

Edgar Filing: BIOENVISION INC - Form 10-K

BIOENVISION INC  
Form 10-K  
September 11, 2006

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-K

Mark One)

Annual report pursuant to Section 13 or 15(d) of the Securities  
----- Exchange Act of 1934.

For the fiscal year ended June 30, 2006.

OR

----- Transition report pursuant to Section 13 or 15(d) of the Securities  
Exchange Act of 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number: 0-18299

BIOENVISION, INC.  
-----

(Exact name of registrant as specified in its charter)

Delaware 13-4025857  
-----  
(State or other jurisdiction of (IRS Employer  
incorporation or organization) Identification No.)

345 Park Avenue, 41st Floor  
New York, New York 10154  
-----  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 750-6700

Securities Registered Pursuant to Section 12(b) of the Act: None

Securities Registered Pursuant to Section 12(g) of the Act: Common Stock, \$0.001  
par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as  
defined in Rule 405 of the Securities Act. Yes \_\_\_ No   
-----

Indicate by check mark if the registrant is not required to file reports  
pursuant to Section 13 or Section 15(d) of the Act. Yes \_\_\_ No   
-----

Indicate by checkmark whether the registrant (1) has filed all reports required  
to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during  
the past 12 months (or for such shorter period that the registrant was required  
to file such reports), and (2) has been subject to such filing requirements for  
the past 90 days. Yes  No \_\_\_  
-----

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of

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

Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. Large accelerated filer \_\_\_  
Accelerated filer X Non-accelerated filer \_\_\_.

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

The aggregate market value of the voting stock held by non-affiliates computed by reference to the last price at which the stock was sold, as of August 1, 2006, was \$190,285,863.

The number of shares of Bioenvision common stock, par value \$.001 per share, outstanding as of August 1, 2006 was 41,456,616.

Portions of the registrant's definitive proxy statement for its 2006 annual meeting of stockholders are incorporated by reference into Items 10, 11, 12, 13, and 14 of Part III of this Form 10-K.

BIOENVISION, INC.  
Annual Report on Form 10-K  
Fiscal Year Ended June 30, 2006  
INDEX

PART I	
ITEM 1. BUSINESS.....	1
ITEM 1A. RISK FACTORS.....	11
ITEM 1B. UNRESOLVED STAFF COMMENTS.....	24
ITEM 2. PROPERTIES.....	24
ITEM 3. LEGAL PROCEEDINGS.....	24
ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.....	24
PART II	
ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.....	25
ITEM 6. SELECTED FINANCIAL DATA.....	27
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATION.....	28
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.....	37
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.....	37
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.....	37
ITEM 9(a) CONTROLS AND PROCEDURES.....	38
ITEM 9(b) OTHER INFORMATION.....	40
PART III	
ITEM 10. DIRECTORS AND OFFICERS OF THE REGISTRANT.....	40
ITEM 11. EXECUTIVE COMPENSATION.....	40
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.....	41
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.....	41
ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.....	41

# Edgar Filing: BIOENVISION INC - Form 10-K

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.....41

## PART I

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

### Item 1. Business

#### Overview

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

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

In March 2006, we entered into a Marketing and Distribution Agreement with Mayne Pharma Limited, a public company in Australia, to sell, market and distribute Evoltra(R) (Clofarabine) in Australia and New Zealand in certain cancer indications. We anticipate entering into similar arrangements with other marketing and distribution partner(s) around the world (outside North America) to capitalize on the commercial potential of Evoltra(R) (Clofarabine), with a

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

fully integrated sales and marketing team being a primary focus for the sales and marketing partner(s) we may select at any time or from time to time.

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

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

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

Bioenvision holds an exclusive worldwide license for clofarabine (outside Japan and Southeast Asia) and an exclusive, irrevocable option to develop, market and distribute clofarabine for all human applications in Japan and Southeast Asia. Bioenvision granted an exclusive sublicense to Genzyme to co-develop clofarabine for cancer indications in the US and Canada. Genzyme is commercializing clofarabine for certain cancer indications in the US and Canada under the brand name Clolar(R). Bioenvision holds an exclusive license in the US and Canada for all

-1-

non-cancer indications. Bioenvision originally obtained clofarabine development and commercialization rights under patents held by Southern Research Institute.

In the U.S., in December 2004, the Food and Drug Administration, or FDA, approved clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine was the first new medicine initially approved in the U.S., for children with leukemia in more than a decade. Our U.S. partner, Genzyme Corporation, received Orphan Drug designation status for clofarabine in the U.S., providing marketing exclusivity for 7 years. Genzyme is marketing clofarabine under the brand name Clolar(R) in the U.S.

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

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

In addition to Evoltra(R) and Modrenal(R), we are currently in clinical development of Suvus(R) for chronic hepatitis C. This product is also in

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

pre-clinical development for the treatment of West Nile Virus and influenza.

For the year ended June 30, 2006, our total revenue and net loss applicable to common stockholders were approximately \$5,309,000 and \$24,236,000, respectively. Our revenues from U.S. and European operations are detailed in Note 7 to our Consolidated Financial Statements included in this Annual Report on Form 10-K. While we seek to increase profitability and cash flow from operations, we will need to continue to achieve growth of product sales and other revenues sufficient for us to attain these objectives. The rate of our future growth will depend, in part, upon our ability to successfully market and distribute our approved products and upon our ability to successfully develop or acquire and commercialize new product candidates.

### Products and pipeline

Candidate	Indication	Status	U.S. and Canada rights	Ex-U.S. and Canada rights
Evoltra(R) Clofarabine (Clolar(R))	Relapsed or Refractory Acute Lymphoblastic Leukemia (ALL)	Marketed in U.S. (pediatric); Filed in E.U. (pediatric)	Genzyme	Bioenvision
	Acute Myelogenous Leukemia (AML)	Phase II in E.U. (adult)	Genzyme	Bioenvision
	Refractory Chronic Lymphocytic Leukemia (CLL)	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(R)	Breast Cancer	At Market in U.K & Germany.; Phase IV in U.K.; Phase II in U.K.	Bioenvision	Bioenvision
	Prostate Cancer	Phase II in U.S.	Bioenvision	Bioenvision
Suvus	Hepatitis C	Investigator Sponsored Phase II in Europe and Middle East	Bioenvision	Bioenvision

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

### Our Products

#### Evoltra(R) (Clofarabine)

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

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

In addition, clofarabine (Evoltra(R)) is in clinical development for the treatment of myelodysplastic syndrome (MDS), chronic lymphocytic leukemia (CLL), chronic myeloid leukemia (CML), non-Hodgkin's lymphoma (NHL), multiple myeloma (MM), solid tumors and as a preconditioning regimen for transplantation.

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

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

In the U.S., in December 2004, the Food and Drug Administration, or FDA, approved clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine was the first new medicine initially approved in the U.S., for children with leukemia in more than a decade. Our U.S. partner, Genzyme Corporation, received Orphan Drug designation status for clofarabine in the U.S., providing marketing exclusivity for 7 years. 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 leukemia 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 1970's, 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

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

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 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 a NDA was filed by Genzyme with the FDA in March 2004, based upon the interim

3

results of 70 patients enrolled in these two trials. In August 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 Phase II regulatory study of clofarabine as a first-line treatment for older adult patients newly diagnosed with AML. We completed enrollment of this Bioenvision-sponsored Phase II regulatory trial in February 2006 and locked the database in anticipation of our submitting a Marketing Authorization Application with EMA later in calendar 2006 based in large part upon this clinical data.

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 marketing in pediatric AML, requesting additional information. In connection with the approval that was granted by the FDA, Genzyme is required to conduct further controlled clinical studies of clofarabine to verify and describe its clinical benefit in ALL.

Clofarabine is currently being evaluated in an IST Phase II clinical trial for refractory CLL in the U.S. In addition, commencing in fourth quarter of calendar 2006, we intend to investigate clofarabine in European Phase II clinical trials for MDS and solid tumor cancer indications. 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. Bioenvision believes the

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

initial data from the Phase I clinical trials indicate sufficient possible activity for clofarabine in certain solid tumor types to warrant further clinical development. 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.

Pursuant to the terms of our co-development agreement with Genzyme, the successor-in-interest to ILEX Oncology, Inc. following the merger consummated between Genzyme and Ilex in December 2004, 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 and except for non-cancer indications). 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, or SRI, the inventor of clofarabine, on our European annual net sales. Although we have not received payment from Genzyme for our development costs incurred since the Genzyme's acquisition of Ilex, we are actively discussing these reimbursements with Genzyme in an ongoing dialogue and are actively working on developing a consensus with Genzyme management for a development plan and budget going forward.

Pursuant to the terms of our co-development agreement with SRI, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications except for certain 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 SRI to market and distribute clofarabine in Japan and Southeast Asia for all human applications. We have exercised the right to convert the option into an exclusive license and are actively negotiating with SRI to finalize the terms of the license for clofarabine rights in Japan and Southeast Asia and hope to conclude a transaction in the second half of 2006.

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

4

Modrenal (R)

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

Modrenal's(R) approved indication enables us to promote Modrenal(R) for use immediately after relapse to initial hormone therapy such as tamoxifen or one of a class of drugs known as aromatase inhibitors (including Faslodex and Arimidex). However, we are initially positioning Modrenal(R) 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



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

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(R) 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 together included 714 patients with post-menopausal advanced breast cancer who received Modrenal(R) 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(R) 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(R) 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(R) has an acceptable side-effect profile. On the basis of these data, Modrenal(R) 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(R) in May 2004 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. Our strategy may include seeking regulatory approval for Modrenal(R) 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. We will continue to develop our commercial and regulatory strategies for Modrenal(R) as we continue to analyze the results of these clinical data.

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. We plan to use the data from these clinical trials to support a filing process for mutual recognition for approval of Modrenal(R) on a country-by-country basis in Europe. Each such approval, if granted, would be based upon Modrenal's(R) approval in the U.K. for post-menopausal advanced breast cancer following relapse to initial hormone therapy. The 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(R) 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(R). 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

We anticipate that revenues derived from clofarabine and Modrenal(R) will permit us to further develop the other products currently in our product pipeline. The work to date on these compounds has been limited because of the need to concentrate on clofarabine and Modrenal(R) but management believes these compounds have potential value.

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

### Suvus (TM)

Suvus(TM), especially when photo-sensitized by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Investigator sponsored Phase II clinical trials have been completed in the Middle East to study

5

Suvus'(TM) use in treating hepatitis C virus infection. We announced interim results at the UBS Global Life Sciences Conference in New York in September 2005 and continue to monitor these data. Suvus(TM) was given to 25 patients with genotype 4 hepatitis C who had failed a prior treatment, including interferon in many of the patients. Sixteen (64%) of the patients had cirrhosis. Suvus(TM) was given orally for 100 days and measurement of the viral load was made at 50 days. At 50 days, 22 (88%) patients had shown a reduction in viral load of greater than 70%. Of these responders, 14 (64%) had a clearance of greater than 90%, with four responders having complete viral clearance.

Seven of the 25 patients have had viral load measured at 100 days. Six of these patients show continued reduction in viral load and the seventh patient, who had been one of the three non-responders at 50 days, had a greater than 90% reduction in viral load. No major adverse events were noted.

Methylene blue, the parent compound in Suvus(TM), is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. Prior to the fourth quarter of 2005, we tested for impairment our methylene blue intangibles acquired in connection with the Pathagon acquisition and determined that, based on our assumptions, the sum of the expected future cash flows, undiscounted and pertaining solely and exclusively to approved indications, exceeded the carrying value of its long-lived assets and therefore we did not recognize an impairment. Due to the loss of an intellectual property patent suit relating to the international use of methylene blue in fresh frozen plasma we re-evaluated the intangible asset relating to methylene blue at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, again relating solely and exclusively to approved uses of methylene blue, were less than the carrying value. As a result, we recognized a non-cash impairment loss of \$5,276,000, equal to the difference between the estimated future cash flows for approved uses of methylene blue, discounted at an appropriate rate, and the carrying amount of the asset. Making the impairment determination and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective. At June 30, 2006, we received an independent third-party valuation of this intangible asset which confirmed that such estimated future cash flows continued to be worth more than the carrying value of methylene blue and, therefore, no further impairment was deemed to be required.

### Velostan

Velostan is a cytostatic drug currently under investigation as an anticancer agent and as an antimicrobial. 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(R) Technology

With the acquisition of Pathagon in February 2002, we acquired patents,

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

technology and technology patents relating to OLIGON(R) anti-infective technology, and have licensed rights from Oklahoma Medical Research Foundation for the use of thiazine dyes, including methylene blue, for other anti-infective uses.

The OLIGON(R) 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(R) 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(R) 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(R) technology have been granted and additional patents have been filed. In addition, patents have been filed in Europe, Canada and Japan.

### Gene Therapy Technology

Our product portfolio also includes a variety of gene therapy products that, 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

6

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. The gene therapy technology has been allocated limited resources for development because of the emphasis on the commercial development of clofarabine. However, it is our intention to add resource to the development of this platform technology when sufficient revenue resources allow.

### Animal Health Products

We also have one animal health product, Vetoryl(R) (trilostane), 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 U.K., 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 U.K. 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 U.S. for \$5.5 million of total consideration (including milestone payments) and a royalty of 2% - 4% of annual net sales.

### Patents and Proprietary Rights

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

Our success will depend, in part, upon our ability to obtain and enforce protection for our products 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. Our policy is to file patent applications in the U.S. 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 U.S. 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 U.S. patents one of which expired in 2005 and two of which expire in 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. In addition, for Gene Therapy we have international process and use patent applications filed which, if patents are issued, will expire in April 2018 and for OLIGON(R) we have process, use and composition of matter patents in the U.S. and internationally which expire on or before April 2019 and a patent application in Japan which expires in October 2018.

