoption should be measured and accounted for in accordance with SFAS 123R. Unvested equity-classified awards that were granted prior to the effective date should continue to be accounted for in accordance with SFAS 123 except that amounts must be recognized in the income statement. We are currently evaluating the impact of this standard and its transitional alternatives.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 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, as amended by EITF No. 00-27. 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.

**Net Loss Per Share**

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options and warrants to purchase 11,572,415 and 13,145,020 shares of common stock have not been included in the calculation of net loss per share for the three



F-8

---

months and nine months ended March 31, 2005 and 2004, respectively, as their effect would have been anti-dilutive.

***Comprehensive Loss***

Total comprehensive loss for the three months ended March 31, 2005 and 2004 was \$ (3,186,208) and \$(3,868,247), respectively. Total comprehensive loss for the nine months ended March 31, 2005 and 2004 was \$(10,513,894) and \$(8,362,721).

***Recent Accounting Pronouncements***

In December 2004, the FASB issued SFAS 153 *Exchange of Non-monetary assets*. This statement was a result of a joint effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. One such difference was the exception from fair value measurement in APB Opinion No. 29, *Accounting for Non-Monetary Transactions*, for non-monetary exchanges of similar productive assets. SFAS 153 replaces this exception with a general exception from fair value measurement for exchanges of non-monetary assets that do not have commercial substance. A non-monetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. This statement is effective for non-monetary assets exchanges occurring in fiscal periods beginning after June 15, 2005.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*. SFAS 151 amends Accounting Research Bulletin ( ARB ) No. 43, Chapter 4. This statement clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). SFAS 151 is the result of a broader effort by the FASB and the IASB to improve financial reporting by eliminating certain narrow differences between their existing accounting standards. This statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on the results of operations or financial position of the company.

**NOTE B - Interim Financial Statements**

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments consisting of normal accrued adjustments necessary to present fairly the consolidated financial position of the Company as of March 31, 2005, the consolidated results of operations for the three months and nine months ended March 31, 2005 and 2004, the Condensed Consolidated Statements of Stockholders Equity for the nine months ended March 31, 2005, and cash flows for the nine months ended March 31, 2005 and 2004. Certain reclassifications of balances previously reported have been made to conform to the current presentation.

The condensed consolidated balance sheet at June 30, 2004 has been derived from the restated audited financial statements at that date (see Note I), 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-KSB filed by the Company for the year ended June 30, 2004.

The condensed consolidated results of operations for the three months and nine months ended March 31, 2005 and 2004 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

**NOTE C - License and Co-Development Agreements**

***Clofarabine***

The Company has a license from Southern Research Institute ( SRI ), Birmingham, Alabama, to develop and market purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia, lymphoma and certain solid tumor cancers. The lead compound of these purine-based nucleosides is known as clofarabine. 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 clofarabine for the treatment of leukemia and lymphoma and studying its potential role in treatment of solid tumors.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

To facilitate the development of clofarabine, in March 2001, the Company entered into a co-development agreement with ILEX Oncology, Inc. ( ILEX ), our sub-licensor until it was acquired by Genzyme Corporation ( Genzyme ) on December 21, 2004, for the development of clofarabine 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 clofarabine in cancer indications. 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 (excluding Japan and Southeast Asia) 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, Canada, Japan and Southeast Asia. Under the co-development agreement, Genzyme will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay Genzyme a royalty on 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, would pay 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 Southern Research Institute based on certain milestones. The Company also is obligated to pay certain royalties to Southern Research Institute with respect to clofarabine.

The Company received a nonrefundable upfront payment of \$1.35 million when it entered into the co-development agreement with Genzyme and received an additional \$3.5 million 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 FDA, the Company received an additional (i) \$2 million in April 2004 and (ii) \$2 million in September 2004. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. 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 the three months ended March 31, 2005 and 2004, the Company recognized revenues of approximately \$110,000, and \$22,000, respectively, in connection with the milestone payments received to date. For the nine months ended March 31, 2005 and 2004, the Company recognized revenues of approximately \$329,000, and \$51,000, respectively, in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Genzyme. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with research and development costs including approximately (i) \$55,000 and \$11,000 for the three months ended March 31, 2005 and 2004, respectively, and (ii) \$165,000 and \$26,000 for the nine months ended March 31, 2005 and 2004, respectively related to such charges.

#### ***Modrenal(R)***

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

The Company received a nonrefundable upfront payment of \$1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, currently through September 2022. The Company recognized revenues of approximately \$15,000 and \$29,000 in connection with the upfront payment from Dechra for the three months ended March 31, 2005 and 2004, respectively. The Company



recognized revenues of approximately \$72,000 and \$87,000 in connection with the upfront payment from Dechra for the nine months ended March 31, 2005 and 2004, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made 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 and \$6,000 for the three months ended March 31, 2005 and 2004, respectively. Research and Development costs related to this agreement include approximately \$14,000 and \$18,000 for the nine months ended March 31, 2005 and 2004, respectively.

#### ***Operational Developments***

The Company submitted a Marketing Authorization Application, or MAA, the European equivalent of a U.S. new drug application, or NDA, with the EMEA in July 2004 for European approval of clofarabine in relapsed or refractory pediatric acute leukemia.

In June 2003, the Company entered into a supply agreement with Ferro-Pfanstiehl Laboratories ( Ferro ) pursuant to which Ferro has agreed to manufacture and supply certain of the Company's requirements for clofarabine-active pharmaceutical ingredient ( API ). Subject to certain circumstances, this agreement will expire on the fifth anniversary date of the first regulatory approval of clofarabine drug product.

In June 2003, the Company entered into a development agreement with Ferro, as amended and restated on December 31, 2004, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply Clinical Trials Monitor and GMP supplier qualifications of the API. Subject to certain circumstances, this agreement expires upon the completion of the development program. The development agreement is milestone-based and payments are to be paid upon completion of each milestone. If Ferro has not completed the development agreement by December 2007, the development agreement will automatically terminate without further action by either party.

In May 2003, we entered into a sub-license agreement with Dechra, pursuant to which Dechra has been granted a sub-license for all of the Company's rights and entitlements to market and distribute Modrenal® in the United States and Canada solely in connection with animal health applications. Subject to certain circumstances, this agreement expires upon expiration of the last patent related to Modrenal® or the completion of the last royalty set forth in the agreement. Cumulatively, through March 31, 2005, we have recognized revenue and costs related to this agreement of approximately \$198,000 and \$40,000 respectively. The Company received an upfront non-refundable payment of \$1.25 million upon execution of this agreement and may receive up to an additional \$3.75 million upon the achievement by Dechra of certain milestones set forth in the agreement.

In May 2003, we entered into a master services agreement with Penn-Pharmaceutical Services Limited ( Penn ), pursuant to which Penn has agreed to label, package and distribute clofarabine on our behalf and at our request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three month prior written notice.

In April 2003, we entered into an exclusive license agreement with CLL-Pharma ( CLL ), pursuant to which CLL has agreed to perform certain development works and studies to create a new formulation of Modrenal®. CLL intends to use its proprietary MIDDs.-patented technology (Micellar Improved Drug Delivery Solution) to perform this service on behalf of the Company. This new formulation, once in hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell Modrenal® throughout Europe. Through March 31, 2005, the Company paid an advance of \$175,000 related to development services provided by CLL over an eighteen month period, which advance was initially recorded as a prepaid development cost by the Company.

**NOTE D- Intangible Assets**

|                          | <u>3/31/2005</u> | <u>6/30/2004</u> |
|--------------------------|------------------|------------------|
| Patents & Trademarks     | 17,999,099       | 17,757,101       |
| Accumulated Amortization | (4,199,196)      | (3,193,441)      |
|                          | 13,799,903       | 14,563,660       |

Amortization of patents and trademarks amounted to \$1,006,000 and \$1,009,000 for the nine months ended March 31, 2005 and 2004, respectively. Intangible assets are recorded at cost and amortized over periods generally ranging from 10-20 years. Amortization for each of the next five fiscal years is expected to amount to approximately \$1,343,000 annually.

**NOTE E - Equity Transactions**

In June 2002, the Company granted options to an officer of the Company to purchase 380,000 shares of common stock at an exercise price of \$1.95 per share, which equaled the fair value on the date of grant. Of this amount 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003, the Company entered into an Employment Agreement with such officer of the Company, pursuant to which, among other things, the exercise price for all of the 380,000 options were changed to \$0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of \$.735 per share which vested immediately. As a result of the repricing of all of the 380,000 options, the Company remeasured the intrinsic value of these options at the end of each reporting period based on changes in the stock price. For the three months ended March 31, 2005 and 2004 the Company recognized stock based employee compensation income (expense) of approximately \$650,000 and \$(1,944,000), respectively, as a result of the March 31, 2003 re-pricing. For the nine months ended March 31, 2005 and 2004 the Company recognized stock based employee compensation income (expense) of approximately \$431,000 and \$(2,598,000), respectively.

For the three months ended March 31, 2005 and 2004, the Company recorded compensation expense of approximately \$22,000 and \$18,000, respectively, as a result of options granted to certain employees. For the nine months ended March 31, 2005 and 2004, the Company recorded compensation expense of approximately \$66,000 and \$18,000, respectively, as a result of options granted to certain employees.

On January 20, 2004, the Company granted 25,000 options to a board member for serving as a member of the Board of Directors, at an exercise price of \$4.55 per share which vest ratably on the first and second anniversaries of the grant date. The Company recognized approximately \$12,000 and \$9,000 as a consulting expense for the three months ended March 31, 2005 and 2004 relating to said options. The Company recognized approximately \$35,000 and \$9,000 as a consulting expense for the nine months ended March 31, 2005 and 2004 relating to said options.

On January 6, 2005, the Company granted 7,500 options to a board member for serving as a member of the Board of Directors, at an exercise price of \$8.17 per share which 1,875 vest immediately on the grant date and the remaining 5,625 vest ratably on the first, second and third anniversaries of the grant date. The Company recognized approximately \$11,000 as a consulting expense for the three and nine months ended March 31, 2005.

On June 22, 2004, the Company entered into a consulting agreement pursuant to which the consultant will provide certain investor relations services on behalf of the Company. In connection therewith, the Company issued a warrant to said consultant pursuant to which he has the right to purchase 50,000 shares of the Company's common stock at a price of \$8.25 per share upon the completion of certain milestones, as set forth in such agreement. The Company recognized approximately \$243,000 as a consulting expense for the nine months ended March 31, 2005.

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 upon satisfaction of certain milestones included in the warrant. The Company recognized approximately \$44,000 as consulting income and approximately \$125,000 as consulting expense for the nine months ended March 31, 2005, relating to said warrants.





