

BIOENVISION INC  
Form 10-K  
September 12, 2007

**UNITED STATES  
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, 2007

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 001-31787

**BIOENVISION, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**13-4025857**

(IRS Employer Identification No.)

**345 Park Avenue, 41st Floor, New York, NY**

(Address of principal executive offices)

**10154**

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class  
**Bioenvision common stock, \$0.001 par value**

Name of Exchange on Which Registered  
**The NASDAQ Stock Market LLC  
(NASDAQ Global Market)**

Securities registered pursuant to 12(g) of the Act:

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

None

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 15(d) of the Act. Yes  No

Indicate by check mark 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 preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of 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. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

The aggregate market value of voting common stock held by non-affiliates of the registrant as of December 29, 2006: \$188,144,251

The number of shares of the registrant's common stock outstanding as of September 5, 2007: 55,037,771

### Documents Incorporated by Reference

Portions of our definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days after the end of the our fiscal year are incorporated by reference into Part III of this Annual Report on Form 10-K.

---

**BIOENVISION, INC.**

**ANNUAL REPORT ON FORM 10-K**

**FISCAL YEAR ENDED JUNE 30, 2007**

**INDEX**

**PART I**

<u>ITEM 1. BUSINESS</u>	1
<u>ITEM 1A. RISK FACTORS</u>	10
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	25
<u>ITEM 2. PROPERTIES</u>	25
<u>ITEM 3. LEGAL PROCEEDINGS</u>	25
<u>ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	27

**PART II**

<u>ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	27
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	29
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION</u>	30
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	42
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	42
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	42
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	42
<u>ITEM 9B. OTHER INFORMATION</u>	45

**PART III**

<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	45
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	45
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	45
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE</u>	45
<u>ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	45

**PART IV**

<u>ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	46
---	----

## 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 Management's 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**

Unless the context otherwise requires, as used in this annual report, the terms Bioenvision, Company, our, or we refer to Bioenvision, Inc. and its subsidiaries.

*Overview*

We are a product-orientated biopharmaceutical company primarily focused upon the acquisition, development, and marketing of compounds and technologies for the treatment of cancer. Our product pipeline includes Evoltra® (clofarabine) which has marketing approval in both the European Union ( E.U. ) and United States ( U.S. ) for the treatment of pediatric relapsed or refractory acute lymphoblastic leukemia, Modrenal® (trilostane), which has marketing approval in the United Kingdom ( U.K. ) for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy, and other products.

On May 29, 2007, we entered into an Agreement and Plan of Merger (the Merger Agreement ) with Genzyme Corporation, our North American co-development partner for clofarabine ( Genzyme ) and Wichita Bio Corporation, a wholly-owned subsidiary of Genzyme ( Wichita Bio ). We are holding a special meeting of our stockholders to vote on this proposed merger, **which is currently scheduled for October 4, 2007**. The merger is the second and final step in the proposed acquisition of Bioenvision by Genzyme. The first step was the tender offer for all of the outstanding common stock and all of the outstanding preferred stock of Bioenvision, which expired on July 10, 2007. Pursuant to the tender offer, Wichita Bio purchased 8,398,098 shares of common stock, representing approximately 15.3% of the outstanding shares of our common stock as of the date hereof, and 2,250,000 shares of preferred stock, representing 100% of the outstanding shares of our preferred stock as of the date hereof. Following the tender offer and as of the date hereof, Genzyme beneficially owns approximately 22 % of the outstanding shares of Bioenvision common stock on an as-converted basis, including all outstanding shares of Bioenvision preferred stock. If the merger is completed, Wichita Bio, will be merged with and into Bioenvision, we will become a wholly-owned subsidiary of Genzyme and each share of our common stock issued and outstanding immediately before the merger, other than treasury shares, shares for which appraisal rights have been perfected and shares held by Genzyme or Wichita Bio, will automatically be canceled and will cease to exist and will be converted into the right to receive \$5.60 in cash, without interest. See **"Factors Relating to the Proposed Merger with Genzyme"** beginning on page 10.

*Our Products****Evoltra® (Clofarabine)***

Evoltra® is our lead product. In May 2006 the European Medicines Agency (the EMEA ) approved Evoltra® 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® has been granted orphan drug designation (ODD), providing marketing

exclusivity for 10 years in Europe, which 10-year period commenced in May 2006 upon our receipt of E.U. marketing approval. We have a direct sales force in the U.K. and a dedicated sales force through Innovex, an affiliate of Quintiles Corporation, in several other countries within the E.U. Subject to the outcome of the merger, we plan to increase either our direct sales force or our dedicated sales force through Innovex as we continue to work through reimbursement procedures and expand our marketing initiatives to exploit new commercial opportunities within the E.U.

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

1

---

significant increase in the size of the potential market available to Evoltra®. In addition, we have ODD in this new target indication may provide further market exclusivity in the EU.