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

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

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 clofarabine and another arrangement with Edwards Lifesciences for the marketing of short-term vascular access catheters using the OLIGON(R) technology. Recently, we have entered into arrangements with Innovex, an affiliate of Quintiles Corporation, for the sales and marketing of Evoltra(R) (clofarabine) in certain E.U. countries from the date of marketing approval in May 2006 through November 2007, subject to certain circumstances. However, in order to market Evoltra(R) effectively and independently, 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. We are currently considering the most appropriate long term strategy to capitalize on the commercial value of Evoltra(R) which may include pursuing an independent, fully-integrated sales and marketing force within the E.U. or, alternatively, marketing and distributing Evoltra(R) through one or more sales agents or marketing and distribution partner(s) in the E.U. or any other part of the world within which we have marketing rights to Evoltra(R). In this regard, in March 2006, we entered into a Marketing and Distribution Agreement with Mayne Pharma Limited, a public company in Australia, to develop, market and distribute Evoltra(R) (Clofarabine) in Australia and New Zealand in certain cancer indications. We anticipate entering into similar arrangements with other marketing and distribution partner(s) around the world (outside North America) to capitalize on the commercial potential of Evoltra(R) (Clofarabine), with a fully integrated sales and marketing team being a primary focus for the sales and marketing partner(s) we may select at any time or from time to time.

We have also engaged in our own marketing and sales efforts in connection with the marketing and sale of Modrenal(R) in the U.K.

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

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 are 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. We do not have and do not intend to establish any internal product testing, manufacturing or distribution capabilities; rather, we will rely solely and exclusively on third party providers of these services for the foreseeable future.

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

### 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

8

benefits of scientific, clinical and other personnel; analytical and other testing costs; professional fees; and insurance and other administrative expenses. We have spent approximately \$11,727,000 and \$10,895,000 on research and development activities for the fiscal years ended June 30, 2006 and 2005, 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:

- o pre-clinical laboratory and animal tests;
- o submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin;
- o adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use;
- o submission to the FDA of a new drug application; and
- o 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

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

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

9

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

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

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, local and foreign 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 U.S. 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 be assured 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 U.S., 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 June 30, 2006, we had 33 full-time employees based in New York, New York, and Edinburgh, Scotland.

## 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 annual report as an inactive textual reference only.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports are available free of charge through the Investor Relations section of our web site as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, NW, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site (<http://www.sec.gov>) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

## Item 1A. Risk Factors

### Factors that May Affect Our Business

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

You should carefully consider the following risks before you decide to buy our common stock. Our business, financial condition or operating results may suffer if any of the events described in the following risk factors actually occur. All known risks are presented in this annual report on Form 10-K. 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.

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, raising capital, entering into various collaborative agreements for the in-licensing and/or development of products and technologies, hiring personnel and developing and testing our

11

products. We have not generated any substantial revenues to date and we are not profitable. 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 loss applicable to common stockholders of approximately \$24,236,000 for the fiscal year ended June 30, 2006. At June 30, 2006, we had an accumulated deficit of approximately \$86,567,000. We anticipate that we may continue to incur operating losses for the foreseeable future. We may never generate substantial 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 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 our lead drugs, Evoltra(R) and Modrenal(R), each of which has received at least one regulatory approval, additional pre-clinical and clinical studies are required in our effort to seek further approved indications for these drugs.

Modrenal(R) is approved and we market Modrenal(R) in the U.K. for the treatment of advanced, post-menopausal breast cancer. Currently, we are conducting a Phase II clinical trial in the U.K. for its treatment of pre-menopausal breast cancer which is a new potential indication for this approved drug.

Evoltra(R) is being studied in pediatric ALL, adult AML, MDS, solid tumor cancers and certain non-cancer indications in studies ranging from pre-clinical to Phase II/III.

The results from pre-clinical testing and early clinical trials have often

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

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:

- o inability of vendors to manufacture sufficient quantities of materials for use in clinical trials;
- o slower than expected rate of patient recruitment or variability in the number and types of patients in a study;
- o inability to adequately follow patients after treatment;
- o unforeseen safety issues or side effects;
- o lack of efficacy during the clinical trials; or
- o 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(R), an anti-microbial compound, and Suvus(TM), an anti-viral agent, respectively, which we acquired in February 2002 in the Pathagon acquisition. At June 30, 2005, due to the loss of an intellectual property patent suit relating to the international use of Suvus(TM) in fresh frozen plasma, we re-evaluated the fair value of the intangible assets relating to Suvus(TM). At that date, we estimated that our undiscounted future cash flows pertaining solely and exclusively to approved uses of Suvus(TM) were less than the carrying value of our long-lived asset. As a result, we recognized a non-cash impairment loss of \$5,276,000, equal to the difference between the estimated future cash flows related solely to approved uses of Suvus(TM), discounted at an appropriate rate, and the carrying amount of the asset. Making the determinations of impairment and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows of the assets. At June 30, 2006, subsequent to the recognition of the impairment, the net intangible assets

12

associated with these products amounted to approximately \$6,886,000 and constituted approximately 11% of our total assets and approximately 15% of our stockholders' equity.

We do not currently devote any significant time or resources to the research and development of OLIGON and only intend to do so if, and to the extent, we successfully commercialize our lead drugs, Evoltra(R) and Modrenal(R), over the next two years. Historically, we have not devoted significant time or resource

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

to the research and development of Suvus(TM) but our management and board of directors is currently considering the appropriate level of time and resource to be devoted to Suvus(TM) over the next several years. 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 a further impairment of these assets in the future, which could result in a material impact on our future results of operations. Changes in events or circumstances that may affect long-lived assets, particularly in the pharmaceutical industry, makes judgments and assumptions with respect to the future cash flows highly subjective and may include, but are not limited to, cancellations or terminations of license agreements or the risk of competition that could render our products noncompetitive or obsolete.

We depend on our co-development agreement with Genzyme and if it does not proceed as planned, we may incur delay in the commercial value realized from Evoltra(R) ( clofarabine), which may delay our ability to generate significant revenues and cash flow from the sale of Evoltra(R).

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 certain cancer indications in the U.S. and Canada.

If Genzyme fails to meet its obligations under the co-development agreement including its obligation to cooperate and share data with us, we could lose valuable time in further developing clofarabine and further commercializing the drug both in the U.S. and in Europe. We can not provide assurance that Genzyme will cooperate with us or 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 Evoltra(R) 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 and/or market Evoltra(R), obtain necessary regulatory approvals, and generate sales and cash flow from the sale of Evoltra(R).

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 successfully complete such responsibilities or, if successfully completed, to complete such tasks in timely fashion.

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-indication marketing partner. No assurance can be given that we or Genzyme have the oncology experience required to work successfully with the applicable regulatory authorities to build upon the licensed indications for Clofarabine.

With respect to Modrenal(R), our long-term drug development objectives for Modrenal(R) may include attempting to test the drug and get approval in the U.S. for treatment of advanced post-menopausal breast cancer patients. These trials

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

would take significant time and resources and no assurance can be given that developing the drug in this indication will result in a U.S. approval for Modrenal(R) in advanced post-menopausal breast cancer patients.

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

- o discovery during pre-clinical testing or clinical trials that the products are ineffective or cause harmful side effects;
- o failure to receive necessary regulatory approvals;

13

- o inability to manufacture on a large or economically feasible scale;
- o failure to achieve market acceptance; or
- o preclusion from commercialization by proprietary rights of third parties.

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

We rely on compounds and technology licensed from third parties and termination of any of those licenses would result in the loss of significant rights

We hold an exclusive worldwide license for clofarabine (outside Japan and Southeast Asia) and we are currently negotiating the terms of a proposed exclusive license for clofarabine in Japan and Southeast Asia. We granted an exclusive sublicense to Genzyme to develop and commercialize clofarabine for cancer indications in the US and Canada. We hold an exclusive license in the US and Canada for all non-cancer indications. We originally obtained clofarabine development and commercialization rights under patents held by Southern Research Institute ("SRI").

Our licenses generally may be terminated by SRI under the co-development agreement under certain circumstances. If any of our licenses are terminated, we may lose certain rights to manufacture, sell, market and distribute clofarabine or other product candidates which would significantly reduce our actual and potential revenues and have a material and negative impact on our operations. With regard to our license negotiations with SRI pursuant to which we may license the rights to manufacture, sell, market and distribute clofarabine in Japan and Southeast Asia, no assurance can be given that we will successfully in-license these rights; or if we do that these rights will be in-licensed on terms favorable to us.

If we are unsuccessful in developing and commercializing our products, our business, financial condition and results of operations could be materially adversely affected which could have a negative impact on the value of our securities.

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

Many of our products and processes are in the early or mid-stages of research, development and/or commercialization and, therefore, will require the commitment of substantial financial resources, extensive research, development, sales and marketing activities prior to being ready for sale or marketed in significant quantities. All of our commercially available products will require further development, clinical testing and regulatory approvals as we seek approvals in new indications and geographic markets. If it becomes too expensive to sustain our present commitment of resources on a long-term basis, we will be unable to continue certain necessary research and development activities. Furthermore, we cannot be certain that our clinical testing will render satisfactory results, or that we will receive required regulatory approvals for our new products or new indications. If any of our products, even if developed and approved, cannot be successfully commercialized, our business, financial condition, results of operations and liquidity could be materially adversely affected which could have a negative impact on the value of our common stock or debt securities obligations.

During the next several years, we will be very dependent on the commercial success of Evoltra(R).

At our present and anticipated level of operations, we may not be able to achieve and maintain profitability without continued growth in our revenues. The growth of our business during the next several years will be largely dependent on the commercial success of Evoltra(R) and our other products. We do not have long-term data on the use of the product and cannot predict whether Evoltra(R) will gain widespread acceptance, which will mostly depend on the acceptance of regulators, physicians, patients and other key opinion leaders as a relatively safe and effective drug that has certain advantages as compared to existing or future therapies.

14

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, state and local 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:

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

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

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

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



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

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 EMA, 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

16

developed by us have received orphan drug designation and new drug application approval, and the same is true with the EMA 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.

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

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 Evoltra(R) and Modrenal(R), our co-lead drugs, have demonstrated activity are areas of unmet clinical need, such as Evoltra's(R) 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(R), envision, initially, that Modrenal(R) 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 Evoltra(R) or Modrenal(R) 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 Evoltra(R), 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 AG. Potential competitors with respect to Modrenal(R) 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(R) 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

17

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

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

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 have no commercial manufacturing facilities and if the third-party manufacturers upon whom we rely fail to produce consistently and on a timely basis the raw materials or finished products in the volumes that we require or fail to meet quality standards and maintain necessary licensure from regulatory authorities, we may be unable to meet demand for our products, potentially resulting in lost revenues.

We have never manufactured any of our products and our third party manufacturers will need to consistently manufacture appropriate commercial quantities of drug supply for our products in order to fully exploit the commercial potential for our commercial products. No assurance can be given our products will be consistently manufactured 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

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

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 six full-time sales employees and two full-time marketing employees. Recently, we have entered into arrangements with Innovex, an affiliate of Quintiles Corporation, for the sales and marketing of Evoltra(R) (clofarabine) in certain E.U. countries from the date of marketing approval in May 2006 through November 2007, subject to certain circumstances. 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.

18

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 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 near retirement age and although he does not, to our knowledge, plan on leaving us in the near future, no assurance can be given that he will not do so. 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 Evoltra(R) 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

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

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(R) have expired in the U.S. and foreign countries. Thus, we and our licensor, Stegram Pharmaceutical Ltd., are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal(R). 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 SRI. 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

19

provide a competitive advantage over our competitors. Moreover, we cannot guarantee that SRI 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 potential 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.

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

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 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, Evoltra(R) and Modrenal(R), in territories outside of the U.S. Specifically, we currently market Modrenal(R) in the United Kingdom and Evoltra(R) throughout Europe. Further, more than 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:

- o difficulty in establishing or managing distribution relationships;
- o different standards for the development, use, packaging, pricing and marketing of our products and technologies;
- o our inability to locate qualified local employees, partners, distributors and suppliers;
- o the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment;
- o general geopolitical risks, such as political and economic instability, changes in diplomatic and trade relations, and foreign currency risks; and
- o risks related to the fluctuation in currency exchange rates.

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, Clinical 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

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

associated with our drug development activities.

20

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 June 30, 2006, we had stockholders' equity of approximately \$46,588,000 and working capital of approximately \$40,065,000. 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. Because we will be required to fund additional operating losses in the foreseeable future, our financial position will continue to 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(R), this would cause a decline in sales of Modrenal(R). 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 EMA, 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

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

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 claims made product liability insurance coverage in an amount which we believe is commercially reasonable. 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

21

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



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

intended by regulatory or governing bodies, our reputation may be harmed and our operations and revenues may be adversely affected.

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.

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, 2006, our stock price has ranged from a high of \$9.18 to a low of \$4.76. 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 amounts of our common stock by stockholders or by our officers and directors may cause the price of our common stock to decline.

Officers, directors and employees, and certain other stockholders hold significant numbers of shares of our common stock. Some of those shares are

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

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:

- o our board of directors approves the transaction before the third party acquires 15% of our common stock;
- o the third party acquires at least 85% of our common stock at the time its ownership exceeds the 15% level; or
- o 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.

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

As of June 30, 2006, we had 41,456,616 shares of common stock outstanding, 2,250,000 shares of Series A Convertible Participating 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 11,563,313 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from \$1.25 to \$8.80 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

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

compensation, although we do not expect to do so in the future. As of June 30, 2006, 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 cumulative Series A Convertible Participating 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 the holder's percentage ownership of our common stock. The resale of many of the shares of

23

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.

### Item 1B. Unresolved Staff Comments

None.

### Item 2. Description of Property

As of the date of this report we do not own any interest in real property. We currently lease 5,549 square feet of office space at our principal executive offices at 345 Park Avenue, 41st Floor, New York, New York 10154 for base rent of approximately \$26,351 per month. These facilities are the center for all of our administrative functions in the United States. Also, we rent approximately 2,437 square feet of office space in Edinburgh, Scotland for approximately (pound)15,120 per month. In June of 2006, we signed an addendum to the Edinburgh lease whereby beginning in September of 2006 we will be leasing additional space of 1,004 square feet for approximately and additional (pound)6,600 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 U.S. and Europe. We do not plan to conduct laboratory research in any of our facilities in the near future, rather, we plan to conduct research through collaborative arrangements with SRI and others.

### Item 3. Legal Proceedings

We are not currently engaged in any legal proceedings.

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. Each of the parties had moved for summary judgment dismissing all but one of the claims of the other parties. Those motions were all denied by the Court, and a trial date had been set for early 2006. On April 10, 2006, an out of court settlement was reached and each party executed a release, releasing all claims against the other. A Stipulation of Discontinuance was filed with the court.