## Edgar Filing: BIOENVISION INC - Form POS AM

On August 9, 2004, the Company issued two warrants to a consultant pursuant to which said consultant has the right to purchase 45,000 shares of the Company's common stock at a price of \$6.10 per share. The Company recognized approximately \$57,000 as consulting expense for the three months ended March 31, 2005 and approximately \$142,000 as a consulting expense for the nine months ended March 31, 2005 relating to said warrants.

For the three and nine months ended March 31, 2005, the Company granted 651,000 and 774,000 options to certain employees at exercise prices ranging from \$5.44 to \$8.87 per share, respectively. No expense was recognized for the three and nine months ended March 31, 2005 in connection with said grants as each option was granted at fair market value.

On December 3, 2004, we issued 62,500 shares of common stock to a consultant for services rendered. In connection with such issuance we recognized approximately \$497,000 as compensation expense for the three and nine months ended March 31, 2005.

During the three months ended March 31, 2005, certain warrant holders of the Company exercised their warrants to acquire 20,442 shares of the Company's common stock. The Company received proceeds of approximately \$24,000 during the three months ended March 31, 2005 from the exercise of such warrants. During the nine months ended March 31, 2005, certain warrant holders of the Company exercised their warrants to acquire 1,598,411 shares of the Company's common stock. The Company received proceeds of approximately \$3,279,000 during the nine months ended March 31, 2005 from the exercise of such warrants.

During the three month period ended March 31, 2005, certain holders of options to purchase an aggregate of 437,715 shares of the Company's common stock were exercised. The Company received proceeds of approximately \$259,000 during the three months ended March 31, 2005 from the exercise of such options. During the nine month period ended March 31, 2005, certain holders of options to purchase an aggregate of 788,542 shares of the Company's common stock were exercised. The Company received proceeds of approximately \$627,000 during the nine months ended March 31, 2005 from the exercise of such options.

On February 8, 2005, we completed a secondary public offering in which we sold we sold 7,500,000 common shares at \$8.00 per share, with net proceeds to the Company of approximately \$55.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

### **NOTE F-Quarterly Tax Accounting Policy**

Income taxes have been provided for using the liability method in accordance with SFAS No. 109, Accounting for Income Taxes. The provision for income taxes reflects management's estimate of the effective tax rate expected to be applicable for the full fiscal year. This estimate is re-evaluated by management each quarter based on the Company's estimated tax expense for the year. The Company also pays capital stock tax to certain state and local jurisdictions. The Company evaluates the amount due on a quarterly basis.

### **NOTE G - Related Party Transactions**

In May 2002, we completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock and in March of 2004 we consummated a private placement pursuant to which we raised \$12.8 million with a second closing in May 2004 in which we raised an additional \$3.5 million. An affiliate of SCO Capital Partners LLC, one of our stockholders, served as financial advisor to the Company in connection with these financings and earned a placement fee of approximately \$1.2 million in connection with May 2002 private placement and a placement fee of \$1.1 million and warrants to purchase 260,290 shares of common stock for \$6.25 per share for the March and May 2004 financings.

### **NOTE H Litigation**

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the Tessman Defendants) in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state



court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously.

#### NOTE I Restatement

In May of 2005, the Company identified an error with respect to the accounting for income taxes in connection with the Pathagon acquisition completed on February 1, 2002. The Company had originally concluded that the realization of the deferred tax asset related to the net operating losses and other deductible temporary differences existing at the acquisition date, and generated after the acquisition date, did not meet the more likely than not criteria and, as a result, a valuation allowance was established on the deferred tax assets of the Company. The Company's restated accounting treatment determined that the deferred tax liability recorded in connection with the Pathagon acquisition creates taxable income as the taxable temporary differences reverse. Consequently, the ability to realize the deferred tax assets is more likely than not and a valuation allowance is not required against the deferred tax assets, to the extent the deferred tax liability offsets the deferred tax assets. This restated accounting treatment resulted in the recognition of our deferred tax assets to the extent of our deferred tax liabilities. The deferred tax asset, in excess of the deferred tax liability, is not more likely than not to be realized, and therefore, is fully valued.

The Company restated its previously reported financial statements and all interim periods as of and for the years ended June 30, 2004 and 2003, to record additional benefit relating to the recognition of deferred tax assets as indicated in the first paragraph of this note. In years ended June 30, 2004, June 30, 2003, and June 30, 2002, the Company previously recorded the reduction to the deferred tax liability and a corresponding tax benefit of \$537,000, \$537,000 and \$253,000, respectively. In the restated financial statements for years ended June 30, 2004 and June 30, 2003, the Company recorded deferred tax assets, with a corresponding additional deferred tax benefit of \$923,000 and \$1,580,000, respectively, offsetting the deferred tax liability resulting from the Pathagon acquisition. Additionally, as of the acquisition date on February 1, 2002, a deferred tax asset was recorded for \$2,363,000 with a corresponding reduction to goodwill. This represented the deferred tax assets that existed at the date of acquisition and for which the previously recorded valuation allowance was eliminated.

As a result of the above, the Company previously restated its consolidated financial statements as of June 30, 2004 in its Form 10-KSB/A. The following is a summary of the effects of the income tax accounting corrections on the Company's consolidated financial statements for the three and nine months ended March 31, 2004, and for the three months ended September 30, 2004 and December 31, 2004.

For the three and six months ended September 30, 2004 and December 31, 2004, the Company had recorded a deferred tax liability for \$5,647,000 and \$5,505,000, respectively. Due to the correction of an error, the Company has now reported no net deferred tax asset or deferred tax liability for the three, six and nine months ended September 30, 2004, December 31, 2004 and March 31, 2005.

|                                                      | Three months ended March 31, 2004 |             | Nine months ended March 31, 2004 |              |
|------------------------------------------------------|-----------------------------------|-------------|----------------------------------|--------------|
|                                                      | As Reported                       | As Restated | As Reported                      | As Restated  |
| Consolidated Statements of Operations:               |                                   |             |                                  |              |
| Income tax benefit                                   | \$ 134,351                        | \$ 506,087  | \$ 402,928                       | \$ 1,065,575 |
| Net loss                                             | (4,064,277)                       | (3,692,543) | (8,437,397)                      | (7,774,750)  |
| Net loss available to common stockholders            | (4,239,982)                       | (3,868,247) | (9,025,369)                      | (8,362,721)  |
| Basic and diluted net loss per share of common stock | \$ (0.21)                         | \$ (0.19)   | \$ (0.50)                        | \$ (0.46)    |

The restatement has no effect on total cash flows from operating, investing, or financing activities as shown in the Consolidated Statement of Cash Flows. However, the restatement did affect the individual components of net loss and deferred tax benefit within the net cash from operating activities.



Edgar Filing: BIOENVISION INC - Form POS AM

| 2005                                                                   | First Quarter | First Quarter | Second Quarter | Second Quarter |
|------------------------------------------------------------------------|---------------|---------------|----------------|----------------|
|                                                                        | (as reported) | (as restated) | (as reported)  | (as restated)  |
| Goodwill                                                               | 3,902,705     | 1,540,162     | 3,902,705      | 1,540,162      |
| Total assets                                                           | 41,337,877    | 38,975,334    | 41,564,030     | 39,201,487     |
| Deferred tax liability                                                 | 5,646,573     | -             | 5,505,486      | -              |
| Total liabilities                                                      | 16,471,168    | 10,824,595    | 16,209,427     | 10,703,941     |
| Accumulated deficit                                                    | (44,169,063)  | (40,885,033)  | (48,143,183)   | (45,000,239)   |
| Shareholder s equity                                                   | 24,866,709    | 28,150,739    | 25,354,603     | 28,497,546     |
| Revenue                                                                | 1,085,328     | 1,085,328     | 1,175,923      | 1,175,923      |
| Loss before income tax benefit                                         | (3,094,551)   | (3,094,551)   | (4,004,831)    | (4,004,831)    |
| Income tax benefit                                                     | 134,226       | -             | 141,087        | -              |
| Net loss                                                               | (2,960,325)   | (3,094,551)   | (3,863,744)    | (4,004,831)    |
| Net loss available to common shareholders                              | (3,086,666)   | (3,220,892)   | (3,974,119)    | (4,115,206)    |
| Net loss available to common shareholders per basic and dilutive share | \$(0.11)      | \$(0.11)      | \$(0.13)       | \$(0.14)       |

The quarterly net loss per common share amounts are rounded to the nearest cent. Annual net loss per common share may vary depending on the effect of such rounding.

Additionally, the Company restated the pro-forma stock based compensation disclosures required under SFAS 123 determined under fair value based method due to the correction of an error noted during February 2005. Refer to Note 1 for further discussion.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Stockholders of Bioenvision, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Bioenvision, Inc. and Subsidiaries (the "Company") as of June 30, 2004 and 2003 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Bioenvision, Inc. and Subsidiaries as of June 30, 2004 and 2003, and the consolidated results of their operations and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

As more fully described in Note 9, the June 30, 2004 and 2003 financial statements have been restated.

s/ Grant Thornton LLP

GRANT THORNTON LLP

New York, New York

September 16, 2004 (except for paragraphs 13 and 14 of Note 1, and Note 9, as to which the date is May 27, 2005)

F-16

---

Bioenvision, Inc. and Subsidiaries

**CONSOLIDATED BALANCE SHEETS**

ASSETS

Current assets

Cash and cash equivalents  
Restricted cash  
Deferred costs  
Accounts receivable  
Other assets  
Total current assets

Property and equipment, net

Deferred costs  
Intangible assets, net  
Goodwill  
Security deposits  
Other long term assets

Total assets

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable  
Accrued expenses  
Accrued dividends payable  
Deferred revenue  
Total current liabilities

Deferred revenue

Deferred tax liability  
Total liabilities

Stockholders' equity

Preferred stock - \$0.001 par value; 20,000,000 and 5,920,000 shares authorized and 3,341,666 and 5,916,666 shares issued and outstanding at June 30, 200

Common stock - \$0.001 par value; 70,000,000 and 50,000,000 shares authorized and 28,316,163 and 17,122,739 shares issued and outstanding at June 30,