On August 16, 2007, we announced that, in connection with the status of our application to the EMEA to include a new indication for clofarabine for the treatment of adult AML in elderly patients who have one or more of the following: adverse cytogenetics, secondary AML,  $\geq$  70 years old or significant co-morbidities and who are therefore not considered suitable for intensive chemotherapy, the EMEA has agreed to accept supplemental information from us by November 16, 2007. This timeframe will enable us to prepare a more comprehensive response to the EMEA, including interim data from the ongoing, multicenter AML-16 trials that have been initiated by the National Cancer Research Institute ( NCRI ). We currently anticipate that in December 2007 the Rappasteur will provide its assessment report and that in January 2008 the EMEA will either provide us with an opinion on whether or not we will be granted marketing authorization of clofarabine for this new indication or provide us with a second Request for Supplemental Information.

It should be noted that the foregoing may be subject to change and the EMEA's assessment report and opinion may require us to provide further data and/or to attend an oral explanation. The opinion of the EMEA is also required to be adopted by the European Commission as a pre-condition to the grant of marketing authorization of clofarabine for the treatment of adult AML. In addition, in relation to our variation application to include this new indication, the EMEA has requested that data from the ongoing AML-16 trials be provided. The AML-16 trials, sponsored by the NCRI, randomize clofarabine against the standard of care (low-dose cytarabine) for the treatment of elderly patients with adult AML who are not considered suitable for intensive chemotherapy. We believe we will be able to make data from these trials available to the EMEA by November 2007. There can be no assurances, however, that this data will be made available to us for its application. The AML-16 trials will not be fully enrolled at the time of submission of our response to the EMEA and there can be no assurances that interim data will be satisfactory, or that the data itself will be supportive of our application. Further, if the EMEA does not accept this data, we may have to run an additional randomized study.

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

In September 2006, we executed a License Agreement with SRI, pursuant to which we successfully licensed the manufacturing, marketing and distribution rights to clofarabine in Japan and Southeast Asia (the Japan License ). Since taking on these rights, we have organized Bioenvision JapanCo., Ltd., a wholly-owned subsidiary of Bioenvision, Inc ( JapanCo ), and appointed a director in charge of corporate and product development for JapanCo.

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

Also, in conjunction with our North American co-development partner, Genzyme, clofarabine (Evoltra®) is in clinical development for the treatment of myelodysplastic syndrome (MDS), chronic lymphocytic leukemia (CLL), non-Hodgkin's lymphoma (NHL), solid tumors and as a preconditioning regimen for transplantation. Although we are currently not directly involved with these programs, Genzyme is required to share the data generated thereunder in accordance with the terms of our co-development agreement.

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

We have an exclusive worldwide license for clofarabine. We granted an exclusive sublicense to Genzyme to co-develop clofarabine for certain cancer indications in the US and Canada. Genzyme is commercializing clofarabine for certain cancer indications in the US and Canada under the brand name Clolar®. 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 under a co-development agreement dated August 31, 1998. On May 24, 2007, we entered into an amendment to that agreement, pursuant to which the parties agreed to modify and/or clarify certain of the economic terms of their arrangement including, without limitation, terms related to royalties, milestones, profit sharing and assignability provisions.

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 received Orphan Drug Designation status for clofarabine in the U.S., providing marketing exclusivity for 7½ years, expiring in 2012.

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 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 (BIOV-121) in February 2006 and we submitted an application for label extension to the EMEA in February of 2007 based in large part upon this clinical data.

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

Pursuant to the terms of our co-development agreement with 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.

During the performance of the co-development agreement, we have disagreed with Genzyme from time to time on the interpretation of certain of the parties' respective rights and obligations under the co-development agreement. Some of these disagreements have been resolved by the parties in the ordinary course of business. In some instances, the parties have continued to perform their obligations under the co-development agreement while reserving their rights with respect to disagreements that they were not able to resolve. For example, the parties have disagreed as to the proper interpretation of the language in Section 3.6 of the co-development agreement. Section 3.6 provides that if Genzyme fails to file a new drug application for chronic leukemia or solid tumors within a prescribed period of time, then we shall have the right to make such filing. If we prepared and filed a new drug application for the treatment of chronic leukemia or solid tumors, and if that application were to be approved, the parties do not agree as to whether we would then have the right to market and sell clofarabine in North America for those indications or whether Genzyme would retain those rights under Section 6.1 of the co-development agreement. Given the disagreement as to the

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

interpretation of the parties' rights under the co-development agreement, and given the challenges of developing clofarabine for the treatment of chronic leukemia or solid tumors and preparing and filing a new drug application for those uses, we have elected at this time to focus our resources and efforts on the development and commercialization of clofarabine outside of the United States while reserving our rights under Section 3.6 of the co-development agreement.