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

### Item 4. Submission of Matters to a Vote of Security Holders

None.

24

## PART II

### Item 5. Market for Common Equity and Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our common stock trades on the Nasdaq National Market under the symbol "BIVN". The following table sets forth the high and low sales of our common stock for the periods indicated, as reported by Nasdaq:

	High	Low
	-----	-----
Fiscal year ended June 30, 2005		
First Quarter.....	\$9.24	\$5.90
Second Quarter.....	11.74	6.86
Third Quarter.....	9.18	5.17
Fourth Quarter .....	7.50	5.30
Fiscal year ended June 30, 2006		
First Quarter.....	\$9.18	\$6.60
Second Quarter.....	8.22	5.42
Third Quarter.....	8.95	6.35
Fourth Quarter .....	7.55	4.76

The last reported sale price of our common stock on the Nasdaq National Market on August 4, 2006 was \$4.49.

As of August 4, 2006, there were approximately 143 holders of record of our common stock.

#### Dividend Policy

We have never declared or paid cash dividends on our common 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.

25

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

### 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, 2006:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,203,167	\$ 5.68	503,500
Equity compensation plans not approved by security holders (1)	--	--	--
<b>Total</b>	<b>3,203,167</b>	<b>\$ 5.68</b>	<b>503,500</b>

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

The Board of Directors adopted, and our stockholders approved our 2003 Stock Incentive Plan at the Annual Meeting held in January of 2004. 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. There are 4,500,000 shares reserved for grants of options and rights under the plan and at June 30, 2006, 3,996,500 of these options and rights had been issued.

#### Issuer Purchases of Equity Securities

None.

#### Item 6. Selected Financial Data.

The following Selected Consolidated Financial Data should be read in conjunction with our Consolidated Financial Statements and the related Notes thereto, Management's Discussion and Analysis of Financial Condition and Results of Operations and other financial information included elsewhere in this Annual Report. The data set forth below with respect to our Consolidated Statements of Operations for the years ended June 30, 2006, 2005 and 2004, the Consolidated Balance Sheets as of June 30, 2006 and 2005 and the Consolidated Statements of Cash Flows Data for the years ended June 30, 2006, 2005 and 2004 are derived

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

from our Consolidated Financial Statements which are included elsewhere in this Annual Report and are qualified by reference to such Consolidated Financial Statements and related Notes thereto.

The data set forth below with respect to our Consolidated Statements of Operations for the years ended June 30, 2003 and 2002, the Consolidated Balance Sheets as of June 30, 2004, 2003 and 2002 and the Consolidated Statements of Cash Flows Data for the years ended June 30, 2003 and 2002 are derived from our Consolidated Financial Statements, which are not included elsewhere in this Annual Report. Our historical results are not necessarily indicative of future results of operations.

Consolidated Statements of Operations Data -----	Year Ended June 30,			
	2006 ----	2005 ----	2004 ----	2003 ----
Revenue	\$5,309,072	\$4,651,174	\$3,102,214	\$504,857
Cost of products sold	1,662,975	921,262	-	-
Operating expenses				
Research and development	11,726,981	10,894,925	4,882,574	1,689,278
Selling, general and administrative	16,562,770	10,181,711	9,082,420	4,567,413
Depreciation and amortization	974,440	1,438,517	1,348,064	1,344,969
Provision for bad debts	24,564	869,220	-	-
Loss on impairment	-	5,276,162	-	-
Total operating expenses	30,951,730	29,581,797	15,313,058	7,601,660
Loss from operations	(25,642,658)	(24,930,623)	(12,210,844)	(7,096,803)
Other income (expense), net	1,743,895	667,838	99,763	(186,426)
Loss before income taxes	(23,898,763)	(24,262,785)	(12,111,081)	(7,283,229)
Income tax benefit	-	-	1,459,814	2,117,103
Net loss	(23,898,763)	(24,262,785)	(10,651,267)	(5,166,126)
Cumulative preferred stock dividend	(337,500)	(404,079)	(856,776)	(877,818)
Net loss applicable to common stockholders	\$ (24,236,263)	\$ (24,666,864)	\$ (11,508,043)	\$ (6,043,944)
Basic and diluted shares outstanding	40,865,384	34,042,391	20,257,482	16,920,939
Basic and diluted net loss applicable to stockholders per share	\$ (0.59)	\$ (0.72)	\$ (0.57)	\$ (0.36)

Edgar Filing: BIOENVISION INC - Form 10-K

As of June 30,

Consolidated Balance

Sheets Data	2006	2005	2004	2003	2002
Cash & cash equivalents	\$3,377,937	\$31,407,533	\$18,875,675	\$7,929,686	\$12,882,
Short-term securities	41,637,106	32,746,948	-	-	
Intangible assets, net	7,549,520	8,252,936	14,563,660	15,779,399	16,921,
Total assets	62,250,464	80,790,135	42,170,844	26,173,132	32,380,
Total current liabilities	8,592,018	6,738,722	3,460,419	2,264,896	2,447,
Total shareholder's equity	46,587,721	66,613,815	30,800,827	21,323,737	25,554,

Year Ended June 30,

Consolidated Statements of Cash Flows

Data	2006	2005	2004	2003	2002
Net cash used in operating activities	(20,794,013)	(13,417,438)	(4,641,193)	(4,411,581)	(2,675,
Net cash used in investing activities	(7,463,820)	(33,384,403)	(130,917)	(541,254)	(455,
Net cash provided by financing activities	433,370	59,296,122	15,730,847	-	16,01,

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation.

The following discussion and analysis provides information which management believes is relevant to an assessment and understanding of our results of operations and financial condition. The discussion should be read together with our audited consolidated financial statements and notes included under Item 8 of this Annual Report on Form 10-K, which are presented beginning at page F-1.

Summary of Critical 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, 2006 included under Item 8 in this Annual Report on Form 10-K, which are presented beginning at page F-1.

These policies were selected because they represent the critical accounting policies and methods that are broadly applied in the preparation of the consolidated financial statements.

Revenue Recognition

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

In accordance with SEC Staff Accounting Bulletin No. 104, or SAB 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. 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 term of the licensing arrangement using the straight line method, which approximates the life of the last to expire of the underlying patents.

Royalty revenue from product licensees is recorded when persuasive evidence of an arrangement exists, the price is fixed or determinable, the goods have been delivered and collectibility is reasonably assured.

28

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.

Research and development contract revenue includes sales in our pre-commercial stage named patient program for Evoltra(R) as well as certain payments due from our co-development partner relating to the reimbursement of 50% for certain of our ongoing research costs in the development of Evoltra(R) outside the United States.

The Company follows the guidance of Emerging Issues Task Force, or ETIF, 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 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.

### Stock-Based Compensation

On July 1, 2005, the Company adopted the fair value recognition provisions of SFAS No. 123 (R) (revised 2004), "Share-Based Payment" ("SFAS 123 (R)"), requiring the Company to recognize expense related to the fair value of stock-based compensation. The modified prospective transition method was used as allowed under SFAS 123 (R). Under this method, the stock-based compensation expense includes: (a) compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of July 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, "Accounting for Stock-Based Compensation"; and (b) compensation expense for all stock-based compensation awards granted subsequent to July 1, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS 123 (R). Prior to the adoption of SFAS 123 (R), the Company had accounted for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees", as permitted by SFAS 123. Under APB Opinion No. 25, no stock-based employee compensation cost was reflected in reported net loss,



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

when options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant.

We utilize the Black-Scholes model to measure the value of an employee option. The Black-Scholes model is a trading options-pricing model that neither considers the non-traded nature of employee stock options, nor the restrictions on such trading, the lack of transferability or the ability of employees to forfeit the options prior to expiry. If the model adequately permitted consideration of the unique characteristics of employee stock options, the resulting estimate of the fair value of the stock options could be different. Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. We determine expected volatility based on historical activity. We believe that these market-based inputs provide a better estimate of our future stock price movements. We also use historical exercise patterns as our best estimate of future exercise patterns. We utilize historical turnover rates in estimating expected forfeitures separately for executives and non-executives.

### Impairment of Long-Lived Assets

We believe that the accounting estimate relating to impairment of our intangible assets involves a critical accounting estimation methodology. The estimate is highly susceptible to change from period to period because it requires management to make significant judgments and assumptions about future revenue, operating costs and development expenditures. Some of the more significant estimates and assumptions inherent in the intangible asset impairment estimation process include: the timing and amount of projected future cash flows; the discount rate selected to measure the risks inherent in the future cash flows; and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry as well as expected changes in standard of practice for indications addressed by the asset. Changes in events or circumstances that may affect long-lived assets, particularly in the pharmaceutical industry, makes judgments and assumptions with respect to the future cash flows highly subjective and may include, but are not limited to, cancellations or terminations of license agreements or the risk of competition that could render our products noncompetitive or obsolete.

### Overview and Company Status

We are a product-oriented biopharmaceutical company primarily focused upon the acquisition, development, distribution and marketing of compounds and technologies for the treatment of cancer, autoimmune disease and infection. Our product pipeline includes Evoltra(R) (Clofarabine), Modrenal(R) (for which Bioenvision has obtained regulatory approval for marketing in the United Kingdom for the treatment of post-menopausal breast cancer

29

following relapse to initial hormone therapy), and certain anti-infective technologies including the OLIGON(R) technology; an advanced biomaterial that has been incorporated into various FDA approved medical devices and Suvus(TM), an antimicrobial agent currently in clinical development for refractory chronic hepatitis C infection.

Evoltra(R) is our lead product. In May 2006 the European Medicines Agency approved Evoltra(R) for the treatment of acute lymphoblastic leukemia (ALL) in pediatric patients who have relapsed or are refractory to at least two prior regimens. The licensed indication includes patients who were less than 21 years of age at the time of initial diagnosis of their leukemia. Evoltra(R) has been granted orphan drug designation, providing marketing exclusivity for 10 years in

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

Europe, which 10-year period commenced in May 2006 upon our receipt of EMA marketing approval. We have a dedicated sales force in the U.K. and several other countries within the E.U. and will continue to expand our sales force as we continue to work through pricing and reimbursement in individual countries within the E.U.

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

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

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

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

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

In the U.S., in December 2004, the Food and Drug Administration, or FDA, approved clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine was the first new medicine initially approved in the U.S., for children with leukemia in more than a decade. Our U.S. partner, Genzyme Corporation, received Orphan Drug designation status for clofarabine in the U.S., providing marketing exclusivity for 7 years. Genzyme is marketing clofarabine under the brand name Clolar(R) in the U.S.

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

With the approval of Evoltra(R) under the EMA's centralized process, we intend to continue to expand our sales force by adding six to 10 sales specialists in each of five other key regions within the E.U. either directly or through a sales agent or marketing and distribution partner(s) which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria,

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

Belgium, Denmark and Sweden. Further, we intend to penetrate all of the other markets within the E.U. upon establishing traction in the E.U.'s major markets. Initially, outside the U.K., we maintain a fully dedicated sales force through Innovex, an affiliate of Quintiles Limited, which we intend to convert to a direct sales force of our own by fourth quarter calendar 2007.

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

30

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

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

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

In May 2003, we entered into a License and Sub-License Agreement with Dechra Pharmaceuticals, plc, or Dechra, pursuant to which we sub-licensed the marketing and development rights to Vetoryl(R) (trilostane), solely with respect to animal health applications, in the U.S. and Canada, to Dechra. We received \$1.25 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(R) technology and we have had discussions with potential product licensing partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans.

You should consider the likelihood of our future success to be highly speculative in light of our limited operating history, as well as the limited resources, problems, expenses, risks and complications frequently encountered by similarly situated companies. To address these risks, we must, among other things:

- o satisfy our future capital requirements for the implementation of our business plan;
- o commercialize our existing products; o complete development of products presently in our pipeline and obtain necessary regulatory approvals for use;
- o implement and successfully execute our business and marketing strategy to

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

- commercialize products;
- o establish and maintain our client base;
  - o continue to develop new products and upgrade our existing products;
  - o continue to establish and maintain relationships with manufacturers for our products;
  - o respond to industry and competitive developments; and
  - o attract, retain, and motivate qualified personnel.

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

31

### Results of Operations

Year Ended June 30, 2006 Compared to Year Ended June 30, 2005

We reported revenues of approximately \$5,309,000 and \$4,651,000 for the years ended June 30, 2006 and 2005, respectively, representing an increase of approximately \$658,000. This increase was primarily an increase in royalties from US sales of clofarabine of approximately \$773,000 and named patient reimbursements of approximately \$2,044,000 for sales of Evoltra(TM) . This increase was partially offset by a decrease in research and development contract revenue of approximately \$1,910,000 as the Company did not record revenue for the year ended June 30, 2006, related to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of Evoltra(TM) outside the United States because it determined that the criteria for recognizing such contract revenue had not been met. If and when the Company determines that collectibility is reasonably assured, the Company will record the revenue.

The cost of products sold for years ended June 30, 2006 and June 30, 2005 was approximately \$1,663,000 and \$921,000, respectively, representing an increase of approximately \$742,000. The cost of products sold reflects the direct costs associated with our commercial sales and royalties due on the sale of our lead products of approximately \$1,277,000 and \$525,000 for the years ended June 30, 2006 and 2005, respectively.

Research and development costs for the years ended June 30, 2006 and 2005 were approximately \$11,727,000 and \$10,895,000 respectively, representing an increase of approximately \$832,000.

Our research and development costs include costs associated with the six projects shown in the table below, five of which the Company currently devotes time and resources:

Product	(in thousands)		Change
	2006	2005	
-----	----	----	-----
Evoltra(R)	\$9,125	\$8,697	\$428

Edgar Filing: BIOENVISION INC - Form 10-K

Modrenal (R)	2,283	1,972	311
Suvus (TM)	319	131	188
Velostan	-	79	(79)
OLIGON (R)	-	16	(16)
Gene Therapy	-	-	-
	-----	-----	-----
Total	\$11,727	\$10,895	\$832
	=====	=====	=====

Evoltra(R) research and development costs for the years ended June 30, 2006 and 2005 were approximately \$9,125,000 and \$8,697,000, respectively, representing an increase of approximately \$428,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials of Evoltra(R) being conducted in Europe (which includes the filing process for EU approval) coupled with recording stock-based compensation expense, relating to stock options granted to employees that devote their time to clofarabine research and development.