Additional paid-in capital

Deferred compensation

Accumulated deficit

Accumulated other comprehensive income

Stockholders' equity

Total liabilities and stockholders' equity

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

F-17

---



Bioenvision, Inc. and Subsidiaries

**CONSOLIDATED STATEMENTS OF OPERATIONS**

|                                                                                                                                                                                        | Year ended<br><u>June 30,</u><br><b>2004</b><br><u>Restated- See Note 9</u> | 2003<br><u>Restated- See Note 9</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|-------------------------------------|
| License and royalty revenue                                                                                                                                                            | \$ 1,187,212                                                                | \$ 504,857                          |
| Research and development contract revenue                                                                                                                                              | <b>1,915,002</b>                                                            | -                                   |
| Total revenue                                                                                                                                                                          | <b>3,102,214</b>                                                            | 504,857                             |
| Costs and expenses                                                                                                                                                                     |                                                                             |                                     |
| Research and development                                                                                                                                                               | <b>4,882,574</b>                                                            | 1,689,278                           |
| Selling, general and administrative<br>(includes stock based compensation expense of \$3,491,252<br>and \$1,812,894 for the twelve months ended June 30, 2004 and 2003, respectively.) | <b>9,082,420</b>                                                            | 4,567,413                           |
| Depreciation and amortization                                                                                                                                                          | <b>1,348,064</b>                                                            | 1,344,969                           |
| Total costs and expenses                                                                                                                                                               | <b>15,313,058</b>                                                           | 7,601,660                           |
| Loss from operations                                                                                                                                                                   | <b>(12,210,844)</b>                                                         | (7,096,803)                         |
| Interest income (expense)                                                                                                                                                              |                                                                             |                                     |
| Interest and finance charges                                                                                                                                                           | -                                                                           | (325,000)                           |
| Interest income                                                                                                                                                                        | <b>99,763</b>                                                               | 138,574                             |
| Net loss before income tax benefit                                                                                                                                                     | <b>(12,111,081)</b>                                                         | (7,283,229)                         |
| Income tax benefit                                                                                                                                                                     | <b>1,459,814</b>                                                            | 2,117,103                           |
| Net loss                                                                                                                                                                               | <b>(10,651,267)</b>                                                         | (5,166,126)                         |
| Cumulative preferred stock dividend                                                                                                                                                    | <b>(856,776)</b>                                                            | (877,818)                           |
| Net loss available to common stockholders                                                                                                                                              | <b>\$ (11,508,043)</b>                                                      | \$ (6,043,944)                      |
| Basic and diluted net loss per share of common stock                                                                                                                                   | <b>\$ (0.57)</b>                                                            | \$ (.36)                            |
| Weighted-average shares used in<br>computing basic and diluted<br>net loss per share                                                                                                   | <b>20,257,482</b>                                                           | 16,920,939                          |

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



Bioenvision, Inc. and Subsidiaries

**CONSOLIDATED STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)**

|                                                    | Preferred Stock |         | Common Stock |              | Paid In     | Deferred       | Accumulated Other | Comprehensive  | Total Stockholders |
|----------------------------------------------------|-----------------|---------|--------------|--------------|-------------|----------------|-------------------|----------------|--------------------|
|                                                    | Shares          | \$      | Shares       | \$           | Capital     | Compensation   | Income            | (Deficit)      |                    |
| Balance at June 30, 2002 as reported               | 5,916,666       | \$5,917 | 16,887,786   | \$16,887,786 | \$91,554    | \$(21,027,299) | \$152,346         | \$24,639,406   |                    |
| Correction of an error (see Note 9)                |                 |         |              |              |             | <u>915,145</u> |                   | <u>915,145</u> |                    |
| Balance at June 30, 2002 as restated               | 5,916,666       | 5,917   | 16,887,786   | 16,887,786   | 91,554      | (20,112,154)   | 152,346           | 25,554,551     |                    |
| Net loss for the year- restated                    |                 |         |              |              |             | (5,166,126)    |                   | (5,166,126)    |                    |
| Cumulative preferred stock dividend                |                 |         |              |              |             | (877,818)      |                   | (877,818)      |                    |
| Shares issued to consultants for services          |                 |         | 234,953      | 234,953      | 258,080     |                |                   | 1,258,315      |                    |
| Warrants issued in connection with services        |                 |         |              |              | 182,350     |                |                   | 182,350        |                    |
| Repricing of options                               |                 |         |              |              | 372,465     |                |                   | 372,465        |                    |
| Balance at June 30, 2003 - restated                | 5,916,666       | 5,917   | 17,122,739   | 17,122,739   | 423,044     | (26,156,098)   | 152,346           | 21,323,737     |                    |
| Net loss for the year - restated                   |                 |         |              |              |             | (10,651,267)   |                   | (10,651,267)   |                    |
| Cumulative preferred stock dividend                |                 |         |              |              |             | (856,776)      |                   | (856,776)      |                    |
| Currency translation adjustment                    |                 |         |              |              |             |                | (12,748)          | (12,748)       |                    |
| Deferred compensation                              |                 |         |              |              |             | \$(223,990)    |                   | (223,990)      |                    |
| Shares issued in connection with private placement |                 |         | 2,602,898    | 2,602,898    | 265,495     |                |                   | 16,268,098     |                    |
| Costs related to private placement                 |                 |         |              |              | (1,301,035) |                |                   | (1,301,035)    |                    |
| Preferred stock converted to common stock          | (2,575,000)     | (2,575) | 5,150,000    | 5,150,000    | (3,075)     |                |                   |                |                    |
| Expense related to repricing of options            |                 |         |              |              | 2,381,066   |                |                   | 2,381,066      |                    |
| Cashless exercises of options to shares            |                 |         | 2,122,682    | 2,122,682    | 212,222     |                |                   |                |                    |
| Warrants issued in connection with services        |                 |         |              |              | 671,601     |                |                   | 671,601        |                    |
| Shares issued to consultants for services          |                 |         | 14,510       | 14,510       | 305,972     |                |                   | 305,987        |                    |
| Shares issued to employee                          |                 |         | 20,000       | 20,000       | 28,400      |                |                   | 28,400         |                    |
| Options issued in connection with services         |                 |         |              |              | 93,987      |                |                   | 93,987         |                    |
| Options issued to employees                        |                 |         |              |              | 262,601     |                |                   | 262,601        |                    |
| Shares issued from warrant conversions             |                 |         | 1,283,334    | 1,283,334    | 509,883     |                |                   | 2,511,166      |                    |
| Balance at June 30, 2004 - restated                | 3,341,666       | \$3,342 | 28,316,163   | \$28,316,163 | 1,617,702   | \$(223,990)    | \$(37,664,141)    | \$139,598      | \$30,800,827       |

The accompanying notes are an integral part of this financial statement.



Bioenvision, Inc. and Subsidiaries

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

|                                                                              | Year ended<br><u>June 30,</u><br><u>2004</u><br>Restated- See Note 9 | <u>2003</u><br>Restated- See Note 9 |
|------------------------------------------------------------------------------|----------------------------------------------------------------------|-------------------------------------|
| Cash flows from operating activities                                         |                                                                      |                                     |
| Net loss                                                                     | <u>\$ (10,651,267)</u>                                               | <u>\$ (5,166,126)</u>               |
| Adjustments to reconcile net loss to net cash used in operating activities   |                                                                      |                                     |
| Depreciation and amortization                                                | <b>1,348,064</b>                                                     | 1,344,969                           |
| Deferred tax benefit                                                         | <b>(1,459,814)</b>                                                   | (2,117,103)                         |
| Compensation costs-shares and warrants issued to non-employees               | <b>1,071,575</b>                                                     | 1,440,429                           |
| Compensation costs-re-pricing of options                                     | <b>2,381,066</b>                                                     | 372,465                             |
| Compensation costs-options issued to employees                               | <b>38,611</b>                                                        | -                                   |
| Changes in assets and liabilities                                            |                                                                      |                                     |
| Deferred costs                                                               | <b>(3,645,631)</b>                                                   | (63,573)                            |
| Deferred revenue                                                             | <b>7,223,105</b>                                                     | 870,139                             |
| <i>Accounts payable</i>                                                      | <b>1,084,474</b>                                                     | (22,924)                            |
| Other current assets                                                         | <b>(147,335)</b>                                                     | (105,976)                           |
| Other long term assets                                                       | <b>126,870</b>                                                       | (126,869)                           |
| Accounts receivable                                                          | <b>(2,602,773)</b>                                                   | 25,000                              |
| Security deposits                                                            |                                                                      | (79,111)                            |
| Other accrued expenses and liabilities                                       | <b>591,862</b>                                                       | (782,901)                           |
| Net cash used in operating activities                                        | <u><b>(4,641,193)</b></u>                                            | <u><b>(4,411,581)</b></u>           |
| Cash flows from investing activities                                         |                                                                      |                                     |
| Purchase of intangible assets                                                | <b>(112,580)</b>                                                     | (191,848)                           |
| Capital expenditures                                                         | <b>(18,337)</b>                                                      | (59,406)                            |
| Restricted cash                                                              | <b>= -</b>                                                           | (290,000)                           |
| Net cash used in investing activities                                        | <u><b>(130,917)</b></u>                                              | <u><b>(541,254)</b></u>             |
| Cash flows from financing activities                                         |                                                                      |                                     |
| Proceeds from issuance of common stock                                       | <b>14,967,064</b>                                                    | -                                   |
| Proceeds from exercise of options, warrants and other convertible securities | <b>2,539,565</b>                                                     | -                                   |
| Cash dividend paid                                                           | <b>(1,775,782)</b>                                                   | =                                   |
| Net cash provided by financing activities                                    | <u><b>15,730,847</b></u>                                             | =                                   |
| Effect of exchange rate on cash                                              | <u><b>(12,748)</b></u>                                               | -                                   |
| Net increase (decrease) in cash and cash equivalents                         | <b>10,945,989</b>                                                    | (4,952,835)                         |
| <i>Cash and cash equivalents, beginning of year</i>                          | <u><b>7,929,686</b></u>                                              | <u><b>12,882,521</b></u>            |
| Cash and cash equivalents, end of year                                       | <u><b>\$ 18,875,675</b></u>                                          | <u><b>\$ 7,929,686</b></u>          |

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

F-20

---

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 1 - Organization and significant accounting policies**

Description of business

Bioenvision, Inc. ( Bioenvision or the Company ) is an emerging biopharmaceutical company whose primary business focus is the acquisition, development and distribution of drugs to treat cancer. The Company has a broad range of products and technologies under development, but its two lead drugs are clofarabine and Modrenal®. Modrenal® is approved for marketing in the U.K. for advanced breast cancer. The Company's plan is to bring Modrenal® into the U.S. to perform further clinical trials and to access the U.S. market. Most of the Company's other drugs are now in clinical trials in various stages of development.

The Company was incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed its name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998.

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

Basis of presentation

Prior to the acquisition of Pathagon and the May 2002 private placement in which the Company raised gross proceeds of \$17.7 million (see Note 6), the Company devoted most of its efforts to establishing a new business (raising capital, research and development, etc.) and had been a development stage enterprise. Management believes they now have the financial resources to market some of the Company's late-stage products which can lead to significant revenues from royalty payments and drug sales. Accordingly, effective June 30, 2002, the financial statements do not reflect the required disclosure for a Development Stage Enterprise.

Principles of consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Inter-company accounts and transactions have been eliminated.