3

---



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. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the development and marketing of clofarabine, which we currently expect to expire in 2021.

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

#### *Modrenal®*

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

Modrenal®'s approved indication enables us to promote Modrenal® for use immediately after relapse to initial hormone therapy such as tamoxifen or one of a class of drugs known as aromatase inhibitors (including Faslodex and Arimidex). However, we are initially positioning Modrenal® as a third or fourth line treatment option in post-menopausal advanced breast cancer.

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

We began marketing Modrenal® in May 2004 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. We have the exclusive right to market and distribute Modrenal® throughout the world for all human applications, except for South Africa and Japan where the drug is marketed for the treatment of low-renin hypertension. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the marketing of Modrenal®. Given that we have new patent applications filed, which are subject to issuance, we expect the last of our underlying patents to expire in 2020.

#### *Other Products and Technologies*

We anticipate that revenues derived from Evoltra® and Modrenal® 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 Evoltra® and Modrenal® but management believes these compounds have potential value.

#### *Suvus®*

Suvus®, 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 Suvus® use in treating relapsed/refractory, chronic hepatitis C virus infection. Suvus® 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® 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®, is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. In December of 2005, we submitted to the Egyptian Ministry of Health ( Ministry ) a protocol for an investigator sponsored clinical trial in Egypt for refractory genotype IV Hepatitis C. Concurrent with the submission of the protocol, we filed a marketing authorization with the Ministry for the use of methylene blue in hepatitis C based on the Phase II data. Our plan was to attain product approval (then anticipated to be received by the end of calendar 2006) and then commence with further investigator sponsored clinical trials in Egypt into which we would sell methylene blue at a price discounted to the current treatments available. The trials were intended to be performed whether marketing approval was received or not.

In September of 2006, the Ministry provided feedback on our filing and requested that, among other things, an Egyptian-based company be added to our distribution process. We responded to the Ministry in January of 2007. In March of 2007, we received another request from the Egyptian authorities relating again to the manufacturing process and we submitted our responses in April 2007. Separately, in February of 2007, we hired a third party to assist us in performing a strategic review of our asset portfolio which was completed during the fourth quarter of fiscal 2007. In conjunction with this analysis, our board of directors determined that we would no longer devote any further resources to the development of methylene blue, unless and until a secure revenue source could be identified as a pre-condition to the use of methylene blue in a clinical trial. As a result of our inability to obtain a secure source to fund further development of methylene blue, along with the the inability to commence a clinical study into which we could sell the product, we re-evaluated the intangible asset at June 30, 2007. We recognized a non-cash impairment loss equal to its carrying value of approximately \$3,311,000.

## *OLIGON® Technology*

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

The OLIGON® technology is based on the antimicrobial properties of silver ions. The broad spectrum activity of silver ions against bacteria, including antibiotic-resistant strains, has been known for decades. OLIGON® materials have application in a wide range of devices and products, including vascular access devices, urology catheters, pulmonary artery catheters and thoracic devices, renal dialysis catheters, orthopedic devices and several other medical and consumer product applications. One application of the OLIGON® technology has been licensed to a third party, which is currently marketing the technology in its line of short-term vascular access catheters. Six U.S. patents for the OLIGON® technology have been granted and additional patents have been filed. In addition, patents have been filed in Europe, Canada and Japan.

In January 2007, we entered into a licensing agreement with Foster Corporation, a Connecticut-based compounder of biomedical materials ( Foster ) to license out exclusive rights to manufacture, market and distribute our proprietary anti-microbial OLIGON® technology. Under the terms of the license agreement, we will have a revenue sharing agreement on future sublicenses and a royalty on all sales by Foster. Foster is required to comply with annual minimum marketing and research and development expenditures within the first 3 years of the term of the license.

At June 30, 2007, we completed an analysis of this intangible asset which confirmed that such estimated future cash flows continued to be worth more than the carrying value of OLIGON® and, therefore, no impairment was deemed to be required.

### ***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 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.

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

We also have one animal health product, Veteryl® (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 trilostane 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 \$5,500,000 of total consideration (including milestone payments) and a royalty of 2% - 4% of annual net sales.

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

Our success will depend, in part, upon our ability to obtain and enforce protection for our products under 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 U.S. 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 U.S. 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® 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 technology or that we can meaningfully protect our trade secrets.

### ***Sales and Marketing***

Currently we have an arrangement in place with Genzyme for the co-development and marketing of clofarabine in the US. We have entered into arrangements with Innovex for the sales and marketing of Evoltra® (clofarabine) in certain E.U. countries. However, in order to market Evoltra® effectively and independently, we need to establish a much more integrated marketing and sales force with distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. We have been considering the most appropriate long term strategy to capitalize on the commercial value of Evoltra®. 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® (Clofarabine) in Australia and New Zealand in certain cancer indications.