Modrenal(R) research and development costs for the years ended June 30, 2006 and 2005 were approximately \$2,283,000 and \$1,972,000, respectively, representing an increase of approximately \$311,000. This increase is due primarily to the costs associated with our Phase II clinical trial in pre-menopausal cancer and Phase IV clinical trial in patients with post-menopausal cancer, which are each being conducted in the UK.

Suvus(TM) research and development costs for the years ended June 30, 2006 and 2005 were approximately \$319,000 and \$131,000, respectively, representing an increase of approximately \$188,000. The increase primarily reflects the costs associated with the ongoing, multi-center investigator sponsored Phase II clinical trial being conducted in Egypt during the twelve months ended June 30, 2006 and costs associated with the preparation of an IND application to be filed with FDA.

32

Velostan research and development costs for the years ended June 30, 2006 and 2005 were approximately \$0 and \$79,000, respectively, representing a decrease of approximately \$79,000. There were no research and development costs associated with Velostan for the year ended June 30, 2006 because our third party vendors must develop a manufacturing process to create a raceamic form of the compound for use in the Company's clinical development program in order for us to continue our development activities with this compound. No assurance can be given the Company will be able to create the L-form Velostan required for the clinical development program or, if it can, the timing of such development.

OLIGON(R) research and development costs for the years ended June 30, 2006 and 2005 were \$0 and \$16,000, respectively, representing a decrease of \$16,000. Our continued lack of devoted resource to develop this compound reflects our continued emphasis on the development of Evoltra(R) during this period.

The clinical trials and development strategy for the Evoltra(R) and Modrenal(R) 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

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

rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) Evoltra(R) research and development costs have been approximately \$23,441,000; (ii) Modrenal(R) research and development costs have been approximately \$8,652,000; (iii) Velostan research and development costs have been approximately \$380,000; (iv) Suvus(TM) research and development costs have been approximately \$508,000; (v) OLIGON(R) research and development costs have been approximately \$24,000; and (vi) Gene Therapy research and development costs have been approximately \$451,000.

Selling, general and administrative expenses for the years ended June 30, 2006 and 2005 were approximately \$16,563,000 and \$10,182,000, respectively, representing an increase of approximately \$6,381,000. This increase primarily is due to:

- o an increase of approximately \$3,450,000 in employee stock based compensation expense (a non-cash item) primarily due to the Company's adoption of SFAS 123 (R) on July 1, 2005 and the extension of the exercise period of 1,500,000 vested options originally granted to an officer of the Company from five to ten years;
- o an increase in sales and marketing costs of approximately \$1,200,000 related to the Company's development of a sales and marketing force in Europe;
- o an increase in payroll due to the significant increase in employee headcount in both New York and Edinburgh offices of approximately \$540,000;
- o an increase of approximately \$256,000 due to an increase in insurance premiums paid by the Company.

Depreciation and amortization expense for the years ended June 30, 2006 and 2005 were approximately \$974,000 and \$1,439,000, respectively, representing a decrease of approximately \$465,000. The decrease is due to the Company recording an impairment charge of approximately \$5,276,000 at June 30, 2005, which decreased the cost basis of our methylene blue intangibles.

Provision for bad debts for the years ended June 30, 2006 and 2005 were approximately \$25,000 and \$869,000, respectively, representing a decrease of approximately \$844,000. The decrease is due to the Company recording a valuation allowance relating to certain of the outstanding receivable balances from our co-development partner totaling \$869,000 in the prior year.

### Year Ended June 30, 2005 Compared to Year Ended June 30, 2004

We reported revenues of approximately \$4,651,000 and \$3,102,000 for the years ended June 30, 2005 and 2004, respectively, representing an increase of approximately \$1,549,000. 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 \$450,000, an increase in research and development contract revenue due to increased sales in the Named Patient Program, increased reimbursements from Genzyme related to clofarabine research and development expenses, in the amount of approximately \$488,000, and revenue from the sale of Modrenal(R) of approximately \$611,000.

33

The cost of products sold for years ended June 30, 2005 and June 30, 2004 were approximately \$921,000 and \$0, respectively. The cost of products sold reflects the direct costs associated with our sales of Modrenal(R) and royalties due on the sale of our lead products of approximately \$525,000.

Research and development costs for the years ended June 30, 2005 and 2004

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

were approximately \$10,895,000 and \$4,883,000 respectively, representing an increase of approximately \$6,012,000.

Our research and development costs include costs associated with the six projects shown in the table below, five of which the Company currently devotes time and resources:

	(in thousands)		
Product	2005	2004	Change
-----	----	----	-----
Evoltra (R)	\$8,697	\$2,650	\$6,047
Modrenal (R)	1,972	2,026	(54)
Suvus (TM)	131	48	83
Velostan	79	152	(73)
OLIGON (R)	16	7	9
Gene Therapy	-	-	-
	-----	-----	-----
Total	\$10,895	\$4,883	\$6,012
	=====	=====	=====

Evoltra(R) research and development costs for the years ended June 30, 2005 and 2004 were approximately \$8,697,000 and \$2,650,000, respectively, representing an increase of approximately \$6,047,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials of Evoltra(R) being conducted in Europe, certain of which are partially reimbursed by Genzyme.

Modrenal(R) research and development costs for the years ended June 30, 2005 and 2004 were approximately \$1,972,000 and \$2,026,000, respectively, representing a decrease of approximately \$54,000. The decrease primarily reflects the Company's primary focus on Evoltra(R) during this period.

Suvus(TM) research and development costs for the years ended June 30, 2005 and 2004 were approximately \$131,000 and \$48,000, respectively, representing an increase of approximately \$83,000. The increase primarily reflects the costs associated with the ongoing, multi-center investigator sponsored Phase II clinical trial being conducted in Egypt and Southern Europe during the year ended June 30, 2005.

Velostan research and development costs for the years ended June 30, 2005 and 2004 were approximately \$79,000 and \$152,000, respectively, representing a decrease of approximately \$73,000. The decrease primarily reflects the Company's primary focus on Evoltra(R) during this period.

OLIGON research and development costs for the years ended June 30, 2005 and 2004 were \$16,000 and \$7,000, respectively, representing an increase of approximately \$9,000. The increase primarily reflects pre-development costs incurred in connection with continuing co-partnering discussions.

The clinical trials and development strategy for the Evoltra(R) and Modrenal(R) 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

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

rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) Evoltra(R) research and development costs have been approximately \$14,315,000; (ii) Modrenal(R) research and development costs have been approximately \$6,369,000; (iii) Velostan research and development costs have been approximately \$380,000; (iv) Suvus(TM) research and development costs have been approximately \$189,000; (v) OLIGON research and development costs have been approximately \$25,000; and (vi) Gene Therapy research and development costs have been approximately \$451,000.

34

Selling, general and administrative expenses for the years ended June 30, 2005 and 2004 were approximately \$10,182,000 and \$9,082,000, respectively, representing an increase of approximately \$1,100,000. This increase primarily is due to:

- o an increase in payroll due to the significant increase in employee headcount in both New York and Edinburgh offices of approximately \$800,000;
- o an increase in consulting and legal fees due to the Company's expansion of regulatory and investor relations initiatives, and the restatement of the Company's financial statements included in the Company's 2004 annual report on Form 10-KSB, in the amount of \$1,559,000;
- o an increase in sales and marketing costs of approximately \$592,000 related to the Company's development of a sales and marketing force in the UK;
- o an increase of approximately \$250,000 due to an increase in the Company's annual rent expense; and
- o an increase of approximately \$97,000 due to an increase in insurance premiums paid by the Company.

These increases are substantially offset by a decrease in costs associated with the variable accounting treatment of options issued to an officer of the Company in the amount of approximately \$2,200,000.

Depreciation and amortization expense for the years ended June 30, 2005 and 2004 were approximately \$1,439,000 and \$1,348,000, respectively, representing an increase of approximately \$91,000. This increase primarily reflects the corresponding increase in our net asset base.

Provision for bad debts for the years ended June 30, 2005 and 2004 were approximately \$869,000 and \$0, respectively. The increase is due to the Company recording a valuation allowance relating to certain of the outstanding receivable balances from our co-development partner totaling \$869,000 in the current year. Management believes the amounts billed to its co-development partner and previously recorded as revenue through March 31, 2005 are supportable and continues to actively pursue collection of the outstanding balances. During its quarterly closing process the Company further evaluated the collectibility of such amounts and concluded that based upon the available information a valuation allowance was required. Additionally, based on the delay in payment from our co-development partner and other information, management concluded that collectibility was no longer reasonably assured and therefore, did not recognize revenue on amounts billed in the quarter ended June 30, 2005.

Prior to the fourth quarter of 2005, we tested for impairment our methylene blue intangibles acquired in connection with the Pathagon acquisition and determined that, based on our assumptions, the sum of the expected future cash flows, undiscounted and pertaining solely and exclusively to approved indications, exceeded the carrying value of its long-lived assets and therefore we did not recognize an impairment. Due to the loss of an intellectual property



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

patent suit relating to the international use of methylene blue in fresh frozen plasma, we re-evaluated the intangible asset relating to methylene blue at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, again relating solely and exclusively to approved uses of methylene blue, were less than the carrying value. As a result, we recognized a non-cash impairment loss of \$5,276,000, equal to the difference between the estimated future cash flows for approved uses of methylene blue, discounted at an appropriate rate, and the carrying amount of the asset. Making the impairment determination and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective.

The Company has been incurring losses since inception and therefore has not recorded an income tax provision for the years ended June 30, 2005 and 2004. The Company has recorded a deferred income tax benefit of approximately \$0 and \$1,460,000 for the years ended June 30, 2005 and 2004, respectively.

### Liquidity and Capital Resources

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

On June 30, 2006, we had cash and cash equivalents of approximately \$3,378,000, short-term securities of \$41,637,000 and working capital of \$40,065,000. Management believes the Company has sufficient cash and cash equivalents, short-term securities and working capital to continue currently planned operations through June 30, 2007.

35

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

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

For the fiscal year ended June 30, 2006 and 2005, net cash used in operating activities was approximately \$20,794,000 and \$13,417,000, respectively, representing an increase of approximately \$7,377,000. This increase is primarily due to increased costs associated with (i) our expanded research and development activity, (ii) selling general and administrative expenses, including an increase in costs associated with the expanded sales and marketing and administrative infrastructure and costs associated with the internal build out of the Company and (iii) cash paid for insurance premiums. For the fiscal year ended June 30, 2006 and 2005, net cash used in investing activities was approximately \$7,464,000 and \$33,384,000, respectively,

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

representing a decrease of approximately \$25,920,000. This decrease is primarily due to the Company investing the proceeds from our February 2005 secondary offering in short-term securities in the fiscal year ended June 30, 2005 in order to obtain a higher investment yield. For the fiscal year ended June 30, 2006 and 2005, net cash provided by financing activities was approximately \$433,000 and \$59,296,000 representing a decrease of \$58,863,000. This decrease is primarily due to the completion of the secondary public offering in February 2005 which yielded net proceeds of approximately \$55,747,000.

For the fiscal years ended June 30, 2005 and 2004, net cash used in operating activities was approximately \$13,417,000 and \$4,641,000, respectively, representing an increase of approximately \$8,776,000. This increase is primarily due to increased costs associated with (i) our expanded research and development activity, with Evoltra(R) specifically, (ii) selling general and administrative expenses, including an increase in costs associated with the expanded sales and marketing and administrative infrastructure and costs associated with the internal build out of the Company and (iii) cash paid for insurance premiums. For the fiscal years ended June 30, 2005 and 2004, net cash used in investing activities was approximately \$33,384,000 and \$131,000, respectively, representing an increase of approximately \$33,253,000. This increase is primarily due to the Company investing the proceeds from our February 2005 secondary offering in short-term securities in order to obtain a higher investment yield. For the fiscal years ended June 30, 2005 and 2004, net cash provided by financing activities was approximately \$59,296,000 and \$15,731,000 representing an increase of \$43,565,000. This increase is primarily due to the completion of the secondary public offering in February 2005 which yielded proceeds of \$55,747,000, net of related expenses.

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

	Payments Due in				
	2007	2008	2009	2010	2011
Operating Leases	\$ 1,019,728	\$ 819,600	\$ 371,623	\$178,570	-
Contractual obligations	214,602	-	-	-	-
Total	\$ 1,234,330	\$ 819,600	\$ 371,623	\$178,570	-

The contractual obligations relate to minimum payments due for research conducted on modrenal.

Off-balance sheet arrangements

We have no off-balance sheet arrangements.

### Recent Accounting Pronouncements

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

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

the tax benefit to be recognized in the financial statements. FIN 48 is effective in fiscal years beginning after December 15, 2006. We do not expect the adoption of FIN 48 to have a material impact on the results of operations or financial condition of the Company.

In May 2005, the FASB issued SFAS 154 "Accounting Changes and Error Corrections," a replacement of APB Opinion 20 and SFAS 3. SFAS 154 changes the accounting for, and reporting of, a change in accounting principle. SFAS 154 requires retrospective application to prior period's financial statements of voluntary changes in accounting principle, and changes required by new accounting standards when the standard does not include specific transition provisions, unless it is impracticable to do so. SFAS 154 is effective for accounting changes and corrections made in fiscal years beginning after December 15, 2005.

### Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

### Item 8. Financial Statements and Supplementary Data

The consolidated financial statements of Bioenvision, Inc. and its subsidiaries including the notes thereto and the report thereon, is presented beginning at page F-1.

### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

As more fully disclosed in Bioenvision's current report on Form 8-K filed on April 19, 2006, on April 18, 2006, Bioenvision appointed J.H. Cohn LLP ("J.H. Cohn") as its new independent registered public accounting firm for the fiscal year ending June 30, 2006. The decision to engage J.H. Cohn was made by the Audit Committee of the Company's Board of Directors. J.H. Cohn replaced Deloitte & Touche LLP who, as more fully disclosed in Bioenvision's current report on Form 8-K/A filed on February 21, 2006, resigned as the Company's independent registered public accounting firm, effective February 15, 2006.

### Item 9A. Controls and Procedures

#### Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

As of the end of the period covered by this annual report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rules 13a-15(e) and 15d-15(e)). Based upon the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by

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

us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission.