Use of estimates

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

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 1 - Organization and significant accounting policies - continued**

Revenue Recognition

In accordance with SEC Staff Accounting Bulletin No. 104, upfront nonrefundable fees associated with research and development collaboration agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the estimated research and development period using the straight-line method. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis using the straight-line method. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved. Continuation of certain contracts and grants are dependent upon the Company and/or its co-development partners achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project.

Upfront nonrefundable fees associated with licensing arrangements are recorded as deferred revenue and recognized over the licensing arrangement using the straight line method, which approximates the life of the patent.

In May 2003, the Emerging Issues Task Force ( EITF ) reached a consensus on EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables ( EITF 00-21 ). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations, but could affect the timing or pattern of revenue recognition for future collaborative research and/or license agreements.

Research and development

Research and development costs are charged to expense as incurred.

Stock based compensation

At June 30, 2004, the Company has stock based compensation plans which are described more fully in Note 6. As permitted by SFAS No. 123, Accounting for Stock Based Compensation, the Company accounts for stock based compensation arrangements with employees in accordance with provisions of Accounting Principles Board ( APB ) Opinion No. 25 Accounting for Stock Issued to Employees. Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. For year ended June 30, 2004, the Company recognized stock based employee compensation cost of \$2,381,066 as a result of the re-pricing of 380,000 options granted to an employee pursuant to the terms of his Employment Agreement (see Note 9). The Company also recognized a compensation expense of \$38,611 for the year ended June 30, 2004 as a result of 505,000 options granted to certain employees on January 20, 2004.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force no. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services, as amended by EITF 00-27. 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. The Company expects to continue applying the provisions of APB 25 for equity issuances to employees.





**BIOENVISION, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****JUNE 30, 2004 AND 2003****Note 1 - Organization and significant accounting policies - continued**

The following table illustrates the effect on net loss and loss per share as if the fair value based method had been applied to all outstanding and unvested awards in each period.

|                                                                                                                                                         | Year Ended June 30, |                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|
|                                                                                                                                                         | 2004                | 2003               |
| Net loss available to common stockholders, as reported as restated                                                                                      | \$(11,508,043)      | \$(6,043,944)      |
| Add: Stock based employee compensation expense included in reported net loss, net of tax effects                                                        | 2,419,677           | 372,465            |
| Deduct: Total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects as restated | <u>(861,297)</u>    | <u>(1,214,723)</u> |
| Pro forma net loss available to common stockholders as restated                                                                                         | \$(9,949,663)       | \$(6,886,202)      |
| Loss per share                                                                                                                                          |                     |                    |
| Basic and diluted as reported as restated                                                                                                               | \$(0.57)            | \$(0.36)           |
| Basic and diluted pro forma as restated                                                                                                                 | \$(0.49)            | \$(0.41)           |

During 2005, the Company corrected an error on the pro-forma stock based compensation disclosures required under SFAS 123 determined under fair value based method in the table above. The Company originally did not calculate the incremental stock based compensation relating to the re-pricing of an officer's options in accordance with SFAS 123. This has decreased such amounts previously reported in the proforma net loss for the years ended June 30, 2004 and June 30, 2003 by \$412,000 and \$0, respectively.

The fair value of options at the date of grant was established using the Black-Scholes model with the following weighted average assumptions:

|                               | <u>2004</u> | <u>2003</u> |
|-------------------------------|-------------|-------------|
| Expected average life (years) | 3.5         | 4.00        |
| Risk free interest rate       | 2.35%       | 3.00%       |
| Expected volatility           | 80%         | 80%         |
| Expected dividend yield       | 0.00        | 0.00        |

**Income taxes**

The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes (FAS 109). Under FAS 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. The Company records a valuation allowance for certain temporary differences for which it is more likely than not that it will not receive future tax benefits.



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 1 - Organization and significant accounting policies continued**

Net loss per share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options and warrants to purchase 13,674,242 and 15,749,543 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2004 and 2003, respectively, as their effect would have been anti-dilutive.

Foreign currency translation

Through June 30, 2001, the functional currency of the Company was the Pound Sterling and its reporting currency was the United States dollar. Translation adjustments arising from differences in exchange rates from these transactions were reported as accumulated other comprehensive income in stockholders' equity (deficit). Effective July 1, 2001, the functional and reporting currency is the United States dollar. The functional currency of Bioenvision Limited, the Company's wholly-owned subsidiary with offices in Edinburgh, Scotland, is the Pound Sterling.

Cash and cash equivalents

The Company considers all highly liquid financial instruments with a maturity of three months or less when purchased to be cash equivalents. The Company invests all its funds with a single financial institution which provides for FDIC insurance of \$100,000. The Company has invested \$13 million in certificates of deposit which bear interest at a rate of 1.34% per annum, all of which will come due in December 2004. All funds invested in the Certificate of Deposit may be withdrawn at any time without penalty and therefore are classified as cash equivalents.

Accounts Receivable

Accounts receivable are concentrated in that of the approximately \$2,628,000 of accounts receivable, \$2,244,000 (85%) are due from ILEX and an additional \$334,000 (13%) are due from Stegram Pharmaceuticals. To limit credit risk, the Company periodically evaluates the financial condition and payment history of each of these parties.

Advertising costs

Costs related to advertising and other promotional expenditures are expensed as incurred.

Deferred costs

Deferred costs represent royalty payments that became due and payable to SRI and to Stegram Pharmaceutical Ltd, which relate to milestone payments received in connection with the Ilex Co-Development Agreement and the Dechra Sub-License Agreement, respectively. These costs have been presented together with research and development costs on the statement of operations for the years ended June 30, 2004 and 2003.

Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Property and equipment are depreciated on a straight-line basis over their estimated useful lives, which range from 3 to 7 years.



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 1 - Organization and significant accounting policies - continued**

Fair Value of Financial Instruments

The Company has estimated the fair value of financial instruments using available market information and other valuation methodologies in accordance with Statement of Financial Accounting Standards No. 107, Disclosures about Fair Value of Financial Instruments. Management of the Company believes that the fair value of financial instruments, consisting of cash, accounts receivable, accounts payable and accrued liabilities, approximates carrying value due to the immediate or short-term maturity associated with these instruments.

Goodwill and Other Intangible Assets

Goodwill represents the excess of costs over the fair value of identifiable net assets of Pathagon. Intangible assets include patents and licensing rights acquired in connection with the acquisition of Pathagon. The Company accounts for these assets in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 142, Goodwill and Other Intangible Assets. Goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 144, Accounting for Impairment or Disposal of Long-Lived Assets ( SFAS No. 144 ). The Company does not have any intangible assets with an indefinite useful life.

Long-Lived Assets

The Company adopted the provisions of SFAS No. 144 on July 1, 2003. In accordance with SFAS No. 144, long-lived assets, such as property and equipment and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Prior to the adoption of SFAS No. 144, the Company accounted for long-lived assets in accordance with SFAS No. 121, Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of.

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**NOTE 2 - Acquisition of Pathagon**

On February 1, 2002, the Company completed the acquisition of Pathagon. The acquisition was accounted for as a purchase business combination in accordance with SFAS 141. The Company issued 7,000,000 shares of common stock to complete the acquisition, which was valued at \$12,600,000 based on the 5-day average trading price of the stock (\$1.80) surrounding November 22, 2001, the day of the Company's announcement of the agreed upon acquisition. The acquired patents and licensing rights of OLIGON(R) and methylene blue (collectively referred to as Purchased Technologies), were recorded at their fair market value which was approximately \$17,576,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of these assets. Since the estimated fair value of the Purchased Technologies was at least equal to the amount paid, the purchase price, net of assumed liabilities, was allocated to Purchased Technologies. The transaction qualified as a tax-free merger which resulted in a difference between the tax basis value of the assets acquired and the fair market value of the patents and licensing rights. As a result, a deferred tax liability was recorded for approximately \$7,909,000. The purchase price exceeded the fair market value of the net assets acquired resulting in the recording of Goodwill of \$2,341,000. The Company recorded a charge to goodwill of \$801,395 for fiscal year ended June 30, 2003 as a result of a change in tax rates used to compute the deferred tax liability arising as a result of this acquisition. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro-forma financials would not be meaningful and thus are not presented.

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

The OLIGON(R) technology is a patented anti-microbial technology that can be incorporated into the manufacturing process of many implantable devices. The patented process, involving two dissimilar metals (silver and platinum) creates an electrochemical reaction that releases silver ions that destroy bacteria, fungi and other pathogens. The Company intends to commercialize the technology in partnership with leading medical devices manufacturers.

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

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

**BIOENVISION, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****JUNE 30, 2004 AND 2003****NOTE 3 - Intangible Assets**

|                                             |               |               |
|---------------------------------------------|---------------|---------------|
| Intangible assets consist of the following: | June 30, 2004 | June 30, 2003 |
| Patents and licensing rights                | \$17,757,101  | \$17,644,521  |
| Less:accumulated amortization               | (3,193,441)   | (1,865,122)   |
|                                             | -----         | -----         |
|                                             | \$14,563,660  | \$15,779,399  |
|                                             | =====         | =====         |

Amortization of patents and licensing rights amounted to \$1,328,318 and \$1,334,241 for the years ended June 30, 2004 and June 30, 2003, respectively. Other intangible assets are recorded at cost and amortized over periods generally ranging from 10-20 years. Amortization for each of the next five fiscal years will amount to approximately \$1,355,000 annually.

**NOTE 4 - License and Co-Development Agreements****Clofarabine**

We have a license from Southern Research Institute ( SRI ), Birmingham, Alabama, to develop and market purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. The lead compound of these purine-based nucleosides is known as clofarabine. Under the terms of the agreement with SRI, we were granted the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by us and by SRI from the technology. We plan to develop clofarabine initially for the treatment of leukemia and lymphoma and to study its potential role in treatment of solid tumors.

In August 2003, SRI granted us an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

To facilitate the development of clofarabine, we entered into a co-development agreement with ILEX Oncology, Inc. ( ILEX ) in March 2001. Under the terms of the co-development agreement, ILEX is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia). ILEX is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada. The Company retains the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia). The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. Under the co-development agreement, ILEX will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay ILEX a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. In turn, ILEX, which would have U.S. and Canadian distribution rights, would pay the Company a royalty on sales in the U.S. and Canada. In addition, the Company is entitled to certain milestone payments. Under the terms of the co-development agreement, ILEX also pays royalties to Southern Research Institute based on certain milestones. The Company also is obligated to milestones and royalties to Southern Research Institute in respect to clofarabine.