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

### ***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.

### ***Research and Development***

In developing new products, we consider a variety of factors including: (i) existing or potential marketing opportunities for these products; (ii) our capability to arrange for these products to be manufactured on a commercial scale; (iii) whether or not these products complement our existing products; (iv) the opportunities to leverage these products with the development of additional products; and (v) the ability to develop co-marketing relationships with pharmaceutical and/or other companies with respect to the products. We intend to fund future research and development activities at a number of medical and scientific centers in Europe and the United States. Costs related to these activities are expected to include: clinical trial expenses; drug production costs; salaries and benefits of scientific, clinical and other personnel; analytical and other testing costs; professional fees; and insurance and other administrative expenses. We have spent approximately \$21,065,000 and \$11,727,000 on research and development activities for the fiscal years ended June 30, 2007 and 2006, 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 U.S. generally involves the following:

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

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

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

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

In the case of products for life-threatening diseases such as cancer, the initial human testing is often conducted in patients with disease rather than in healthy volunteers. Since these patients already have the targeted disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials and so these trials are frequently referred to as Phase I/II trials. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all.

Furthermore, we, the FDA, the institutional review board or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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

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

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

Any products manufactured or distributed under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events 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 U.S. 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 the date hereof, we had 32 full-time employees based in New York, Edinburgh, Scotland and Tokyo, Japan.

### ***Financial Statements***

Financial information about segments and geographic areas is incorporated herein by reference to Note 7 *Geographic Information* of the Notes to the Consolidated Financial Statements that appears in Item 8 of this Form 10-K.

### ***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 annual report. 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**

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.

### **Factors Relating to the Proposed Merger with Genzyme**

Our ability to complete the merger with Genzyme is subject to risks and uncertainties, including, but not limited to, the failure to obtain stockholder approval, the occurrence of any event, change or other circumstances

that could give rise to the termination of the Merger Agreement and other risks to consummation of the transaction. Additional risk factors associated with the proposed merger with Genzyme are as follows.

***Our business could be adversely impacted by uncertainty related to the proposed merger with Genzyme.***

Whether or not the merger is completed, the announcement and pendency of the merger could impact or cause disruptions in our business and operations, which with Genzyme could have an adverse effect on our results of operations and financial condition, including, but not limited to:

- our current business partners may experience uncertainty associated with the merger and may attempt to negotiate changes in existing business relationships, decide to delay, defer, or cancel purchases of our products pending completion of the merger or termination of the Merger Agreement and/or consider entering into business relationships with parties other than us, either before or after completion of the merger, and we may face additional challenges in competing for new and renewal business;
- our employees may experience uncertainty about their future roles with the combined company, which might adversely affect our ability to retain and hire key managers and other employees;
- the attention of our management may be directed toward the completion of the merger and transaction-related considerations and may be diverted from the day-to-day business operations of our business;
- we have incurred and will continue to incur significant expenses related to the merger;
- in certain ways our ability to operate our business freely might be restricted by particular restrictions in the Merger Agreement;
- the uncertainty of retaining business with our suppliers and vendors can be further exacerbated by the merger, and delay in the completion of the merger or termination of the Merger Agreement could have an adverse effect on our business, financial condition, results of operations or prospects if the merger is not completed; and
- we may be unable to respond effectively to competitive pressures, industry developments and future opportunities.

***Our stock price and financial results could be adversely impacted by uncertainty related to the proposed merger with Genzyme.***

Our stock price may be adversely affected as a result of the fact that we have incurred and will continue to incur significant expenses related to the proposed merger that will not be recovered if it is not completed. As a consequence of the failure of the merger to be completed, our business could be materially and adversely affected.

If the merger is approved, we will become a wholly-owned subsidiary of Genzyme and our common stock will cease to be listed on The NASDAQ Global Market and no longer will be publicly traded.

***We are subject to litigation that could have an adverse effect upon our business, financial condition, results of operations or reputation.***

We are a defendant in multiple putative class action lawsuits that have been filed in connection with the merger against us, our directors, Genzyme and Wichita Bio, the Genzyme subsidiary which will merge with and into us resulting in us becoming a wholly owned subsidiary of Genzyme. Among other things, the lawsuits seek to enjoin the completion of the merger. We have contacted the plaintiffs' counsel to determine whether a settlement can be reached. If an acceptable settlement cannot be reached, we expect to contest the plaintiffs' claims vigorously.

On or about August 22, 2007, David P. Luci, our former general counsel, filed an action in New York State Supreme Court, New York County purporting to assert claims against us, our chief financial officer and certain of our current and former directors. The complaint purports to allege, among other things, that we breached contractual and other obligations allegedly owed to him in connection with the termination of his employment with us, and purports to demand damages, in the aggregate, of \$108,400,000. We believe that the action is without merit and intend to mount a vigorous defense.