37

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements in accordance with U.S. generally accepted accounting principles.

Our internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In connection with the preparation of our annual consolidated financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of June 30, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting was effective as of June 30, 2006.

J.H. Cohn LLP, the independent registered public accounting firm that audited our consolidated financial statements included elsewhere in our report on Form 10-K, has issued their report on management's assessment of and the effectiveness of internal control over financial reporting, a copy of which is included below.

38

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

The Board of Directors and Stockholders of Bioenvision, Inc.:

We have audited management's assessment, included in the accompanying "Management's Report on Internal Control Over Financial Reporting", that Bioenvision, Inc. and Subsidiaries ("Bioenvision") maintained effective internal control over financial reporting as of June 30, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Bioenvision's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of Bioenvision's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Bioenvision maintained effective internal control over financial reporting as of June 30, 2006, is fairly stated, in all material respects, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also in our opinion, Bioenvision maintained, in all material respects, effective internal control over financial reporting as of June 30, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2006 consolidated balance sheet and related statements of operations, stockholders' equity and cash flows of Bioenvision and our report dated August 21, 2006 expressed an unqualified opinion on those statements.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
August 21, 2006

39

#### Changes in Internal Controls

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Remediation of Past Material Weaknesses in Internal Controls Over Financial Reporting

In connection with the filing of our annual report on Form 10-KSB, for the fiscal year ended June 30, 2005, under the direction of our principal executive officer and principal financial officer, we evaluated our disclosure controls and procedures and concluded that as of June 30, 2005, the following material weakness in internal control over financial reporting existed:

- o we did not maintain effective controls relating to the timely identification, evaluation and accurate resolution of non-routine or complex accounting matters, specifically, (i) we did not timely identify and evaluate a change of circumstances that resulted in an impairment of our intangible assets relating to certain patents, (ii) we did not timely identify and accurately resolve an accounting issue related to contractual revenue recognition and (iii) we did not timely evaluate our accounts receivable for the need of a valuation allowance, each of which resulted in a material adjustment to our consolidated financial statements for the fiscal year ended June 30, 2005.

Management discussed this material weakness with the audit committee. As of December 31, 2005, we had taken the following measures to remediate the above material weakness in our internal controls over financial reporting that existed as of June 30, 2005. The remedial actions included:

- o improving training and education for all relevant personnel involved in the preparation and review of the Company's financial statements;
- o the formation of a Disclosure Committee;
- o hiring an additional accountant; and
- o Use of prepared checklists for the preparation of periodic SEC reports to ensure the completeness and accuracy of those reports. The Company has adopted the practice of using prepared checklists for upcoming SEC periodic reports that set forth new and changing requirements to ensure that those requirements are satisfied in the periodic reports.

We believe that the material weakness referenced above has been remediated as of June 30, 2006.

Edgar Filing: BIOENVISION INC - Form 10-K

Item 9B. Other Information.

None.

PART III

Item 10. Directors and Executive Officers of the Registrant

Pursuant to Paragraph G(3) of the General Instructions to Form 10-K, the information required by Part III (Items 10, 11, 12, 13 and 14) is being incorporated by reference herein from our definitive proxy statement (or an amendment to our Annual Report on Form 10-K) to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended June 30, 2006 in connection with our 2006 Annual Meeting of Stockholders.

Item 11. Executive Compensation

See Item 10.

40

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

See Item 10.

Item 13. Certain Relationships and Related Transactions

See Item 10.

Item 14. Principal Accountant Fees and Services

See Item 10.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are being filed as part of this report:

(1) Consolidated Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Bioenvision appearing on page F-1 of this report.

(2) Consolidated Financial Statement Schedules

The following consolidated financial statement schedule of the Company for each of the years ended June 30, 2006, 2005 and 2004, is filed as part of this Annual Report on Form 10-K and should be read in conjunction with the Consolidated Financial Statements, and the related notes thereto, of the Company.

Page  
Number  
-----

Schedule II -- Valuation and Qualifying Accounts

S-3

(3) Exhibits:

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

Exhibit Number -----	Description -----
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)
41	
3.1(c)	Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)
3.1(d)	Certificate of Designations, Preferences and Rights of series A Preferred Stock (6)
3.1(e)	Certificate of Amendment to the Certificate of Incorporation, filed January 14, 2004 (15)
3.2	Amended and Restated By-Laws of the Registrant. (13)
4.1	Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
4.2	Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
4.3	Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
4.4	Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
4.5	Form of Warrant (6)



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

- 4.6 Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
- 4.7 Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)
- 4.8 Common Stock and Warrant Purchase Agreement, dated as of March 22, 2004, by and among Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
- 4.9 Registration Rights Agreement, dated March 22, 2004, by and between Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
- 4.10 Form of Warrant (16)
- 4.11 Bioenvision, Inc. 2003 Stock Incentive Plan (17)
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc.
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc.
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998. (3)
- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute to
- 42
- 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

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

- Inc dated March 24, 2000. (4)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.14 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
- 10.15 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.16 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.17 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.18 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.19 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.20 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.21 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
- 10.22 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
- 10.23 Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC(14)

- 10.24                    Employment Agreement between Bioenvision Limited and Hugh Griffith, effective as of October 23, 2002 (18)
- 10.25                    Employment Agreement between Bioenvision Limited and Ian Abercrombie, effective as of January 6, 2003 (18)
- 10.26                    Amendment # 2 to the Co-Development Agreement between Bioenvision and ILEX Oncology, Inc. dated December 30, 2003.(21)
- 10.27                    Amendment to the Co-Development Agreement between Bioenvision, Inc. and SRI, dated as of March 12, 2001.(21)
- 10.28                    Letter Agreement For Co-Development Of An Oral Clofarabine Formulation and First Amendment to Co-Development Agreement dated March 12, 2001 between Bioenvision, Inc. and ILEX .(21)
- 10.29                    Joinder made by Bioenvision, Inc., dated February 26, 2004 (22)
- 10.30                    Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Sterling SNIFF, dated as of August 12, 2005 (22)
- 10.31                    Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Steroid SpA, dated as of August 12, 2005 (22)
- 10.32                    Amendment to Employment Agreement, by and between Bioenvision and David P. Luci, dated February 6, 2006 (23)
- 10.33                    Clofarabine Marketing and Development Agreement, by and between Bioenvision Inc. and Mayne Pharma Limited, dated March 24, 2006 (24)
- 14.1                     Bioenvision Inc.'s Code of Business Conduct and Ethics (19)
- 16.1                     Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
- 16.2                     Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
- 16.3                     Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
- 16.4                     Letter from Grant Thornton LLP to the Securities and Exchange Commission , dated April 7, 2005 (20)
- 16.5                     Letter from Deloitte & Touche LLP to the

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

	Securities and Exchange Commission , dated January 19, 2006 (25)
21.1	Subsidiaries of the registrant (4)
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Prior Independent Registered Public Accounting Firm
23.3	Consent of Prior Independent Registered Public Accounting Firm
24.1	Power of Attorney (appears on Signature page)
31.1	Certification of Christopher B. Wood, Chief Executive Officer, as adopted pursuant to

44

	Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of David P. Luci, Chief Accounting Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

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

- (7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.
- (8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.
- (9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.
- (10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.
- (11) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 6, 2001.
- (12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.
- (13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.
- (14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.
- (15) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2004.
- (16) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2004.

45

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

Edgar Filing: BIOENVISION INC - Form 10-K

2006.

(25) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 20, 2006.

46

SIGNATURES AND POWER OF ATTORNEY

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned on September 11, 2006, thereunto duly authorized.

BIOENVISION, INC.

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

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

By /s/ David P. Luci

-----  
David P. Luci  
Chief Financial Officer, General Counsel  
and Corporate Secretary  
(Principal Financial and  
Accounting Officer)

Each person whose signature appears below hereby constitutes and appoints either Christopher B. Wood, M.D. or David P. Luci his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying all that said attorney-in-fact and agent or his substitute or substitutes, or any of them, may lawfully do or cause to be done by virtue hereof. In accordance with the requirements of the Exchange Act, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christopher B. Wood, M.D. ----- Christopher B. Wood, M.D.	Chairman and Chief Executive Officer and Director (Principal Executive Officer)	September 11, 2006
/s/ David P. Luci ----- David P. Luci	Chief Financial Officer, General Counsel and Corporate Secretary (Principal Financial and	September 11, 2006

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

	Accounting Officer)	
/s/ Thomas S. Nelson ----- Thomas S. Nelson, C.A.	Director	September 11, 2006
/s/ Michael Kauffman ----- Michael Kauffman	Director	September 11, 2006
/s/ Andrew N. Schiff ----- Andrew N. Schiff	Director	September 11, 2006
/s/ Steven A. Elms ----- Steven A. Elms	Director	September 11, 2006

47

### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm  
Report of Prior Independent Registered Public Accounting Firm  
Report of Prior Independent Registered Public Accounting Firm  
Consolidated Balance Sheets as of June 30, 2006 and 2005  
Consolidated Statements of Operations for years ended June 30, 2006, 2005 and 2004  
Consolidated Statements of Stockholders' Equity for years ended June 30, 2006, 2005 and 2004  
Consolidated Statements of Cash Flows for years ended June 30, 2006, 2005 and 2004  
Notes to Consolidated Financial Statements  
Report of Independent Registered Public Accounting Firm  
Report of Prior Independent Registered Public Accounting Firm  
Schedule II -- Valuation and Qualifying Accounts

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

### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Bioenvision, Inc.:

We have audited the accompanying consolidated balance sheet of Bioenvision, Inc. and Subsidiaries (the "Company") as of June 30, 2006, and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Bioenvision, Inc. and Subsidiaries as of June 30, 2006, and their results of operations and cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of June 30, 2006, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated August 21, 2006, expressed an unqualified opinion on management's assessment of internal control over financial reporting and an unqualified opinion on the effectiveness of the internal control over financial reporting.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
August 21, 2006

F-1

### REPORT OF PRIOR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Bioenvision, Inc.:

We have audited the accompanying consolidated balance sheet of Bioenvision, Inc. and subsidiaries (the "Company") as of June 30, 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. Our audit also included the consolidated financial



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

statement schedule listed in the Index at Item 15. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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 audit provides a reasonable basis for our opinion.

In our opinion, the 2005 consolidated financial statements present fairly, in all material respects, the financial position of Bioenvision, Inc. and subsidiaries as of June 30, 2005, and the results of its operations and its cash flows for the year ended June 30, 2005, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

/s/ Deloitte & Touche LLP  
Parsippany, New Jersey  
October 12, 2005

F-2

REPORT OF PRIOR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated statement of operations, stockholders' equity (deficit), and cash flows of Bioenvision Inc. and subsidiaries for the year ended June 30, 2004. 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 audit.

We conducted our audit 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 was not required to

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

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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated result of the operations and cash flows of Bioenvision, Inc. and subsidiaries for the year ended June 30, 2004 in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP  
 New York, New York  
 September 16, 2004

F-3

### BIOENVISION, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	June 30, 2006	
	----	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,377,937	\$ 3
Restricted cash	-	
Short-term securities	41,637,106	3
Accounts receivable, less allowances of \$898,714 and of \$869,220, respectively	2,369,446	
Inventories	427,514	
Prepays and other current assets	844,810	
	-----	-----
Total current assets	48,656,813	6
Property and equipment, net	273,632	

Edgar Filing: BIOENVISION INC - Form 10-K

Intangible assets, net	7,549,520	
Goodwill	1,540,162	
Other assets	706,840	
Deferred costs	3,523,497	
	-----	-----

Total assets	\$ 62,250,464	\$ 8
	=====	==

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable	\$ 1,557,507	\$
Accrued expenses and other current liabilities	6,464,445	
Accrued dividends payable	56,404	
Deferred revenue	513,662	
	-----	-----

Total current liabilities	8,592,018	
---------------------------	-----------	--

Deferred revenue	7,070,725	7
	-----	-----

Total liabilities	15,662,743	1
	-----	-----

Commitments and contingencies	-	
-------------------------------	---	--

Stockholders' equity		
Convertible participating preferred stock - \$0.001 par value; 20,000,000 shares authorized; 2,250,000 issued and outstanding at June 30, 2006 and June 30, 2005, respectively (liquidation preference \$6,750,000 and \$6,750,000, respectively)	2,250	
Common stock - \$0.001 par value; 70,000,000 shares authorized; 41,456,616 and 40,558,948 shares issued and outstanding at June 30, 2006 and June 30, 2005, respectively	41,457	
Additional paid-in capital	133,604,996	12
Deferred compensation	-	
Accumulated deficit	(86,567,268)	(6
Receivable from stockholder	(340,606)	
Accumulated other comprehensive income (loss)	(153,108)	
	-----	-----

Total stockholders' equity	46,587,721	6
	-----	-----

Total liabilities and stockholders' equity	\$ 62,250,464	\$ 8
	=====	=====

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

Edgar Filing: BIOENVISION INC - Form 10-K

	2006	2005
	-----	-----
Revenue		
License and royalty revenue	\$ 1,929,526	\$1,463,32
Product sales	668,975	611,34
Research and development contract revenue	2,710,571	2,576,50
	-----	-----
Total revenue	5,309,072	4,651,17
	-----	-----
Costs and expenses		
Cost of products sold (including royalty expense of \$1,277,411, \$524,755 and \$0 for the years ended June 30, 2006, 2005 and 2004, respectively)	1,662,975	921,26
Research and development	11,726,981	10,894,92
Provision for bad debts	24,564	869,22
Selling, general and administrative	16,562,770	10,181,71
Depreciation and amortization	974,440	1,438,51
Loss on impairment	-	5,276,16
	-----	-----
Total costs and expenses	30,951,730	29,581,79
	-----	-----
Loss from operations	(25,642,658)	(24,930,62)
Interest income (expense)		
Interest and finance charges	(66,762)	(79,48)
Interest income	1,810,657	747,32
	-----	-----
Loss before income tax benefit	(23,898,763)	(24,262,78)
Income tax benefit	-	-
	-----	-----
Net loss	(23,898,763)	(24,262,78)
Cumulative preferred stock dividend	(337,500)	(404,07)
	-----	-----
Loss applicable to common stockholders	\$ (24,236,263)	\$ (24,666,86)
	=====	=====
Basic and diluted net loss per share applicable to common stockholders	\$ (0.59)	\$ (0.7
	=====	=====
Weighted-average shares used in computing basic and diluted net loss per share of common stock	40,865,384	34,042,39
	=====	=====