**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 4 License and Co-Development Agreements continued**

The Company received a nonrefundable upfront payment of \$1.35 million when it entered into the co-development agreement with ILEX and received an additional \$3.5 million in December 2003 when it converted ILEX's option to market clofarabine in the U.S. into a sublicense. The Company received an additional \$2 million in April 2004 upon ILEX's filing the New Drug Application for clofarabine with FDA and the Company expects to receive an additional \$2 million from ILEX in October 2004 in connection with the achievement of the NDA filing. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. 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 the years ended June 30, 2004 and 2003, respectively, the Company recognized revenues of approximately \$161,000 and \$370,000 in connection with the upfront and milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with research and development costs including approximately \$81,000 and \$207,000 for the years ended June 30, 2004 and 2003, respectively, related to such charges.

**Modrenal®**

The Company holds an exclusive license, until the expiration of existing and new patents related to Modrenal®, to market Modrenal® in major international territories, and an agreement with a United Kingdom company to co-develop Modrenal® for other therapeutic indications. Management believes that Modrenal® 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®, but will continue to use third-party contractors.

The Company received a nonrefundable upfront payment of \$1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, through May 2014. The Company recognized revenues of approximately \$114,000 and \$12,000 in connection with the upfront payment from Dechra for the years ended June 30, 2004 and 2003, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Stegram 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 include approximately \$23,000 and \$2,000 for the years ended June 30, 2004 and 2003, respectively.

Anti-Estrogen Prostate. We received Institutional Review Board approval from the Dana Faber Cancer Institute for a Phase II study of trilostane for the treatment of androgen independent prostate cancer. The study is being conducted by The Dana Faber Cancer Institute and commenced in July 2004.

**Operational Developments**

In June 2003, we entered into a supply agreement with Ferro-Pfanzstiehl Laboratories ( Ferro ), pursuant to which Ferro has agreed to manufacture and supply 100% of Bioenvision's global requirements for clofarabine-API. Subject to certain circumstances, this agreement will expire on the fifth anniversary date of the first regulatory approval of clofarabine drug product.

In June 2003, the Company entered into a development agreement with Ferro, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply CTM and GMP supplier qualifications of the API-



clofarabine. Subject to certain circumstances, this agreement expires upon the completion of the development program. The development agreement is milestone based and payments are to be paid upon completion of each milestone. If Ferro has not completed the development agreement by December 2007, the development agreement will automatically terminate without further action by either party.

In May 2003, we entered into a sub-license agreement with Dechra, pursuant to which Dechra has been granted a sub-license for all of Bioenvision's rights and entitlements to market and distribute Modrenal® in the United States and Canada solely in connection with animal health applications. Subject to certain circumstances, this agreement expires upon expiration of the last patent related to Modrenal® or the completion of the last royalty set forth in the agreement. Through June 30, 2003, we have recognized deferred revenue and deferred costs related to this agreement as described below in this Note 4. The Company received an upfront non-refundable payment of \$1.25 million upon execution of this agreement and may receive up to an additional \$3.75 million upon the achievement by Dechra of certain milestones set forth in the agreement.

In May 2003, we entered into a master services agreement with Penn-Pharmaceutical Services Limited ( Penn ), pursuant to which Penn has agreed to label, package and distribute clofarabine on behalf of and at our request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three month prior written notice.

In April 2003, we entered into an exclusive license agreement with CLL-Pharma ( CLL ), pursuant to which CLL has agreed to perform certain development works and studies to create a new formulation of Modrenal®. CLL intends to use its proprietary MIDDs.-patented technology to perform this service on behalf of the Company. This new formulation, once in hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell Modrenal® throughout Europe. Through June 30, 2003, the Company paid an advance of \$175,000 related to development services to be provided by CLL over an eighteen month period, which advance was initially recorded as a prepaid development cost by the Company.

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 5 - Income taxes**

The components of the income tax benefit, as restated refer to Note 9, are as follows:

|               | June 30,      |               |
|---------------|---------------|---------------|
|               | -----         |               |
|               | 2004          | 2003          |
|               | -----         | -----         |
| Current:      |               |               |
| Federal       | \$ --         | \$ --         |
|               | -----         | -----         |
| State         | --            | --            |
|               | -----         | -----         |
| Deferred:     |               |               |
| Federal       | \$(1,099,000) | (1,593,000)   |
| State         | (361,000)     | (524,000)     |
|               | -----         | -----         |
|               | (1,460,000)   | (2,117,000)   |
|               | -----         | -----         |
| Total benefit | \$(1,460,000) | \$(2,117,000) |
|               | =====         | =====         |

The domestic and foreign components of loss before income taxes are as follows:

|                   | June 30,     |             |
|-------------------|--------------|-------------|
|                   | -----        |             |
|                   | 2004         | 2003        |
|                   | -----        | -----       |
| Domestic          | \$10,781,000 | \$6,351,000 |
| Foreign           | 1,330,000    | 932,000     |
|                   | -----        | -----       |
| Loss before taxes | \$12,111,000 | \$7,283,000 |
|                   | =====        | =====       |



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 5 Income taxes - continued**

The following is a reconciliation of benefit for income taxes from continuing operations computed at the federal statutory rates to the effective rates for the years ended June 30, 2004 and June 30, 2003

|                                                    | June 30, |          |
|----------------------------------------------------|----------|----------|
|                                                    | 2004     | 2003     |
|                                                    | -----    | -----    |
| Consolidated tax benefit at federal statutory rate | (34.00%) | (34.00%) |
| Non-deductible expenses                            | 6.77%    | 3.99%    |
| State income tax benefit, net of federal provision | (4.49%)  | (4.91%)  |
| Valuation allowance                                | 19.25%   | 5.43%    |
| Foreign rate differential                          | 0.44%    | 0.51%    |
| Other, net                                         | (0.02%)  | (0.09%)  |
|                                                    | -----    | -----    |
| Effective tax rate                                 | (12.05%) | (29.07%) |
|                                                    | =====    | =====    |

Significant components of the company's deferred tax assets and liability at June 30, as restated refer to Note 9, are as follows:

|                                                      | June 30,      |               |
|------------------------------------------------------|---------------|---------------|
|                                                      | 2004          | 2003          |
|                                                      | -----         | -----         |
| Deferred tax liability                               |               |               |
| Acquired intangibles                                 | \$(5,781,000) | \$(6,318,000) |
| Deferred costs                                       | (1,577,000)   | (100,000)     |
| Amortization                                         | (43,000)      | (41,000)      |
| Depreciation                                         | (30,000)      | -             |
|                                                      | -----         | -----         |
| Total deferred tax liability                         | (7,431,000)   | (6,459,000)   |
| Deferred tax assets                                  |               |               |
| Net operating loss                                   | 6,384,000     | 4,729,000     |
| Options, warrants and shares issued to non-employees | 345,000       | 74,000        |
| Options issued to employees                          | 104,000       | 50,000        |
| Deferred revenue                                     | 3,427,000     | 501,000       |
| Depreciation                                         | -             | 20,000        |
| Other                                                | 65,000        | 21,000        |
|                                                      | -----         | -----         |
| Total deferred tax assets                            | 10,325,000    | 5,395,000     |
| Valuation allowance for deferred tax assets          | (2,894,000)   | (396,000)     |
|                                                      | -----         | -----         |
| Net deferred tax asset                               | 7,431,000     | 4,999,000     |
|                                                      | -----         | -----         |

Edgar Filing: BIOENVISION INC - Form POS AM

|                            |       |   |               |
|----------------------------|-------|---|---------------|
| Net deferred tax liability | \$    | - | \$(1,460,000) |
|                            | ===== |   | =====         |

F-31

---



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 5 Income taxes - continued**

At June 30, 2004 and June 30, 2003, the Company had approximately \$14,087,000 and \$10,985,000 of net operating loss carryforwards for U.S. Federal and state income tax purposes, respectively that begin to expire in fiscal year ending 2020, with a tax value of \$5,705,000 and \$4,449,000, respectively. At June 30, 2004 and June 30, 2003, the Company also had approximately \$2,263,000 and \$932,000 of net operating loss carryforwards relating to foreign operations, respectively, with no expiration date, with a tax value of \$679,000 and \$280,000, respectively.

At June 30, 2004, the Company has recorded a valuation allowance of \$2,894,000 relating to the net deferred tax asset due the uncertainty of both the foreign and domestic companies being more likely than not to utilize these deferred tax assets. At June 30, 2003, the Company has recorded a valuation allowance of \$396,000. Of this amount, \$116,000 relates to certain US deferred tax assets which will be recognized after the period in which the Pathagon deferred tax liability reverses. The remaining allowance relates to the net operating loss of the foreign operations due to the uncertainty that the Company will realize taxable income in the foreign jurisdiction to utilize the net operating loss carryforward.

Included in the June 30, 2004 net operating loss is \$415,000 related to exercise of non-qualified stock options or disqualifying dispositions of stock acquired with incentive stock options. A valuation allowance has been established against this loss. When the valuation allowance is removed, the tax affected benefit of \$168,000 related to this loss will be credited to equity.

The Tax Reform Act of 1986 enacted a complex set of rules (Internal Revenue Code Section 382) limiting the utilization of net operating losses to offset future taxable income following a corporate ownership change. Generally, this occurs when there is a greater than 50 percentage point change in ownership. Accordingly, such change could limit the amount of net operating losses available in a given year, which could ultimately cause net operating losses to expire prior to utilization.

**NOTE 6 - Stockholders transactions**

**Common Stock and Securities Convertible into Common Stock**

The Board of Directors adopted, and the stockholders approved the 2003 Stock Incentive Plan at the Annual Meeting held in January of 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 3,000,000 shares reserved for grants of options under the plan and at June 30, 2004, options to purchase 2,105,000 shares of common stock had been issued. Stock options vest pursuant to individual stock option agreements. No options granted under the plan are exercisable after the expiration of ten years (or less in 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.

In June 2002, the Company granted options to an officer of the Company to purchase 380,000 shares of common stock at an exercise price of \$1.95 per share, which equaled the stock price on the date of the grant. Of this amount, 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003 the Company entered into an Employment Agreement with such officer of the Company, pursuant to which, among other things, the exercise price for all 380,000 options were changed to \$0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of \$0.735 per share which vested immediately. As a result of the re-pricing of 380,000 options, the Company will re-measure the intrinsic value of these options at the end of each reporting period and will adjust compensation expense based on changes in the stock price. Compensation expense recognized as a result of this re-pricing amounted to \$2,381,066 and \$372,465 for the year ended June 30, 2004 and 2003, respectively.



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 6 Stockholders transactions continued**

On October 23, 2002, the Company granted options to purchase 300,000 shares of common stock at an exercise price of \$1.45 per share to the Commercial Director (Europe) of the Company. Of these options, options to purchase 100,000 shares of common stock vest and become exercisable on each of the first, second and third anniversary of October 23, 2002, the grant date.

On October 23, 2002, the Company granted options to purchase 50,000 shares of common stock at an exercise price of \$1.45 per share to another employee of the Company. Of these options, options to purchase 50,000 shares of common stock vest and become exercisable on each of the first and second anniversary of October 23, 2002, the grant date.