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

While it is not feasible to predict the outcome of these lawsuits, their ultimate resolution could have an adverse effect upon our business, financial condition, results of operations or reputation.

Information about legal proceedings is incorporated herein by reference to Item 3 of this Form 10-K.

***Certain persons have substantial control over us, which could impede stockholder approval of certain transactions.***

Pursuant to the terms of tender and voting agreements made in connection with the Merger Agreement, on July 10, 2007, our directors and executive officers tendered to Wichita Bio all shares of our common stock and

11

---

preferred stock owned by them on that date. Under the terms of the tender and voting agreements, our directors and executive officers have agreed to vote any shares of our common stock owned by them as of the record date in favor of the proposal to approve the Merger Agreement.

Additionally, as a result of these tender and voting agreements and other shares of common stock acquired pursuant to the terms of the Merger Agreement, Genzyme and Wichita Bio beneficially own approximately 21.7% of the outstanding shares of Bioenvision common stock on an as-converted basis, including approximately 15.3% of the voting power of all outstanding shares of our capital stock and 100% of the voting power of all outstanding shares of our preferred stock. Under the terms of the Merger Agreement, absent Genzyme's consent we are required, until consummation of the merger, to preserve our personnel and our business, to maintain insurance policies and to protect our intellectual property rights, among other actions. We are also required to obtain Genzyme's consent prior to, among other things, disposing of assets, making capital expenditures or incurring indebtedness greater than a set amount, changing compensation payable to our officers, directors or employees, making any material acquisitions outside the ordinary course of business, or entering into any extraordinary transactions.

As Genzyme and Wichita Bio are the sole beneficial owners of our outstanding shares of preferred stock, we are required to obtain Genzyme's consent prior to taking any of the following actions: (i) the authorization, issuance or agreement to authorize or issue any new class or series of parity or senior securities or rights of any kind convertible into or exercisable or exchangeable therefor, or the offering, sale or issuance of any existing parity or senior securities or rights of any kind convertible into or exercisable or exchangeable therefor; (ii) the purchase, repurchase or redemption of shares of our common stock, securities or rights of any kind convertible into or exercisable for our common stock or any other of our securities (except in the case of a termination of an employee); (iii) an increase or decrease in the number of members constituting the size of our board of directors; (iv) an increase in the authorized number of shares of our common stock or preferred stock; (v) the effecting of any merger, combination, reorganization, or sale of all or substantially all of our assets; (vi) the declaration or payment of dividends or any other distribution on shares of our common stock or other capital stock; (vii) the amendment of our certificate of incorporation or bylaws or the alteration or change to the rights, preferences or privileges of our preferred stock or any parity or senior securities, in each case so as to affect adversely the rights, preferences or privileges of our preferred stock; or (viii) an increase in the number of shares of our common stock reserved for the employee option pool by more than 5% per year.

These consent rights could have the effect of delaying or preventing a third party from acquiring control over us and could affect the market price of our common stock. In addition, the interests of certain large stockholders may not always coincide with our interests or the interests of other stockholders, and, accordingly, these stockholders could impede transactions or agreements that would otherwise be approved by other stockholders generally.

*As a result of the purchase of our common stock under the terms of the Merger Agreement, trading in our common stock may be more difficult.*

The purchase of our common stock and preferred stock under the terms of the Merger Agreement has reduced the number of holders of our common stock and the number of shares of our common stock that might otherwise trade publicly, which could adversely affect the liquidity and market value of the remaining common stock held by stockholders other than Genzyme. We cannot predict whether the reduction in the number of shares of our common stock that might otherwise trade publicly will have an adverse or beneficial effect on the market price for, or marketability of, our common stock or whether such reduction will cause future market prices to be greater or less than the offer price of \$5.60 per share of common stock.

#### **Factors Relating to our Business**

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

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

We are developing clofarabine in conjunction with Genzyme, our U.S. co-development partner since its acquisition of ILEX Oncology, which occurred on December 21, 2004. No assurance can be given that the operational and managerial relations with Genzyme will proceed favorably or that the timeline for development of clofarabine will not be elongated since 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.

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

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

12

---

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

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

***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® ( clofarabine), which may delay our ability to generate significant revenues and cash flow from the sale of Evoltra®.***

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 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 the 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® 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®, obtain necessary regulatory approvals, and generate sales and cash flow from the sale of Evoltra®.