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

Edgar Filing: BIOENVISION INC - Form 10-K

F-5

BIOENVISION, INC. AND SUBSIDIARIES  
 CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
 FOR THE YEARS ENDED JUNE 30, 2006, 2005 and 2004

	Convertible Participating Preferred Stock		Common Stock		Additional Paid-in Capital	Co
	Shares	\$	Shares	\$		
	-----	-	-----	-	-----	---
Balance at July 1, 2003	5,916,966	\$5,917	17,122,739	\$17,123	\$47,304,449	
Net loss for the period						
Cumulative preferred stock dividend for the period						
Currency translation adjustment						
Deferred compensation						
Shares issued in connection with private placement			2,602,898	2,603	16,265,495	
Cost 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	
Options exercised for common stock			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	
Warrants exercised for common stock			1,283,334	1,283	2,509,883	
Balance at July 1, 2004	3,341,666	\$3,342	28,316,163	\$ 28,316	\$68,517,702	
Net loss for the period						
Cumulative preferred stock dividend for the period						
Currency translation adjustment						
Deferred compensation						
Preferred stock converted to						

Edgar Filing: BIOENVISION INC - Form 10-K

common stock	(1,091,666)	(1,092)	2,183,332	2,183	(1,092)
Income related to repricing of options					(314,950)
Warrants issued in connection with services				-	524,928
Shares issued in connection with services			62,500	63	496,188
Options exercised for common stock			685,833	686	707,638
Warrants exercised for common stock			1,811,120	1,811	3,277,151
Shares issued in connection with public offering, net of related expenses			7,500,000	7,500	55,739,152
Balance at June 30, 2005	2,250,000	\$2,250	40,558,948	\$ 40,559	\$128,946,717

	Accumulated Deficit	Receivable from Stockholder	Accumulated Other Comprehensive Income (Loss)	Total Equity
Balance at July 1, 2003	\$ (26,156,098)	\$ -	\$152,346	\$21,323,737
Net loss for the period	(10,651,267)			(10,651,267)
Cumulative preferred stock dividend for the period	(856,776)			(856,776)
Currency translation adjustment			(12,748)	(12,748)
Deferred compensation				(223,990)
Shares issued in connection with private placement				16,268,098
Cost related to March private placement financing				(1,301,035)
Preferred stock converted to common stock				-
Expense related to repricing of options				2,381,066
Options exercised for common stock				-
Warrants issued in connection with services				671,601
Shares issued to consultants for services				305,987
Shares issued to employee				28,400
Options issued in connection with services				93,987
Options issued to employees				262,601
Warrants exercised for common stock				2,511,166
Balance at July 1, 2004	\$ (37,664,141)	\$ -	\$ 139,598	30,800,827
Net loss for the period	(24,262,785)			(24,262,785)

Edgar Filing: BIOENVISION INC - Form 10-K

Cumulative preferred stock dividend for the period	(404,079)			(404,079)
Currency translation adjustment			(38,658)	(38,658)
Deferred compensation				78,344
Preferred stock converted to common stock				-
Income related to repricing of options				(314,950)
Warrants issued in connection with services				524,928
Shares issued in connection with services				496,250
Options exercised for common stock				708,324
Warrants exercised for common stock				3,278,962
Shares issued in connection with public offering, net of related expenses				55,746,652
Balance at June 30, 2005	\$ (62,331,005)	\$ -	\$ 100,940	\$ 66,613,815

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

F-6

BIOENVISION, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
FOR THE YEARS ENDED JUNE 30, 2006, 2005 and 2004  
(Continued)

	Convertible Participating Preferred Stock Shares	\$	Common Stock Shares	\$	Additional Paid-in Capital	Def Comp
	-----	-	-----	-	-----	-----
Balance at June 30, 2005	2,250,000	\$2,250	40,558,948	\$ 40,559	\$128,946,717	\$ (1
Net loss for the period						
Cumulative preferred stock dividend						
Currency translation adjustment						

Edgar Filing: BIOENVISION INC - Form 10-K

Due from stockholder Employee and board of director stock-based compensation					3,684,158	
Deferred compensation					(136,457)	1
Options exercised for common stock			491,196	491	390,984	
Warrants exercised for common stock			406,472	407	719,594	
	-----	-----	-----	-----	-----	-----
Balance at June 30, 2006	2,250,000	\$2,250	41,456,616	\$ 41,457	\$133,604,996	\$
	=====	=====	=====	=====	=====	=====

	Accumulated Deficit	Receivable from Stockholder	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	-----	-----	-----	-----
Balance at June 30, 2005	\$ (62,331,005)	\$ -	\$100,940	\$ 66,613,815
Net loss for the period	(23,898,763)			(23,898,763)
Cumulative preferred stock dividend	(337,500)			(337,500)
Currency translation adjustment			(254,048)	(254,048)
Due from stockholder Employee and board of director stock-based compensation		(340,606)		(340,606)
Deferred compensation				9,189
Options exercised for common stock				391,475
Warrants exercised for common stock				720,001
	-----	-----	-----	-----
Balance at June 30, 2006	\$ (86,567,268)	\$ (340,606)	\$ (153,108)	\$ 46,587,721
	=====	=====	=====	=====

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

F-7



Edgar Filing: BIOENVISION INC - Form 10-K

	2006	2005
	-----	-----
Cash flows from operating activities		
Net loss	\$ (23,898,763)	\$ (24,260,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	974,440	1,430,000
Provision for bad debts	24,564	86,000
Deferred tax benefit	-	-
Stock-based compensation	3,693,347	79,000
Deferred cost	133,301	23,000
Deferred revenue	(351,818)	(52,000)
Loss on disposal	1,654	-
Loss on impairment	-	5,270,000
Changes in operating assets and liabilities		
Accrued interest on investments	(1,405,798)	-
Inventories	(143,383)	(28,000)
Prepays and other current assets	(484,937)	(9,000)
Accounts receivable	(574,610)	(5,000)
Other assets	(482,026)	(13,000)
Accounts payable and other liabilities	1,720,017	3,320,000
	-----	-----
Net cash used in operating activities	(20,794,012)	(13,410,000)
	-----	-----
Cash flows from investing activities		
Purchase of intangible assets	(166,926)	(35,000)
Capital expenditures	(102,535)	(27,000)
Release of restricted cash	290,000	-
Redemption of short-term securities	17,834,104	-
Purchase of short-term securities	(25,318,463)	(32,740,000)
	-----	-----
Net cash used in investing activities	(7,463,820)	(33,380,000)
	-----	-----
Cash flows from financing activities		
Proceeds from issuance of common stock, net of related expenses	-	55,740,000
Due from stockholder	(340,606)	-
Proceeds from exercise of options and warrants	1,111,476	3,980,000
Dividends paid	(337,500)	(43,000)
	-----	-----
Net cash provided by financing activities	433,370	59,290,000
	-----	-----
Effect of exchange rate changes on cash	(205,134)	3,000
	-----	-----
Net increase (decrease) in cash and cash equivalents	(28,029,596)	12,530,000
Cash and cash equivalents, beginning of year	31,407,533	18,870,000
	-----	-----
Cash and cash equivalents, end of year	\$ 3,377,937	\$ 31,400,000
	=====	=====

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

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Description of Business and Summary of Significant Accounting Policies

(a) Description of Business:

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

(b) Principles of Consolidation and Use of Estimates:

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Inter-company accounts and transactions have been eliminated. Certain reclassifications of balances previously reported have been made to conform to current presentation.

The preparation of financial statements in conformity with accounting principles generally accepted 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.

(c) Revenue Recognition:

In accordance with SEC Staff Accounting Bulletin No. 104 "Revenue Recognition", or "SAB 104", upfront nonrefundable fees associated with research and development collaboration agreements in which 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. 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 period of the licensing arrangement using the straight-line method, which approximates the life of the last to expire of the underlying patents.

Royalty Revenue from product licenses is recorded as earned.

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

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.

Research and development contract revenue includes sales in our pre-commercial stage named patient program for Evoltra(R) as well as certain payments due from our co-development partner relating to the reimbursement of 50% for certain of our ongoing research costs in the development of Evoltra(R) outside the United States. Currently, the Company has billed but not recorded approximately \$2,513,000 of revenue relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of Evoltra(R) outside the United States. If and when the Company has determined that collectibility is reasonably assured, the Company will record the revenue. At June 30, 2006, the Company continues to hold a reserve for bad debts of \$869,000 relating to the outstanding research and development reimbursements due from the co-development partner.

The Company follows the guidance of Emerging Issues Task Force 99-19, "Reporting Revenue Gross as a Principal versus

F-9

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

Note 1 - Description of Business and Summary of Significant Accounting Policies  
- continued

Net as an Agent" in the presentation of revenue and direct costs of revenue. This guidance requires the Company to assess whether it acts as a principal in the transaction or as an agent acting on behalf of 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.

(d) Research and Development:

Research and development costs are charged to expense as incurred. Research and development costs include the cost of Evoltra(R) sold prior to product approval through our named patient program.

(e) Stock-based Compensation:

On July 1, 2005, the Company adopted the fair value recognition provisions of SFAS No. 123 (R) (revised 2004), "Share-Based Payment" ("SFAS 123 (R)"), requiring the Company to recognize expense related to the fair value of stock-based compensation. The modified prospective transition method was used as allowed under SFAS 123 (R). Under this method, the stock-based compensation expense includes: (a) compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of July 1, 2005, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, "Accounting for Stock-Based Compensation"; and (b) compensation expense for all stock-based compensation awards granted subsequent to July 1, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS 123 (R). Prior to the adoption of SFAS 123 (R), the Company had accounted for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for

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

Stock Issued to Employees", as permitted by SFAS 123. Under APB Opinion No. 25, no stock-based employee compensation cost was reflected in reported net loss, when options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant.

Upon adoption of SFAS 123 (R), the Company reversed the unrecognized deferred compensation costs associated with options granted to certain employees of approximately \$136,000 with a corresponding reduction to the Company's additional paid-in capital (see Note 7). The Company also no longer re-measures the intrinsic value of the 380,000 re-priced options granted to an officer of the Company (see Note 7). The Company recognized compensation expense of approximately \$36,000 for these options for the year ended June 30, 2006, based on the fair value, as determined in accordance with SFAS 123, the guidance then in effect, of the modified award that remains unvested.

Beginning July 1, 2005, the Company is recognizing compensation expense for stock option awards to employees based on their grant-date fair value. We utilize the Black-Scholes model to measure the value of an employee option. Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. We determine expected volatility based on historical activity. We believe that these market-based inputs provide a better estimate of our future stock price movements. We also use historical exercise patterns as our best estimate of future exercise patterns. We utilize historical turnover rates in estimating expected forfeitures separately for executives and non-executives. We have incorporated the following assumptions into the Black Scholes model:

	2006 ----	2005 ----	2004 ----
Risk-free interest rate	3.89-4.95%	2.93-4.05%	1.95-3.28%
Expected weighted average term (in years)	3.79	3.87	3.50
Expected weighted average volatility	66%	80%	80%
Expected dividend yield	0%	0%	0%

The weighted average fair value per share for stock options granted to employees during years ended June 30, 2006, 2005 and 2004 was \$3.63, \$4.75 and \$3.13, respectively.

F-10

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

Note 1 - Description of Business and Summary of Significant Accounting Policies  
- continued

As required by SFAS 123 (R), management made an estimate of expected forfeitures for all unvested awards and is recognizing compensation costs only for those equity awards expected to vest. The impact on previously reported pro forma disclosures under SFAS 123 where forfeitures were recognized as incurred is not material. The Company recorded, as a component of net loss, employee stock-based compensation (expense) income of approximately \$(3,609,000), \$227,000 and (\$2,419,000) for the years ended June 30, 2006, 2005 and 2004, respectively. As of June 30, 2006, the total compensation cost related to unvested equity awards granted to employees but not yet recognized is approximately \$3,844,000. This cost will be amortized on a straight-line basis over the remaining weighted

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

average vesting period of 1.82 years.

For the years ended June 30, 2005 and 2004, the Company accounted for stock-based compensation in accordance with APB No. 25. 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 for the years ended June 30, 2005 and 2004:

	June 30, 2005 ----	June 30, 2004 ----
Net loss applicable to common stockholders, as reported	\$ (24,666,864)	\$ (11,508,043)
Add: Stock-based employee compensation (income) expense as reported	(227,417)	2,419,677
Deduct: Total stock-based employee compensation expense determined under fair value-based method for all awards	(2,427,771) -----	(861,297) -----
Pro forma net loss applicable to common stockholders	\$ (27,322,052) =====	\$ (9,949,663) =====
Loss per share		
Basic and diluted - as reported	\$ (0.72)	\$ (0.57)
Basic and diluted - pro forma	\$ (0.80)	\$ (0.49)

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 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." 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. We utilize the Black-Scholes model to measure the value of warrants issued to consultants.

(f) Income Taxes:

The Company accounts for income taxes under SFAS No. 109, "Accounting for Income Taxes". Under SFAS 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis 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.

(g) 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 income 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 11,563,314, 11,472,414 and 13,674,242 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2006, 2005 and 2004, respectively, as their effect would have

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Description of Business and Summary of Significant Accounting Policies  
- continued

been anti-dilutive. Additionally, convertible participating preferred stock that is convertible into 4,500,000, 4,500,000 and 6,683,332 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2006, 2005 and 2004, respectively, as their effect would have been anti-dilutive.

(h) Comprehensive Loss:

Total comprehensive loss for the years ended June 30, 2006, 2005 and 2004 was \$24,490,311, \$24,705,522 and \$11,520,791, respectively.

(i) Foreign Currency Translation:

The reporting currency of the Company is the US dollar. The functional currency of Bioenvision Limited, the Company's wholly-owned subsidiary, organized under the laws of the United Kingdom with offices in Edinburgh, Scotland, is the Pound Sterling. We translate assets and liabilities to their US dollar equivalents at rates in effect at the balance sheet date and record translation adjustments in accumulated other comprehensive income (loss). We translate statement of operations accounts at average rates for the period. For the years ended June 30, 2006 and 2005, the net foreign currency transaction gains (losses) included in selling, general and administrative expense were approximately \$(2,300) and 27,000, respectively.