On December 31, 2002 the Company issued options to purchase 500,000 shares of common stock at an exercise price equal to \$1.45 per share (average of the high and low bid price on the grant date), to its Chairman and Chief Executive Officer, Dr. Christopher B. Wood. Of these options, subject to certain circumstances, options to purchase 166,666 shares of common stock vest on each of the first, second and third anniversary of the grant date.

On January 9, 2003 the Company issued to an employee of the Company, options to purchase 20,000 shares of common stock at an exercise price of \$1.42 per share, which equaled the stock price on the date of grant. Of these options, subject to certain circumstances, options to purchase 10,000 shares of common stock vest and become exercisable on the first anniversary of the grant date and the remaining options to purchase 10,000 shares of common stock vest and become exercisable on the second anniversary of the grant date.

In January 2003, we entered into an agreement with RRD International LLC ( RRD ), pursuant to which RRD serves as the global product development consultant to the Company in connection with the development of clofarabine, Modrenal® and OLIGON and assists with designing and managing our clinical development program for our products. On April 2, 2003, the Company and RRD further memorialized their agreement pursuant to a formal Master Services Agreement and Registration Rights Agreement and, in connection therewith, the Company issued a Warrant to RRD pursuant to which RRD has the right to acquire 175,000 shares of our common stock at an exercise price of \$2.00 per share, which warrant includes registration rights under certain circumstances. Compensation expense of \$672,000 and \$182,000 was recorded as consulting fees for the years ended June 30, 2004 and June 2003, respectively.

During the three months ended December 31, 2003, the Company issued options to another employee to purchase 25,000 shares of common stock at an exercise price of \$3.53 per share. Of this amount, 12,500 options vest on November 11, 2004 and the remaining 12,500 will vest on November 11, 2005.

During the year ended June 30, 2004, certain holders of 2,575,900 shares of the Company's preferred stock converted such shares into 5,150,000 shares of the Company's common stock. In addition, during the year ended June 30, 2004, certain warrant holders of the Company exercised their warrants to acquire 1,283,334 shares of the Company's common stock. The Company received proceeds of approximately \$2,509,882 during the year ended June 30, 2004, respectively from the exercise of these warrants.

During the year ended June 30, 2004, certain non-employee holders of options exercised pursuant to the cashless exercise feature available to such option holders and the Company issued approximately 2,122,682 shares of its common stock in connection therewith.

On January 3, 2004, the Company issued 14,510 restricted shares of its common stock to a consultant to the Company for certain executive placement services rendered to the Company. The Company recorded compensation expense of approximately \$60,637 for the year ended June 30, 2004 in connection with such issuance.



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**NOTE 6 - Stockholders transactions continued**

On January 14, 2004, a majority of the Company's stockholders authorized an amendment to the Company's certificate of incorporation, approved by the Company's Board of Directors, to increase the number of authorized shares of common stock from 50,000,000 to 70,000,000 and to increase the number of authorized shares of the Company's preferred stock from 10,000,000 to 20,000,000. The shareholder action became effective, and the amendment was filed and became effective, on January 14, 2004.

On January 20, 2004, the Company granted 25,000 options to Dr. Michael Kauffman, for serving as a member of the Board of Directors, at an exercise price of \$4.55 per share which vest ratably on the first and second anniversaries of the grant date. The Company recognized \$20,988 as consulting expenses for the year ended June 30, 2004.

The Company recorded a compensation expense of \$38,611 for the year ended June 30, 2004 as a result of 505,000 options granted to certain employees on January 20, 2004.

On February 4, 2004, the Company issued 20,000 shares of its common stock to an employee of the Company in connection with the exercise of options issued prior to that date which had an exercise price of \$1.42.

On March 11, 2004, the Company issued options to another employee to purchase 50,000 shares of common stock at an exercise price of \$6.50 per share. Of this amount, 16,666.66 options vest on March 11, 2005 and the remaining 33,332.33 will vest on March 11, 2006.

On March 22, 2004, the Company consummated a private placement transaction, pursuant to which it raised \$12.8 million and issued 2,044,514 shares of its common stock and warrants to purchase an additional 408,903 shares of its common stock at an exercise price of \$7.50 per share. The Company recorded proceeds of \$12,151,240 net of all legal, professional and financing fees incurred in connection with the offering. The Company consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Convertible Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional \$3.2 million (net of all legal, professional and financial services incurred) from the second closing and issued an additional 558,384 shares of its common stock and warrants to purchase 111,677 shares of its common stock at an exercise price of \$7.50 per share.

On June 22, 2004, the Company issued options to a new employee to purchase 140,000 shares of common stock at an exercise price of \$8.25 per share. Of this amount, 30,000 options vested on June 22, 2004 and the remaining 110,000 will vest ratably on June 22, 2005 and 2006 respectively.

On June 22, 2004 the Company entered into a consulting agreement pursuant to which consultant will provide certain investor relation services on behalf of the Company. In connection therewith, the Company issued a warrant to said consultant pursuant to which said consultant has the right to purchase 50,000 shares of Company's common stock at a price of \$8.25 per share upon the completion of certain milestones, as set forth in such agreement. No compensation expense of was recorded for the fiscal year ended June 30, 2004 as no such milestones had been met yet at that time.

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**NOTE 6 - Stockholders transactions continued**

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

|                         | No. of Shares | Weighted Avg. Exercise Price |  |  |
|-------------------------|---------------|------------------------------|--|--|
| Balance - June 30, 2002 | 2,200,000     | \$1.25                       |  |  |
| Granted during 2003     | 1,370,000     | 1.19                         |  |  |
| Exercised during 2003   | -             | -                            |  |  |
| Forfeiture during 2003  | -             | -                            |  |  |
| Balance - June 30, 2003 | 3,570,000     | 1.23                         |  |  |
| Granted during 2004     | 720,000       | 5.02                         |  |  |
| Exercised during 2004   | 20,000        | 1.42                         |  |  |
| Forfeiture during 2004  | -             | -                            |  |  |
| Balance - June 30, 2004 | 4,270,000     | \$1.87                       |  |  |

**Stock Options Outstanding**

| Exercise Price Range | Weighted Average |                   | Remaining Contractual Life | Number of Stock Options Exercisable |
|----------------------|------------------|-------------------|----------------------------|-------------------------------------|
|                      | Exercise price   | Number of Options |                            |                                     |
| \$0.74               | \$ 0.74          | 500,000           | 8.12                       | 390,000                             |
| \$1.25 - \$2.75      | \$ 1.29          | 3,050,000         | 6.58                       | 2,491,000                           |
| \$2.76 - \$6.00      | \$ 4.03          | 530,000           | 9.55                       | 0                                   |
| \$6.01 - \$8.25      | \$ 8.12          | 190,000           | 9.90                       | 30,000                              |
|                      |                  | 4,270,000         |                            | 2,911,000                           |

**Preferred Stock**

On May 7, 2002 the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Preferred Stock, par value \$0.001 per share ( Series A Preferred Stock ). Series A Preferred Stock may be converted into two shares of common stock at an initial conversion price of \$1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. In May 2002, the Company consummated a Private Placement of Series A Preferred Stock and received gross proceeds of \$17.7 million. Holders of Series A Preferred Stock also received, in respect of each share of Series A Preferred Stock purchased in the May 2002 Private Placement by the Company, one warrant to purchase one share of the Company's common stock at an initial exercise price of \$2.00, subject to adjustment. The purchasers of Series A Preferred Stock also received certain registration rights. The preferred stock generally carries rights to vote with the holders of common stock as one class on a two-for-one basis. The preferred stock is convertible into the Company's common stock on a two-for-one basis subject to certain adjustments at the earlier to occur of (i) at the election of each holder from and after the issuance date, or (ii) the date at any time after the one year anniversary of the issuance date upon which both (x) the average of the market price for a share of common stock for thirty consecutive trading days exceeds \$10.00 per share, subject to certain adjustments, and (y) the average of the trading volume for the Company's common stock during such period exceeds 150,000, subject to certain adjustments.

F-35

---

**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**NOTE 6 - Stockholders transactions continued**

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Preferred Stock. The Company has paid the dividend in cash to holders of Series A Convertible Preferred Stock through July 30, 2004.

In the event of a voluntary or involuntary liquidation or dissolution of the Company, before any distribution of assets shall be made to the holders of the Company's securities which are junior to the preferred stock (such as the common stock), holders of the preferred stock shall be paid out of the assets of the Company legally available for distribution to the Company's stockholders an amount per share equal to the initial original issue price (\$3.00) subject to certain adjustments plus all accrued but unpaid dividends on such preferred stock.

**NOTE 7 - Related party transactions**

On November 16, 2001, we entered into an engagement letter with SCO Financial Group, pursuant to which SCO would act as our financial advisor. In connection with the engagement letter, we issued a warrant to purchase 100,000 shares of common stock at an exercise price of \$1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The issuance of these shares was capitalized as deferred financing costs and was amortized over a twelve-month period.

In connection with securing a credit facility with SCO Capital, we issued warrants to purchase 1,500,000 shares of our common stock at a strike price of \$1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The credit facility with SCO Capital was terminated in May 2002 at which time the Company received a payoff letter evidencing such termination.

On February 5, 2002, we completed the acquisition of Pathagon Inc. Affiliates of SCO Capital owned 82% of Pathagon prior to the acquisition. In connection therewith, on February 1, 2002 we issued 7,000,000 shares of common stock to the former stockholders of Pathagon Inc.

In May 2002, the Company completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A Convertible Preferred Stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock and in March of 2004 the Company consummated a private placement pursuant to which we raised \$12.8 million with a second closing in May 2004 in which it raised an additional \$3.5 million (See Note 6-Stockholder Transactions above). SCO Financial Group served as financial advisor to the Company in connection with these financings and earned a placement fee of approximately \$1.2 million in connection with May 2002 private placement and a placement fee of \$1.1 million and warrants to purchase 260,291 shares of common stock for \$6.25 per share for the March and May 2004 financings.

Mr. Jeffrey B. Davis, President of SCO Financial Group LLC, has served on the Company's board of directors since February of 2002. Mr. Davis resigned from the Board of Directors of the Company effective June 14, 2004.