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 disagreed with Genzyme with respect to certain provisions of the co-development agreement, which may affect our ability to generate significant revenues and cash flow from the sale of Evoltra®.***

During the performance of the co-development agreement, we have disagreed with Genzyme from time to time on the interpretation of certain of the parties' respective rights and obligations under the co-development agreement. Some of these disagreements have been resolved by the parties in the ordinary course of business. In some instances, the parties have continued to perform their obligations under the co-development agreement while reserving their rights with respect to disagreements that they were not able to resolve. For example, the parties have disagreed as to the proper interpretation of the language in Section 3.6 of the co-development agreement. Section 3.6 provides that if Genzyme fails to file a new drug application for chronic leukemia or solid tumors within a prescribed period of time, then we shall have the right to make such filing. If we prepared and filed a new drug application for the treatment of chronic leukemia or solid tumors, and if that application were to be approved, the parties do not agree as to whether we would then have the right to market and sell clofarabine in North America for those indications or whether Genzyme would retain those rights under Section 6.1 of the co-development agreement. Given the disagreement as to the interpretation of the parties' rights under the co-development agreement, and given the challenges of developing clofarabine for the treatment of chronic leukemia or solid tumors and preparing and filing a new drug application for those uses, we have elected at this time to focus our resources and efforts on the development and commercialization of clofarabine outside of the United States while reserving our rights under Section 3.6 of the co-development agreement. While it is not feasible to predict the outcome of these disagreements, their ultimate resolution could have a material adverse effect on our ability to develop and/or market Evoltra®, obtain necessary regulatory approvals, and generate sales

We depend on our co-development agreement with Genzyme and if it does not proceed as planned, we may incur

and cash flow from the sale of Evoltra®.

***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 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 \$36,242,000 for the fiscal year ended June 30, 2007. At June 30, 2007, we had an accumulated deficit of approximately \$122,809,000. 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® and Modrenal®, 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.

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

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

- inability of vendors to manufacture sufficient quantities of materials for use in clinical trials;
- slower than expected rate of patient recruitment or variability in the number and types of patients in a study;
- inability to adequately follow patients after treatment;
- unforeseen safety issues or side effects;
- lack of efficacy during the clinical trials; or
- government or regulatory delays.

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

Our ancillary products include OLIGON®, an anti-microbial compound, and Suvus®, an anti-viral agent, respectively, which we acquired in February 2002 in the Pathagon acquisition. As a result of the loss of certain aspects of patent protection, we re-evaluated the alternative future uses of methylene blue in human indications. Methylene blue demonstrated effectiveness in the treatment of hepatitis-C through an Investigator Sponsored Phase II clinical trial conducted in the Middle East. In December of 2005, we submitted to the Ministry a protocol for an investigator sponsored clinical trial in Egypt for refractory genotype IV Hepatitis C. Concurrent with the submission of the protocol, we filed a marketing authorization with the Ministry for the use of methylene blue in Hepatitis C based on the Phase II data. Our plan was to attain product approval (then anticipated to be received by the end of calendar 2006) and then commence with further investigator sponsored clinical trials in Egypt into which we would sell methylene blue

at a price discounted to the current treatments available. The trials were intended to be performed whether marketing approval was received or not.

At June 30, 2006, we completed an analysis of methylene blue which confirmed that such estimated future cash flows continued to be worth more than the carrying value of methylene blue. In September of 2006, the Ministry provided feedback on our filing and requested that, among other things, an Egyptian-based company be added to our distribution process. We responded to the Ministry in January of 2007. In March of 2007, we received another request from the Egyptian authorities relating again to the manufacturing process and we submitted our responses in April 2007. Separately, in February of 2007, we hired a third party to assist us in performing a strategic review of our asset portfolio which was completed during the fourth quarter of 2007. In conjunction with this analysis, our board of directors determined that we would no longer devote any further resources to the development of methylene blue, unless and until a secure revenue source could be identified as a pre-condition to the use of methylene blue in a clinical trial. As a result of our inability to obtain a secure source to fund further development of methylene blue, along with the inability to commence a clinical study into which we could sell the product, we re-evaluated the intangible asset at June 30, 2007. We recognized a non-cash impairment loss equal to its carrying value of approximately \$3,311,000. 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.

In January 2007, we entered into a licensing agreement with Foster to license out exclusive rights to manufacture, market and distribute our proprietary anti-microbial OLIGON® technology. Under the terms of the license agreement, we will have a revenue sharing agreement on future sublicenses and a royalty on all sales by Foster. At June 30, 2007, we completed an analysis of our OLIGON® intangible asset which confirmed that such estimated future cash flows continued to be worth more than the carrying value of OLIGON®, and, therefore, no impairment was deemed to be required. The net intangible asset associated with OLIGON® at June 30, 2007 amounted to approximately \$2,786,000.

Based on the remaining estimated useful life of OLIGON® of approximately 12 years and market considerations, no assurance can be given that there will not be an impairment of this asset 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, make 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 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. 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 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.

***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.***

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 marketing 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®.***

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® and our other products. We do not have long-term data on the use of the product and cannot predict whether Evoltra® 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.