(j) Cash and Cash Equivalents and Short-term Securities:

The Company considers all highly liquid financial instruments with a maturity of three months or less when purchased to be cash equivalents. All funds invested in Certificates of Deposit with maturities greater than three months and less than one year are classified as short-term securities determined by management to be available-for-sale securities.

(k) Deferred Costs:

Deferred costs represent payments to Southern Research Institute, or SRI, and to Stegram Pharmaceutical Ltd, which directly relate to milestone payments received in connection with the Genzyme Co-Development Agreement, Mayne-Pharma Pharmaceutical and the Dechra Sub-License Agreement. These costs are being amortized straight-line over the life of the contract and the amortization of these costs has been presented in research and development on the consolidated statement of operations.

(l) Accounts Receivable:

Our accounts receivable are primarily due from wholesale distributors and our co-development partners. We maintain an allowance for doubtful accounts at an amount estimated to be sufficient to provide adequate protection against losses resulting from collecting less than the full payment on our currently outstanding receivables. We make judgments as to our ability to collect

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

receivables and provide allowances for the portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices. In determining our allowances, we analyze our historical collection experience and current economic trends. One customer comprises approximately 33%, 62% and 67% of revenues earned for the years ended June 30, 2006, 2005, and 2004. Based on our evaluation of the collectibility of these accounts receivable, we believe that the balance relating to research and development reimbursements may not be collectible and therefore have reserved this balance at June 30, 2006.

F-12

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

Note 1 - Description of Business and Summary of Significant Accounting Policies  
- continued

(m) Inventories:

Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. We only capitalize inventory that is produced for commercial sale. The Company periodically reviews inventories and items outdated or obsolete are reduced to their estimated net realizable value. Below is a break down of inventories at June 30, 2006 and 2005:

	2006	2005	
Raw materials	\$ 118,213	\$ -	
Work-in-progress	180,048	170,730	
Finished goods	129,253	107,178	
	-----	-----	
 Total	 \$ 427,514	 \$ 277,908	
	=====	=====	

(n) 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.

Asset Description	Estimated Useful Life	2006	2005
Computer equipment and software	3 to 5 years	\$ 390,044	\$ 304,892
Furniture and fixtures	7 years	54,503	49,364
		-----	-----
		444,547	354,256
Less: accumulated depreciation		(170,915)	(74,478)
		-----	-----
Net property and equipment		\$ 273,632	\$ 279,778
		=====	=====

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

The Company recorded depreciation expense for the years ended June 30, 2006, 2005 and 2004 of approximately \$104,000, \$45,000 and \$20,000, respectively.

### (o) 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 SFAS No. 107, "Disclosures About Fair Value of Financial Instruments." Management of the Company believes that the fair value of financial instruments, consisting of cash, cash equivalents, short-term securities, accounts receivable, accounts payable and accrued liabilities, approximates carrying value due to the immediate or short-term maturity associated with these instruments.

### (p) Goodwill and Other Intangible Assets:

Goodwill represents the excess of costs over the fair value of identifiable net assets of Pathagon (see Note 2). Intangible assets include patents and licensing rights acquired in connection with the acquisition of Pathagon. The Company accounts for these assets in accordance with SFAS No. 142, "Goodwill and Other Intangible Assets." Goodwill is 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." For goodwill, each year and whenever impairment indicators are present, we will calculate the implied fair value of each goodwill amount and record an impairment loss for the

F-13

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

Note 1 - Description of Business and Summary of Significant Accounting Policies  
- continued

excess of book value over the implied fair value, if any.

### (q) Impairment of 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 (see Note 3).

### (r) Accrued Expenses:

Below is a breakdown of our accrued expenses and other current liabilities at



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

June 30, 2006 and 2005.

	June 30, 2006	June 30, 2005
Accrued research and development	\$ 4,389,951	\$ 3,098,264
Accrued professional fees	493,924	309,807
Accrued compensation costs	702,097	639,236
Accrued other	878,473	534,137
	-----	-----
 Total accrued expenses	 \$ 6,464,445	 \$ 4,581,444
	=====	=====

Accrued research and development expenses include amounts relating to clinical trials as well as pre-clinical operating costs. Other accrued expenses include inventories, marketing costs, royalties due on product sales, and other operating expense accruals.

(s) Recent Accounting Pronouncements:

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

In May 2005, the FASB issued SFAS 154 "Accounting Changes and Error Corrections," a replacement of APB Opinion 20 and SFAS 3. SFAS 154 changes the accounting for, and reporting of, a change in accounting principle. SFAS 154 requires retrospective application to prior period's financial statements of voluntary changes in accounting principle, and changes required by new accounting standards when the standard does not include specific transition provisions, unless it is impracticable to do so. SFAS 154 is effective for accounting changes and corrections made in fiscal years beginning after December 15, 2005.

F-14

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. Pursuant to paragraph 39 of SFAS 141, the Company can capitalize acquired intangible assets if it meets one of the following two criteria: (1) if they arise from contractual or legal rights (regardless of whether those rights are transferable and separable from the acquired entity or from other rights and obligations); or (2) if they are separable, that is, capable of being separated or divided from the acquired entity and sold, transferred, licensed, rented, or exchanged (regardless of whether there is intent to do so). The Company

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

determined that the patent and licensing rights of the purchased technologies are separately identifiable legal rights. 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 Company assigned values to the intellectual property rights acquired based on the expected future cash flows from the existing approved uses of the technologies. 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.

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.

At the time of acquisition, OLIGON(R) had been approved by the FDA for its use as a coating of catheters or incorporation into catheter material for the avoidance of catheter related sepsis associated with central venous catheters, pulmonary catheters and urinary catheters. By acquiring Pathagon, we inherited the sublicense of the OLIGON(R) technology to Edwards Lifescience for its use in short-term central venous catheters and pulmonary catheters. We plan on further commercializing this technology and are currently in discussions with major international medical device companies to sublicense the OLIGON(R) technology in its other approved uses and possibly incorporate it into a broader range of devices.

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 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.

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

At the time of acquisition, we also inherited a license to certain rights to methylene blue. Methylene blue is an anti-microbial agent used to cleanse fresh frozen plasma of viruses including Hepatitis-B, Hepatitis-C and HIV. At acquisition, it was approved in Europe for sterilizing fresh frozen plasma and is currently marketed and sold by several companies for anti-viral sterilizing of fresh frozen plasma. At acquisition, the Company planned to sublicense the product in certain European Union countries for its use in cleansing plasma. Prior to the loss of an intellectual patent in April of 2005, the Company had been in discussion with the American Red Cross to bring the

F-15

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

#### Note 2 - Acquisition of Pathagon - continued

product into the U.S. market. Since methylene blue is generally regarded as a safe drug, no further approval was needed to sell it for its intended use at acquisition. However, we did plan on performing clinical trials to support to the American Red Cross the commercial viability of methylene blue in sterilizing fresh frozen plasma. See Note 3 for further discussion.

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.

#### Note 3 - Intangible Assets

Intangible assets at June 30, 2006 and 2005 are as follows:

	2006 ----	2005 ----
Patents and licensing rights	\$9,382,450	\$9,337,819
Other intangible assets	298,505	176,207
	-----	-----
	9,680,955	9,514,026
Less: accumulated amortization	(2,131,435)	(1,261,090)
	-----	-----
Total intangible assets, net	\$7,549,520	\$8,252,936

Amortization of patents, licensing rights and other intangible assets amounted to approximately \$870,000, \$1,394,000 and \$1,328,000 for the years ended June 30, 2006, 2005 and 2004, respectively, and are amortized over periods generally ranging from 1-20 years. Other intangible assets are recorded at cost. Amortization for each of the next five fiscal years will amount to approximately

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

\$820,000 annually. The weighted average remaining life of our intangibles at June 30, 2006 is approximately seven years.

At June 30, 2005, we recognized an impairment of approximately \$5,276,000 relating to the methylene blue intangible acquired in connection with the Pathagon acquisition. Due to the loss of an intellectual property patent suit which occurred during the Company's fourth quarter, relating to the international use of methylene blue in fresh frozen plasma, we re-evaluated the intangible asset relating to methylene blue at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, relating solely and exclusively to approved uses of methylene blue, were less than the carrying value of our long-lived asset. As a result, we recognized a non-cash impairment loss of approximately \$5,276,000, equal to the difference between the estimated future cash flows for approved uses of methylene blue, discounted at an appropriate rate, and the carrying amount of the asset. Making the determinations of impairment and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows of the assets. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective. At June 30, 2006, we received an independent third-party valuation of this intangible asset which confirmed that such estimated future cash flows continued to be worth more than the carrying value of methylene blue and, therefore, no further impairment was deemed to be required.

### Note 4 - License and Co-Development Agreements

#### Clofarabine (Evoltra(R))

The Company has a license from SRI to develop, manufacture, market, distribute and sell a class of purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia, lymphoma and certain solid tumor cancers. The lead compound of these purine-based nucleosides is known as clofarabine (Evoltra(R)). 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

F-16

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

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

from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by the Company and by SRI from the technology. Initially, the Company is developing Evoltra(R) for the treatment of leukemia and lymphoma and studying its potential role in treatment of solid tumors.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from the technology (including Evoltra(R)) in Japan and Southeast Asia. The Company intends to convert the option to a license and is actively working on this initiative.

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

To facilitate the development of Evoltra(R) in March 2001, the Company entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX"), our sub-licensor until it was acquired by Genzyme Corporation ("Genzyme") on December 21, 2004, for the development of Evoltra(R) in cancer indications. Under the terms of the co-development agreement, Genzyme is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia), in each case, for the development of Evoltra(R) in cancer indications. Currently, the Company has billed but not recorded approximately \$2,513,000 of revenue relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of Evoltra(R) outside the United States. If and when the Company has determined that collectibility is reasonably assured, the Company will record the revenue. Genzyme is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada for certain cancer indications. The Company retains the right to handle those matters in all territories outside the United States and Canada (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 is required to pay Genzyme a royalty on direct sales outside the U.S., Canada, Japan and Southeast Asia. In turn, Genzyme, which would have U.S. and Canadian distribution rights in cancer indications, is paying the Company a royalty on sales in the U.S. and Canada. Under the terms of the co-development agreement, Genzyme also pays royalties to SRI based on certain milestones. The Company also is obligated to pay certain royalties to SRI with respect to Evoltra(R).

The Company received a nonrefundable upfront payment of \$1,350,000 when it entered into the co-development agreement with Genzyme and received an additional \$3,500,000 in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application (NDA) for clofarabine with the FDA, the Company received an additional (i) \$2,000,000 in April 2004 and (ii) \$2,000,000 in September 2004. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight-line basis over the related service period, through March 2021. For the years ended June 30, 2006, 2005 and 2004, the Company recognized revenues of approximately \$438,000, \$438,000 and \$161,000 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 over the related service period, concurrent with the revenue that is recognized in connection with these research and development costs through 2021. The Company recognized approximately \$219,000, \$219,000 and \$89,000 for the years ended June 30, 2006, 2005 and 2004.

### Modrenal (R)

-----

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

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

its own manufacturing facility for Modrenal(R), but will continue to use third-party contractors.

F-17

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

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

The Company received a nonrefundable upfront payment of \$1,250,000 when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, currently through September 2022. The Company recognized revenues of approximately \$60,000, \$87,000 and \$114,000, respectively, in connection with the upfront payment from Dechra for the years ended June 30, 2006, 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 \$12,000 and \$17,400 and \$23,000 for the years ended June 30, 2006, 2005 and 2004, respectively.

#### Note 5 - Marketing and Distribution Agreements

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

#### Note 6 - Income Taxes

The components of the income tax benefit are as follows:

	Years ended June 30,		
	2006	2005	2004
Current:			
Federal	\$ --	\$ --	\$ --
State	--	--	--
Deferred:			
Federal	--	--	(1,099,000)
State	--	--	(361,000)
	-----	-----	-----

Edgar Filing: BIOENVISION INC - Form 10-K

	--	--	(1,460,000)
	-----	-----	-----
Total benefit	\$ --	\$ --	\$ (1,460,000)
	-----	=====	=====

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

	Years ended June 30,		
	2006	2005	2004
	----	----	----
Domestic	\$ (19,333,000)	\$ (22,601,000)	\$ (10,781,000)
Foreign	(4,566,000)	(1,662,000)	(1,330,000)
	-----	-----	-----
Loss before taxes	\$ (23,899,000)	\$ (24,263,000)	\$ (12,111,000)
	=====	=====	=====

F-18

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 6 - Income Taxes - continued

The following is a reconciliation of benefit for income taxes computed at the federal statutory rates to the effective rates for the years ended June 30, 2006, 2005 and 2004:

	2006	2005	2004
	----	----	----
Consolidated tax benefit at federal statutory rate	(34.0%)	(34.0%)	(34.0%)
Other non-deductible expenses	1.3%	(0.3%)	6.8%
State income tax benefit, net of federal provision	(5.1%)	(6.1%)	(4.5%)
Valuation allowance	36.9%	40.1%	19.3%
Foreign rate differential	0.7%	0.3%	0.4%
Other, net	0.2%	0.0%	(0.1%)
	----	----	-----
Effective tax rate	0.0%	0.0%	(12.1%)
	=====	=====	=====

Significant components of the Company's deferred tax assets and liabilities at June 30 are as follows:

	June 30,	
	-----	-----
	2006	2005

Edgar Filing: BIOENVISION INC - Form 10-K

	-----	-----
Deferred tax liabilities		
Acquired intangibles	\$ (2,780,000)	\$ (2,923,000)
Deferred costs	(1,427,000)	(1,481,000)
Amortization	(203,000)	(115,000)
Depreciation	(16,000)	(33,000)
Other	(3,000)	(3,000)
	-----	-----
Total deferred tax liabilities	(4,429,000)	(4,555,000)
	-----	-----
Deferred tax assets		
Net operating loss	23,966,000	14,344,000
Options, warrants and shares issued to non-employees	273,000	534,000
Options issued to employees	1,081,000	164,000
Deferred revenue	3,072,000	3,214,000
Provision for bad debts	352,000	352,000
Accrued expenses	303,000	126,000
Other	13,000	-
	-----	-----
Total deferred tax assets	29,060,000	18,734,000
Valuation allowance for deferred tax assets	(24,631,000)	(14,179,000)
	-----	-----
Net deferred tax assets	4,429,000	4,555,000
	-----	-----
Net deferred tax liabilities	\$ -	\$ -
	=====	=====

F-19

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 6 - Income Taxes - continued

At June 30, 2006, the Company had estimated \$53,246,000 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 \$21,565,000. At June 30, 2006, the Company also had estimated \$8,005,000 of net operating loss carryforwards relating to foreign operations, respectively, with no expiration date, with a tax value of \$2,402,000.