**NOTE 8 - Commitments and Contingencies**

Leases

The Company leases 3,229 square feet of office space for its New York headquarters under a non-cancelable operating lease expiring on September 30, 2005 and approximately 1,000 square feet in Edinburgh, Scotland under a lease agreement for its subsidiary Bioenvision Ltd. which expires August 31, 2004. Rent expense for both facilities in the aggregate in 2004, was approximately \$241,000. Further, the Company leases two vehicles under leases which expire November 29, 2005 and February 28, 2007. Lease expense in 2004 and 2003, in the aggregate, was approximately \$37,000 and \$30,000, respectively. At June 30, 2004, total minimum rentals under operating leases with initial or remaining non-cancelable lease terms of more than one year were approximately:



F-36

---

**BIOENVISION, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****JUNE 30, 2004 AND 2003****Note 8 Commitments and Contingencies - continued**

|                     |                   |
|---------------------|-------------------|
| Year ended June 30, |                   |
| 2005                | \$206,000         |
| 2006                | 63,000            |
| 2007                | 10,000            |
| 2008                | <u>          </u> |
|                     | \$279,000         |

Employment Agreements

On September 1, 1999, we entered into an employment agreement with Christopher B. Wood, M.D. under which he serves as our Chairman and Chief Executive Officer. The initial term of Dr. Wood's employment agreement is two years with automatic one-year extensions thereafter unless either party gives written notice to the contrary. On December 31, 2002, we entered into a new employment agreement with Dr. Wood, under which he continues to serve as our Chairman and Chief Executive Officer. Under this contract, the term is one year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. Dr. Wood's new employment agreement provides for an initial base salary of \$225,000, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to key employees of the Company. If Dr. Wood's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to his then current annual base salary and any and all unvested options will vest and immediately become exercisable.

On October 23, 2002, we entered into an employment agreement with Hugh S. Griffith, pursuant to which he agrees to serve as our Commercial Director (Europe). The initial term of Mr. Griffith's employment agreement is one-year, with automatic six month extensions thereafter unless either party provides written notice to the contrary. If Mr. Griffith's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 0.5 multiplied by the sum of his then current annual base salary plus a payment equal to six (6) months of his then current base salary in complete satisfaction of the Company's obligation to provide no less than six (6) months prior written notice as set forth in the employment agreement.

On January 6, 2003, we entered into an employment agreement with Ian Abercrombie, pursuant to which he agrees to serve as our Sales Manager (Europe). The initial term of Mr. Abercrombie's employment agreement is one-year, with automatic six month extensions thereafter unless either party provides written notice to the contrary. If Mr. Abercrombie's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a payment equal to six (6) months of his then current base salary in complete satisfaction of the Company's obligation to provide no less than six (6) months prior written notice as set forth in the employment agreement.

On March 31, 2003, we entered into an employment agreement with David P. Luci, pursuant to which he serves as our Director of Finance, General Counsel and Corporate Secretary. The initial term of Mr. Luci's employment agreement is one-year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. If Mr. Luci's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 1.5 multiplied by the sum of (i) his then current annual base salary plus (ii) his then average annual bonus for the preceding two years and any and all unvested options will vest and immediately become exercisable.



**BIOENVISION, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**JUNE 30, 2004 AND 2003**

**Note 8 Commitments and Contingencies - continued**

Litigation

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleged a breach of contract by the Company and demanded judgment against the Company for \$112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary judgment and RLB filed its response on October 27, 2003. On November 12, 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. In March 2004, the complaint and two counterclaims asserted by the Company were dismissed with prejudice.

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the Tessman Defendants) in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously.

**Note 9 Restatements**

In May of 2005, the Company corrected its accounting for income taxes and recognized deferred tax assets which offset the deferred tax liability resulting from the Pathagon acquisition completed on February 1, 2002. The Company had originally concluded that the realization of the deferred tax asset related to the net operating losses and other deductible temporary differences existing at the acquisition date, and generated after the acquisition date, did not meet the more likely than not criteria and, as a result, a valuation allowance was established on the deferred tax assets of the Company. The Company subsequently determined that the deferred tax liability of \$7,107,605 recorded in connection with the Pathagon acquisition creates taxable income as the taxable temporary differences reverse. Consequently, the ability to realize the deferred tax assets is more likely than not and a valuation allowance is not required against the deferred tax assets, to the extent the deferred tax assets offset the deferred tax liability. The deferred tax asset, in excess of the deferred tax liability, is not more likely than not to be realized, and is therefore offset by a valuation allowance.

As the deferred tax liability was amortized each year, the Company recorded the reduction to the liability as an income tax benefit. The Company restated its previously reported financial statements and all interim periods as of and for the years ended June 30, 2004 and 2003, to record additional benefit relating to the recognition of deferred tax assets as indicated in the first paragraph of this note. In years ended June 30, 2004, June 30, 2003, and June 30, 2002, the Company previously recorded the reduction to the deferred tax liability and a corresponding tax benefit of \$536,903, \$536,903 and \$253,000, respectively. In the restated financial statements for years ended June 30, 2004 and June 30, 2003, the Company recorded deferred tax assets, with a corresponding additional deferred tax benefit of \$922,911 and \$1,580,200, respectively, offsetting the deferred tax liability resulting from the Pathagon acquisition. Additionally, as of the acquisition date on February 1, 2002, a deferred tax asset was recorded for \$2,362,543 with a corresponding reduction to goodwill. This represented the deferred tax assets that existed at the date of acquisition and for which the previously recorded valuation allowance was eliminated.



**BIOENVISION, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****JUNE 30, 2004 AND 2003****Note 9 Restatements continued**

| <b>June 30</b>                                       | <b>2004</b>  |              | <b>2003</b>  |              |
|------------------------------------------------------|--------------|--------------|--------------|--------------|
|                                                      | As Reported  | As Restated  | As Reported  | As Restated  |
| Consolidated Balance Sheets:                         |              |              |              |              |
| Goodwill                                             | \$3,902,705  | \$1,540,162  | \$3,902,705  | \$1,540,162  |
| Total assets                                         | 44,533,387   | 42,170,844   | 28,535,675   | 26,173,132   |
| Deferred tax liability                               | 5,780,799    | -            | 6,317,702    | 1,459,814    |
| Total liabilities                                    | 17,150,816   | 11,370,017   | 9,707,283    | 4,849,395    |
| Accumulated deficit                                  | (41,082,397) | (37,664,141) | (28,651,443) | (26,156,098) |
| Total shareholders' equity                           | 27,382,571   | 30,800,827   | 18,828,392   | 21,323,737   |
| <br>                                                 |              |              |              |              |
| <b>Year Ended June 30</b>                            | <b>2004</b>  |              | <b>2003</b>  |              |
|                                                      | As Reported  | As Restated  | As Reported  | As Restated  |
| Consolidated Statements of Operations:               |              |              |              |              |
| Income tax benefit                                   | \$536,903    | \$1,459,814  | \$536,903    | \$2,117,103  |
| Net loss                                             | (11,574,178) | (10,651,267) | (6,746,326)  | (5,166,126)  |
| Net loss available to common stockholders            | (12,430,954) | (11,508,043) | (7,624,144)  | (6,043,944)  |
| Basic and diluted net loss per share of common stock | \$ (0.61)    | \$ (0.57)    | \$ (0.45)    | \$ (0.36)    |

The restatement has no effect on total cash flows from operating, investing, or financing activities as shown in the Consolidated Statement of Cash Flows. However, the restatement did affect the individual components of net loss and deferred tax benefit within the net cash from operating activities.

Additionally, the Company restated the pro-forma stock based compensation disclosures required under SFAS 123 determined under fair value based method due to the correction of an error noted during February 2005. Refer to Note 1 for further discussion.

## BIOENVISION, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## JUNE 30, 2004 AND 2003

## Note 10 Quarterly Financial Data (Unaudited):

| 2004                                                                   | First Quarter<br>(as reported) | First Quarter<br>(as restated) | Second Quarter<br>(as reported) | Second Quarter<br>(as restated) | Third Quarter<br>(as reported) | Third Quarter<br>(as restated) | Fourth Quarter<br>(as reported) | Fourth Quarter<br>(as restated) |
|------------------------------------------------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| Goodwill                                                               | 3,902,705                      | 1,540,162                      | 3,902,705                       | 1,540,162                       | 3,902,705                      | 1,540,162                      | 3,902,705                       | 1,540,162                       |
| Total assets                                                           | 27,412,726                     | 25,050,183                     | 28,690,183                      | 26,327,640                      | 42,481,937                     | 40,119,394                     | 44,533,387                      | 42,170,844                      |
| Deferred tax liability                                                 | 6,183,476                      | 1,130,327                      | 6,049,125                       | 900,326                         | 5,914,774                      | 394,239                        | 5,780,799                       | --                              |
| Total liabilities                                                      | 9,860,203                      | 4,807,054                      | 13,286,085                      | 8,137,288                       | 15,738,593                     | 10,218,058                     | 17,150,816                      | 11,370,017                      |
| Accumulated deficit                                                    | (31,474,458)                   | (28,783,852)                   | (33,436,828)                    | (30,650,572)                    | (37,676,811)                   | (34,518,819)                   | (41,082,397)                    | (37,664,141)                    |
| Shareholders equity                                                    | 17,552,523                     | 20,243,130                     | 15,404,099                      | 18,190,352                      | 26,743,344                     | 29,901,336                     | 27,382,571                      | 30,800,827                      |
| Revenue                                                                | 829,041                        | 829,041                        | 82,495                          | 82,495                          | 846,494                        | 846,494                        | 1,344,184                       | 1,344,184                       |
| Loss before income tax benefit                                         | (2,733,531)                    | (2,733,531)                    | (1,908,162)                     | (1,908,164)                     | (4,198,628)                    | (4,198,630)                    | (3,270,756)                     | (3,270,756)                     |
| Income tax benefit                                                     | 134,226                        | 329,487                        | 134,351                         | 230,001                         | 134,351                        | 506,087                        | 133,975                         | 394,239                         |
| Net loss                                                               | (2,599,305)                    | (2,404,044)                    | (1,773,811)                     | (1,678,163)                     | (4,064,277)                    | (3,692,543)                    | (3,136,781)                     | (2,876,517)                     |
| Net loss available to common shareholders                              | (2,823,015)                    | (2,627,754)                    | (1,962,368)                     | (1,866,720)                     | (4,239,982)                    | (3,868,247)                    | (3,405,586)                     | (3,145,322)                     |
| Net loss available to common shareholders per basic and dilutive share | \$(0.16)                       | \$(0.15)                       | \$(0.11)                        | \$(0.10)                        | \$(0.21)                       | \$(0.19)                       | \$(0.13)                        | \$(0.13)                        |