***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:

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

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

Our industry is subject to extensive government regulation and our products require other regulatory approvals which





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

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

*Foreign Regulatory Approval.* Even if required FDA approval has been obtained with respect to a product, foreign regulatory approval of a product must also be obtained prior to marketing the product internationally. Foreign approval procedures vary from country to country and the time required for approval may delay or prevent marketing. In certain instances, we or our collaborative partners may seek approval to market and sell some of our products outside of the U.S. 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 E.U. approval mechanism for new pharmaceutical products in place, each E.U. country may nonetheless impose its own procedures and requirements, many of which are time consuming and expensive. In addition, many E.U. countries require pricing and reimbursement approvals following marketing authorization. Thus, there can be substantial delays in obtaining required approval from both the FDA and foreign regulatory authorities after the relevant applications are filed. In connection with the status of our application to the EMEA to include a new indication for clofarabine for the treatment of adult AML in elderly patients who have one or more of the following: adverse cytogenetics, secondary AML,  $\geq 70$  years old or significant co-morbidities and who are therefore not considered suitable for intensive chemotherapy, the EMEA has agreed to accept supplemental information from us by November 16, 2007. We currently anticipate that in December 2007 the Rapporteur will provide its assessment report and that in January 2008 the EMEA will either provide us with an opinion on whether or not we will be granted marketing authorization of clofarabine for this new indication or provide us with a second Request for Supplemental Information. Any changes to this anticipated timeframe could have a material adverse effect on our ability to develop and sell products and, therefore, generate revenue and cash flow. See also *Our Products Evoltra® (Clofarabine)* above.

*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.

Our industry is subject to extensive government regulation and our products require other regulatory approvals which

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

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.

17

---

Our industry is subject to extensive government regulation and our products require other regulatory approvals which

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

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

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

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

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

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

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

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

An increase in competition from 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® and Modrenal®, our co-lead drugs, have demonstrated activity are areas of unmet clinical need, such as Evoltra® application to pediatric acute leukemias in which, initially, the drug will be used as a salvage therapy, after other regimens of treatment have failed. Our lead investigators, who have assisted with the development of Modrenal®, envision, initially, that Modrenal® would be used as second or third line therapy, only after patients with advanced post-menopausal breast cancer receive regimens of tamoxifen and/or aromatase inhibitors (or similar drug) treatments. If drug companies develop a compound which is more effective than either Evoltra® or Modrenal® in these therapeutic areas, or equally as effective but at lower prices, 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, many of which have substantially greater capital resources, marketing, research and development staffs and facilities than us. Potential competitors for certain indications of our lead drugs include, with respect to Evoltra®, 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® include Astra-Zeneca and Novartis, which market tamoxifen and other aromatase inhibitors, which could be used by clinicians as first and second line therapies in patients with hormone sensitive, advanced, post-menopausal breast cancer prior to a Modrenal® regimen of treatment. No assurance can be given that the ongoing business activities of our competitors will not have a material adverse effect on our business prospects and projections going forward.

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

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

The pharmaceutical industry is characterized by rapid and significant technological change. We expect that pharmaceutical technology will continue to develop rapidly, and our future success will depend on our ability to develop and maintain a competitive position. Technological development by others may result in products developed by us, branded or generic, becoming obsolete before they are marketed or before we recover a significant portion of the development and commercialization expenses incurred with respect to these products. Alternative therapies or new medical treatments could alter existing treatment regimens, 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 competitor 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 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 further establish direct or indirect sales and distribution capabilities outside of the UK or be successful in gaining market acceptance for proprietary products or for other products. We currently have very limited sales and marketing capabilities outside of the UK. We currently employ six full-time sales employees and two full-time marketing employees. We have also entered into arrangements with Innovex, an affiliate of Quintiles Corporation, for the sales and marketing of Evoltra® (clofarabine) in certain E.U. countries. To market any products directly, we will need to develop a more fulsome marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. To the extent that we enter into co-promotion or other licensing arrangements, any revenues to be received by us will be dependent on the efforts of third parties. The efforts of third parties may not be successful. Our failure to establish marketing and distribution capabilities or to enter into marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

***We rely heavily on our management team and the unexpected loss of any of those personnel could adversely affect our operations; we depend on our ability to attract and retain key personnel.***

We rely heavily on the skills and abilities of our management team. We have entered into employment agreements with our management team. The existence of such agreements, however, does not necessarily assure that we will be able to continue to retain their services. The unexpected loss of any of our key employees could have a material adverse effect on our business.

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

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

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

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

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

Several of the original patents to Modrenal® have expired in the U.S. and foreign countries. Thus, we and our licensor, Stegram Pharmaceutical Ltd., are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal®. We cannot guarantee that such applications will result in issued patents or that such patents if issued will provide adequate protection against competitors. Patents may not be issued from these applications and issued patents may not give us adequate protection or a competitive advantage. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain U.S. or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us.

Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from 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 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.

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.