At June 30, 2006 and 2005, the Company has recorded a valuation allowance of approximately \$24,631,000 and \$14,179,000, respectively, 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.

Included in the tax net operating loss for the years ended June 30, 2006, 2005 and 2004 is approximately \$3,222,000 and \$3,857,000 and \$415,000, respectively



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

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. If the valuation allowance is removed, the tax effected benefit of \$1,305,000, \$1,562,000 and \$168,000, respectively, 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 changes, if any, 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 7 - Stockholders' Transactions

#### Common Stock:

On February 8, 2005, the Company completed a secondary public offering in which it sold 7,500,000 common shares at \$8.00 per share, with net proceeds to the Company of approximately \$55,747,000, after deducting underwriting discounts and commissions and offering expenses.

On December 18, 2004, the Company issued 62,500 shares of its common stock to a consultant to the Company for services rendered to the Company. The Company recorded compensation expense of approximately \$497,000 for the year ended June 30, 2005 in connection with such issuance.

#### Convertible Participating Preferred Stock:

On May 7, 2002 the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Participating Preferred Stock, par value \$0.001 per share. Series A Convertible Participating 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. The Company received gross proceeds of \$17.7 million from the placement. Holders of Series A Convertible Participating Preferred Stock also received, in respect of each share of Series A Convertible Participating 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 Convertible Participating 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, at the holder's option, 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. 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.

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 7 - 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 Participating Preferred Stock. The Company has paid the dividend in cash to holders of its cumulative Series A Convertible Participating Preferred Stock through July 30, 2006.

During the year ended June 30, 2005, certain holders of 1,091,666 shares of the Company's Convertible Participating Preferred Stock converted such shares into 2,183,332 shares of the Company's common stock. During the year ended June 30, 2004, certain holders of 2,575,900 shares of the Company's Convertible Participating Preferred Stock converted such shares into 5,150,000 shares of the Company's common stock.

Stock Options:

The Board of Directors adopted, and the stockholders approved, the 2003 Stock Incentive Plan at the Annual Meeting held in January 2004. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 4,500,000 shares reserved for grants of options under the plan and, at June 30, 2006, options to purchase 3,996,500 shares of common stock had been issued. The Company's policy is to issue new shares for option exercises. Stock options vest pursuant to individual stock option agreements. No 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 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 \$0.735 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 through June 30, 2005. For the years ended June 30, 2005 and 2004, the Company recognized stock-based employee compensation income (expense) of approximately \$315,000 and \$(2,381,000), respectively, related to these options. As a result of the adoption of SFAS 123 (R) on July 1, 2005, the Company no longer re-measures the intrinsic value of the 380,000 re-priced options. The Company

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

determined the fair value of the modified award in accordance with SFAS 123, the guidance then in effect, and has recognized expense of \$36,000 for the year ended June 30, 2006 relating to the portion of the options that were unvested on July 1, 2005.

For the years ended June 30, 2005 and 2004, the Company recorded compensation expense of approximately \$88,000 and \$39,000, respectively, as a result of 505,000 options granted to certain employees at an exercise price below the grant date trading price. Upon adoption of SFAS 123 (R), beginning July 1, 2005, the Company reversed the unrecognized deferred compensation costs of approximately \$136,000, associated with these options, with a corresponding reduction to the Company's additional paid-in capital and is recognizing the fair value estimated in accordance with the original provisions of SFAS 123 for the unvested options. In December 2005, the Company cancelled a total of 251,667 options relating to the unexercised options issued to three of the employees that were originally issued below fair market value with a strike price of \$4.05. The Company reissued these options at the fair market value on January 20, 2004 (original grant date) with a strike price of \$4.55 and provided cash bonuses to the employees in return for the increase in the strike price. The original vesting terms and remaining exercise period of the original grant on date of modification was utilized in the amended grant. The Company has recorded additional compensation expense equal to the amount of the cash bonuses paid of \$125,000. The Company will continue to record compensation expense for the fair value of the stock options over the remaining vesting term.

F-21

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

#### Note 7 - Stockholders' Transactions - continued

On March 30, 2006, the Company extended the exercise period of 1,500,000 vested options originally granted to an officer of the Company from five to ten years. The extension of the exercise period was treated as a modification of an award under SFAS 123 (R) and resulted in the immediate recognition of incremental compensation expense of approximately \$591,000.

On January 6, 2006, the Company granted 15,000 options to each of two board members for serving as a member of the Board of Directors, of which 3,750 options vested immediately and the remaining 11,250 vest ratably on the first, second and third anniversaries of the grant date. The Company recognized approximately \$40,000 as consulting expense for the year ended June 30, 2006.

On January 6, 2005, the Company granted 7,500 options to a board member for serving as a member of the Board of Directors, of 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 \$9,000 and \$13,000 as consulting expense for the years ended June 30, 2006 and 2005, respectively.

On January 20, 2004, the Company granted 25,000 options to a member of the Board of Directors, for serving as a member of the Board of Directors, which vest ratably on the first and second anniversaries of the grant date. The Company recognized \$26,000, \$47,000 and \$21,000 as consulting expenses for the years ended June 30, 2006, 2005 and 2004, respectively.

Edgar Filing: BIOENVISION INC - Form 10-K

During the years ended June 30, 2006 and 2005, certain option holders of the Company exercised with cash their options to acquire 300,000 and 685,833, shares of the Company's common stock, respectively. The Company received proceeds of approximately \$391,000 and \$708,000, respectively, from the exercise of these options.

During the years ended June 30, 2006 and 2005, certain non-employee holders of options exercised pursuant to the cashless exercise feature available to such option holders and the Company issued 191,196 and 212,709 shares of its common stock in connection therewith, respectively.

F-22

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 7 - Stockholders' Transactions - continued

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

	Number of Shares -----	Weighted Average Exercise Price -----	Weighted Average Remaining Contractual Life ----	
Balance - June 30, 2003	3,570,000	\$ 1.23		
Granted	720,000	5.02		
Exercised	(20,000)	1.42		\$
Balance - June 30, 2004	4,270,000	1.87		
Granted	784,000	7.99		
Exercised	(885,500)	1.08		\$
Forfeited	(12,500)	3.53		
Balance - June 30, 2005	4,156,000	3.18		
Granted	1,287,000	6.49		
Exercised	(525,000)	1.28		\$
Cancelled	(252,000)	4.05		
Forfeited	(25,000)	8.22		
Balance - June 30, 2006	4,641,000 =====	\$ 4.24	4.44	\$
Exercisable - June 30, 2006	3,250,000	\$ 3.09	6.34	\$

Edgar Filing: BIOENVISION INC - Form 10-K

A summary of the Company's nonvested employee options at June 30, 2006 and changes during the year ended June 30, 2006 is presented below:

	Non-vested Number of Shares -----	Weighted Average Fair Value at Grant Date -----	Aggregate Intrinsic Value -----
Balance - June 30, 2005	1,434,000	\$ 3.13	
Granted	1,208,000	3.50	
Vested	(1,060,000)	3.07	\$3,254,000
Cancelled	(173,000)	2.70	
Forfeited	(18,000)	4.69	
	-----		
Balance - June 30, 2006	1,391,000	\$ 3.79	
	=====		

F-23

BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 7 - Stockholders' Transactions - continued

Warrants:

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 \$9,000 and \$138,000 as consulting expense for years ended June 30, 2006 and 2005, respectively relating to said warrants. All milestones were met as of June 30, 2006 related to said warrants.

On August 4, 2004, the Company issued a warrant to a consultant pursuant to which said consultant has the right to purchase 40,000 shares of the Company's common stock at a price of \$7.22 per share upon satisfaction of certain milestones included in the warrant. The Company recognized approximately \$75,000 as consulting expense for the year ended June 30, 2005, relating to said warrants. No additional milestones were met during the year ended June 30, 2006.

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. All milestones were met as of June 30, 2005 and the Company recognized approximately \$243,000 as consulting expense for the year then ended.

During the year ended June 30, 2006, certain warrant holders of the Company exercised their warrants to acquire 406,472 shares of the Company's common stock, in which the Company received proceeds of approximately \$720,000 from the

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

exercise of such warrants. During the year ended June 30, 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 year ended June 30, 2005 from the exercise of these warrants. 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 \$2,511,000 from the exercise of these warrants.

Receivable from Stockholder:

Subsequent to the exercise of an option by a former member of management on September 27, 2005, the Company became aware of the statutorily required withholding taxes due to the UK tax regulatory authority. In order to maintain compliance with the UK tax regulatory authority, the Company remitted the taxes due on behalf of the former employee in January 2006 and, in return, received a promissory note from the former member of management dated November 28, 2005 for \$341,000. The payment of these taxes was not part of the option agreement. The Company has classified such note as a receivable from stockholder in the equity section of the consolidated balance sheet.

### Note 8 - Geographic Information

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

Region	2006 ----	2005 ----	2004 ----
United States	\$ 1,929,527	\$ 3,373,547	\$ 2,929,719
United Kingdom	3,379,545	1,277,627	172,495
	-----	-----	-----
Total Revenues	\$ 5,309,072 =====	\$ 4,651,174 =====	\$ 3,102,214 =====

F-24

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

### Note 9 - Commitments and Contingencies

Leases:

The Company leases office space for its New York, New York headquarters under a non-cancelable operating lease expiring on December 29, 2009 and office space in Edinburgh, Scotland under a lease agreement for its subsidiary Bioenvision Ltd. which expires February 29, 2008. Rent expense for both facilities in the aggregate for the years ended June 30, 2006, 2005 and 2004 was approximately \$680,000, \$421,000 and \$421,000, respectively. Further, the Company leases two vehicles under leases which expire November 29, 2008 and one set to expire February 28, 2007. Lease expense was approximately \$49,000, \$34,000 and \$37,000

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

for the years ended June 30, 2006, 2005 and 2004, respectively. At June 30, 2006, total minimum rentals under operating leases with initial or remaining non-cancelable lease terms of more than one year were approximately:

Year ended June 30,	
2007	\$ 1,234,000
2008	820,000
2009	372,000
2010	179,000
	-----
	\$ 2,605,000
	=====

### 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. Each of the parties had moved for summary judgment dismissing all but one of the claims of the other parties. Those motions were all denied by the Court, and a trial date had been set for early 2006. On April 10, 2006, an out of court settlement was reached and each party executed a release, releasing all claims against the other. A Stipulation of Discontinuance was filed with the Court.

F-25

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

#### Note 10 - Quarterly Financial Data (Unaudited)

2006	Quarter Ended 9/30/2005 -----	Quarter Ended 12/31/2005 -----	Quarter Ended 3/31/2006 -----	Quarter Ended 6/30/2006 -----
Revenue	\$670,218	\$1,091,307	\$1,741,095	\$1,806,452
Loss from operations	(5,200,736)	(4,197,037)	(8,591,790)	(7,653,095)
Net loss	(4,804,592)	(3,793,862)	(8,138,302)	(7,162,007)
Net loss applicable to shareholders	\$ (4,889,660) -----	\$ (3,878,931) -----	\$ (8,221,521) -----	\$ (7,246,151) -----

Edgar Filing: BIOENVISION INC - Form 10-K

Basic and diluted net loss applicable to shareholders per share	\$ (0.12)	\$ (0.10)	\$ (0.20)	\$ (0.18)
2005	9/30/2004	12/31/2004	3/31/2005	6/30/2005
	-----	-----	-----	-----
Revenue	\$1,085,328	\$1,175,923	\$1,398,969	\$990,954
Loss from operations	(3,149,988)	(4,061,409)	(3,257,875)	(14,461,351)
Net loss	(3,094,551)	(4,004,831)	(3,072,410)	(14,090,993)
Net loss applicable to shareholders	\$ (3,220,892)	\$ (4,115,206)	\$ (3,155,629)	\$ (14,175,137)
	-----	-----	-----	-----
Basic and diluted net loss applicable to shareholders per share	\$ (0.11)	\$ (0.14)	\$ (0.08)	\$ (0.38)

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

F-26

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Bioenvision, Inc.:

In connection with our audit of the consolidated financial statements of Bioenvision, Inc as of and for the year ended June 30, 2006, we also audited the 2006 consolidated financial statement Schedule II. In our opinion, the 2006 financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information required to be included therein.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
August 21, 2006



Edgar Filing: BIOENVISION INC - Form 10-K

S-1

REPORT OF PRIOR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited in accordance with the standards of the Public Company Accounting Oversight Board (United States) the consolidated financial statements of Bioenvision, Inc. and Subsidiaries referred to in our report dated September 16, 2004, which is included in the Annual Report on Form 10K for the year ended June 30, 2006. Our audit was conducted for the purpose of forming an opinion on the basic financial statements taken as a whole. The Schedule II is presented for purposes of additional analysis and is not a required part of the basic financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic financial statements taken as a whole.

/s/ Grant Thornton LLP

New York, New York  
September 16, 2004

S-2

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS  
Years Ended June 30, 2006, 2005 and, 2004

	Balance at Beginning of Period -----	Charged to Cost and Expense -----	Write-offs To Accounts Recoveries -----
Allowance for doubtful accounts -----			
June 30,			
2006	\$ 869,220	\$ 25,564	\$ -
2005	\$ -	\$ 869,220	\$ -
2004	\$ -	\$ -	\$ -
Deferred tax asset valuation allowance			

Edgar Filing: BIOENVISION INC - Form 10-K

June 30,				
2006	\$ 14,178,975	\$ 10,452,291	(1)	\$
2005	\$ 2,893,873	\$ 11,285,102	(1)	\$
2004	\$ 396,693	\$ 2,498,180	(1)	\$

(1) Reflects the increase in the valuation allowance associated with net operating losses of the Company.

S-3