## BIOENVISION, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## JUNE 30, 2004 AND 2003

## NOTE 10 Quarterly Financial Data (Unaudited) - continued

| 2003                                                                   | First Quarter<br>(as reported) | First Quarter<br>(as restated) | Second Quarter<br>(as reported) | Second Quarter<br>(as restated) | Third Quarter<br>(as reported) | Third Quarter<br>(as restated) | Fourth Quarter<br>(as reported) | Fourth Quarter<br>(as restated) |
|------------------------------------------------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|--------------------------------|--------------------------------|---------------------------------|---------------------------------|
| Goodwill                                                               | 4,704,100                      | 2,341,557                      | 4,704,100                       | 2,341,557                       | 4,704,100                      | 2,341,557                      | 3,902,705                       | 1,540,162                       |
| Total assets                                                           | 32,890,319                     | 30,527,776                     | 31,171,135                      | 28,808,592                      | 29,516,022                     | 27,153,479                     | 28,535,675                      | 26,173,132                      |
| Deferred tax liability                                                 | 7,503,900                      | 3,778,211                      | 7,351,800                       | 3,500,454                       | 7,199,700                      | 3,025,191                      | 6,317,702                       | 1,459,814                       |
| Total liabilities                                                      | 9,962,050                      | 6,236,362                      | 9,267,577                       | 5,416,235                       | 9,055,715                      | 4,881,205                      | 9,707,283                       | 4,849,394                       |
| Accumulated deficit                                                    | (23,160,935)                   | (21,797,790)                   | (24,185,647)                    | (22,696,848)                    | (25,884,959)                   | (24,072,992)                   | (28,651,443)                    | (26,156,098)                    |
| Shareholders equity                                                    | 22,928,269                     | 24,291,414                     | 21,903,558                      | 23,392,357                      | 20,460,307                     | 22,272,274                     | 18,828,392                      | 21,323,738                      |
| Revenue                                                                | 209,091                        | 209,091                        | 209,091                         | 209,091                         | 45,753                         | 45,753                         | 40,922                          | 40,922                          |
| Loss before income tax benefit                                         | (2,064,459)                    | (2,064,459)                    | (955,536)                       | (955,536)                       | (1,634,992)                    | (1,634,992)                    | (2,628,242)                     | (2,628,242)                     |
| Income tax benefit                                                     | 152,100                        | 600,101                        | 152,100                         | 277,757                         | 152,100                        | 475,263                        | 80,603                          | 763,982                         |
| Net loss                                                               | (1,912,359)                    | (1,464,358)                    | (803,436)                       | (677,779)                       | (1,482,892)                    | (1,159,729)                    | (2,547,639)                     | (1,864,260)                     |
| Net loss available to common shareholders                              | (2,133,637)                    | (1,685,636)                    | (1,024,715)                     | (899,058)                       | (1,699,307)                    | (1,376,144)                    | (2,766,485)                     | (2,083,106)                     |
| Net loss available to common shareholders per basic and dilutive share | \$(0.12)                       | \$(0.10)                       | \$(0.06)                        | \$(0.05)                        | \$(0.10)                       | \$(0.08)                       | \$(0.17)                        | \$(0.13)                        |

The quarterly net loss per common share amounts are rounded to the nearest cent. Annual net loss per common share may vary depending on the effect of such rounding.



F-41

---

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated fees and expenses in connection with the issuance and distribution of the securities being registered hereunder, which fees and expenses will be borne solely by the registrant.

| <b>Description</b>                | <b>Amount</b>  |
|-----------------------------------|----------------|
| Legal fees and expenses*          | \$50,000       |
| Accounting fees and expenses*     | 15,000         |
| Printing fees and expenses*       | 15,000         |
| Blue sky fees and expenses*       | 2,000          |
| Transfer agent fees and expenses* | 1,000          |
| Miscellaneous expenses*           | 17,000         |
| <br>Total                         | <br>\$ 100,000 |

\* Estimated pursuant to Rule 511 of Regulation S-K.

**Item 14. Indemnification of Directors and Officers.**

The indemnification of officers and directors of the Registrant is governed by Section 145 of the General Corporation Law of the State of Delaware, DGCL, and our Certificate of Incorporation, as amended, and our By-Laws. Subsection (a) of DGCL Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in the manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Subsection (b) of DGCL Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in a connection with the defense or settlement of such action or suit if the person acted in good faith and in the manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

DGCL Section 145 further provides that to the extent that a present or former director or officer is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. In all cases in which indemnification is permitted under subsection (a) and (b) of Section 145 (unless ordered by a court), it shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances.



because the applicable standard of conduct has been met by the party to be indemnified. Such determination must be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders. The statute authorizes the corporation to pay expenses incurred by an officer or director in advance of the final disposition of a proceeding upon receipt of an undertaking by or on behalf of the person to whom the advance will be made, to repay the advances if it shall ultimately be determined that he was not entitled to indemnification. DGCL Section 145 also provides that indemnification and advancement of expenses permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain liability insurance on behalf of its directors, officers, employees and agents regardless of whether the corporation would have the statutory power to indemnify such persons against the liabilities insured.

Article Seven of our Certificate of Incorporation, as amended, which we refer to as the Certificate, provides that none of our directors shall be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director except for liability (i) for any breach of the director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (involving certain unlawful dividends or stock purchases or redemptions), or (iv) for any transaction from which the director derived an improper personal benefit.

Pursuant to Section 145(g) of the DGCL, our By-Laws, as amended, authorize us to obtain insurance to protect officers and directors from certain liabilities, including liabilities against which the Registration cannot indemnify its officers and directors.

In derivative actions, we may only protect from liability our officers, directors, employees and agents against expenses actually and reasonably incurred in connection with the defense or settlement of a suit, and only if they acted in good faith and in a manner they reasonably believed to be in, or not opposed to, the best interests of the corporation. Indemnification is not permitted in the event that the director, officer, employee or agent is actually adjudged liable to us unless, and only to the extent that, the court in which the action was brought so determines.

Our Certificate permits us to protect from liability our directors except in the event of: (1) any breach of the director's duty of loyalty to us or our stockholders; (2) any act or failure to act that is not in good faith or involves intentional misconduct or a knowing violation of the law; (3) liability arising under Section 174 of the DGCL, relating to unlawful stock purchases, redemptions, or payment of dividends; or (4) any transaction in which the director received an improper personal benefit.

**Item 15. Recent Sales of Unregistered Securities.**

We did not sell any equity securities during our 2004 fiscal year that were not registered under the Securities Act and have not previously been described in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

**Item 16. Exhibits and Financial Statement Schedules.**

| 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)                                    |



## Edgar Filing: BIOENVISION INC - Form POS AM

|         |                                                                                                                                           |
|---------|-------------------------------------------------------------------------------------------------------------------------------------------|
| 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)                                                    |
| 3.2     | Amended and Restated By-Laws of the Registrant. (13)                                                                                      |
| 3.2(a)  | Amendment to Bylaws, effective April 30, 2002 (6)                                                                                         |
| 4.1     | Certificate of Designation (6)                                                                                                            |
| 4.2     | Form of Warrant (6)                                                                                                                       |
| 4.3     | Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)                      |
| 4.4     | Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)                                           |
| 4.5     | Rights Agreement, dated as of November 17, 2004, between Bioenvision, Inc. and American Stock Transfer & Trust Company (15)               |
| 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 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 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)
- 10.15 Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Chirstopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 10.16 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.17 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.18 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implimed, dated as of May 6, 1997. (12)
- 10.19 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.20 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.21 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.22 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.23 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.24 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.25 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)





Edgar Filing: BIOENVISION INC - Form POS AM

|        |                                                                                                                                                               |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.26  | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5) |
| 10.27  | Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)                                        |
| 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)                                                          |
| 21.1   | Subsidiaries of the registrant (4)                                                                                                                            |
| * 23.1 | Consent of Grant Thornton LLP                                                                                                                                 |
| 24.1   | Power of Attorney (appears on signature page)                                                                                                                 |

-----  
\* Filed herewith.

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



Edgar Filing: BIOENVISION INC - Form POS AM

- (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 Current Report on Form 8-K, filed with the SEC on November 18, 2004.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933, as amended.
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent not more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

*Provided, however,* that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of this offering.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on August 4, 2005.

BIOENVISION, INC.

By /s/ Christopher B. Wood

Christopher B. Wood, Chairman of the

Board and Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Christopher B. Wood as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him/her and in his/her name, place and stead, in any and all capacities, to sign any and all amendments and post-effective amendments to this registration statement, and make such changes and additions to this registration statement for the same offering that may be filed under Rule 462(b), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto the attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done and about the premises, as fully to all intents and purposes as he/she might or could do in person, thereby ratifying and confirming all that the attorney-in-fact and agent, or his/her substitutes, may lawfully do or cause to be done by virtue thereof and the registrant hereby confers like authority on its behalf.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| <u>Signatures</u>                                           | <u>Title</u>                                                                             | <u>Date</u>    |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------|----------------|
| <u>/s/ Christopher B. Wood, M.D.</u><br>Christopher B. Wood | Chairman and Chief Executive Officer and Director<br>(Principal Executive Officer)       | August 4, 2005 |
| * David P. Luci                                             | Chief Financial Officer, General Counsel<br>(Principal Financial and Accounting Officer) | August 4, 2005 |
| * Thomas S. Nelson, C.A.                                    | Director                                                                                 | August 4, 2005 |
| * Michael Kauffman                                          | Director                                                                                 | August 4, 2005 |
| * Andrew N. Schiff                                          | Director                                                                                 | August 4, 2005 |

\* By /s/ Christopher B. Wood, M.D.

Christopher B. Wood

Attorney-in-fact

---

**Exhibit Index**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                                                                       |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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)                                                                                                                   |
| 3.2                | Amended and Restated By-Laws of the Registrant. (13)                                                                                                                                                     |
| 3.2(a)             | Amendment to Bylaws, effective April 30, 2002 (6)                                                                                                                                                        |
| 4.1                | Certificate of Designation (6)                                                                                                                                                                           |
| 4.2                | Form of Warrant (6)                                                                                                                                                                                      |
| 4.3                | Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)                                                                                     |
| 4.4                | Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)                                                                                                          |
| 4.5                | Rights Agreement, dated as of November 17, 2004, between Bioenvision, Inc. and American Stock Transfer & Trust Company (15)                                                                              |
| 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)                                                                                      |





Edgar Filing: BIOENVISION INC - Form POS AM

- 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 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 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)
- 10.15 Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Chirstopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 10.16 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.17 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.18 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)
- 10.19 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.20 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.21 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)



Edgar Filing: BIOENVISION INC - Form POS AM

|        |                                                                                                                                                               |
|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.22  | License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)                                                          |
| 10.23  | Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)                      |
| 10.24  | Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)    |
| 10.25  | Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)                                                        |
| 10.26  | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5) |
| 10.27  | Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)                                        |
| 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)                                                          |
| 21.1   | Subsidiaries of the registrant (4)                                                                                                                            |
| * 23.1 | Consent of Grant Thornton LLP                                                                                                                                 |
| 24.1   | Power of Attorney (appears on signature page)                                                                                                                 |

-----  
\* Filed herewith.

(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.



## Edgar Filing: BIOENVISION INC - Form POS AM

- (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 Current Report on Form 8-K, filed with the SEC on November 18, 2004.