***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® and Modrenal®, in territories outside of the U.S. Specifically, we currently market Modrenal® in the U.K. and Evoltra®

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

throughout Europe. Further, more than half of our employees are employed by Bioenvision Limited, our wholly-owned subsidiary with offices in Edinburgh, Scotland and we have recently opened an office in Tokyo, Japan.

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

- difficulty in establishing or managing distribution relationships;
- different standards for the development, use, packaging, pricing and marketing of our products and technologies;
- our inability to locate qualified local employees, partners, distributors and suppliers;
- the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment;
- general geopolitical risks, such as political and economic instability, changes in diplomatic and trade relations, and foreign currency risks; and
- 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, Euro and Yen. Accordingly, as the value of the dollar becomes weaker against the pound sterling, Euro and Yen, ongoing services provided by our U.K. 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 associated with our drug development activities.

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

As of June 30, 2007, we had stockholders' equity of approximately \$50,008,000 and working capital of approximately \$47,811,000. However, depending on the outcome of the proposed merger, 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. As Genzyme and Wichita Bio are the sole beneficial owners of our outstanding shares of preferred stock, we are required to obtain Genzyme's consent prior to any such issuance of equity securities in connection with a financing. 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. See also *Certain persons have substantial control over us, which could impede stockholder approval of certain transactions.*

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

We cannot predict our future capital needs and we may not be able to secure additional financing which could affect





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. 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 EMEA, FDA, the FTC or other government agencies having regulatory authority for product sales. Product recalls, if any in the future, may harm our reputation and cause us to lose development opportunities, or customers or pay refunds. Products may need to be recalled due to disputed labeling claims, manufacturing issues, quality defects, or other reasons. 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 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.

***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, 2007, our stock price has ranged from a high of \$6.41 to a low of \$3.23. 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.

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

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

- our board of directors approves the transaction before the third party acquires 15% of our common stock;
- the third party acquires at least 85% of our common stock at the time its ownership exceeds the 15% level; or
- our board of directors and two-thirds of the shares of our common stock not held by the third party vote in favor of the transaction.

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

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

***Genzyme's rights as the sole beneficial owners of our outstanding shares of preferred stock could prevent an acquisition of our business.***

**As Genzyme and Wichita Bio are the sole beneficial owners of our outstanding shares of preferred stock, we are required to obtain Genzyme's consent prior to the effecting of any merger, combination, reorganization, or sale of all or substantially all of our assets. This could have the effect of discouraging, delaying or preventing a third party from acquiring control over us at a premium price or at all, and could affect the market price of our common stock. Genzyme could impede transactions or agreements that would otherwise be approved by other stockholders generally. **See also *Certain persons have substantial control over us, which could impede stockholder approval of certain transactions.*****

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

As of June 30, 2007, we had 55,035,739 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 6,739,732 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from \$1.25 to \$8.87 per share. We have also reserved for issuance an aggregate of 6,750,000 shares of common stock for a stock option plan for our employees. Historically, from time to time, we have awarded our common stock to our officers, in lieu of cash compensation, although we do not expect to do so in the future. As of June 30, 2007, we have the sale of shares of common stock underlying 8,250,000 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

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

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

securities will result in a dilution to the holder's percentage ownership of our common stock. The resale of many of the shares of common stock which underlie these options and warrants are registered under this prospectus and the sale of such shares may adversely affect the market price of our common stock.

24

---

### 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 \$26,351 per month. These facilities are the center for all of our administrative functions in the U.S. We rent 2,437 square feet of office space in Edinburgh, Scotland for 15,120 per month. In September of 2006 we began leasing additional space of 1,004 square feet for an additional 6,600 per month. Also, we rent office space in Tokyo, Japan for approximately 788,000 JPY 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.

### Item 3. Legal Proceedings

We are a defendant in multiple putative class action lawsuits that have been filed in connection with the merger against us, our directors, Genzyme and Wichita Bio, the Genzyme subsidiary which will merge with and into us resulting in us becoming a wholly owned subsidiary of Genzyme. Among other things, the lawsuits seek to enjoin the completion of the merger. While it is not feasible to predict the outcome of these lawsuits, their ultimate resolution could have an adverse effect upon our business, financial condition, results of operations or reputation.

We have contacted the plaintiffs' counsel to determine whether a settlement can be reached. If an acceptable settlement cannot be reached, we expect to contest the plaintiffs' claims vigorously. We cannot predict or determine the outcome of the litigation.

On June 7, 2007, three purported stockholders of Bioenvision filed a purported class action lawsuit in the Court of Chancery in the State of Delaware, New Castle County against us, each of our directors, Genzyme and Wichita Bio: *Trombley v. Bioenvision, Inc., et al.*, Civ. A. No. 3008. The *Trombley* lawsuit purports to be brought individually and on behalf of all holders of shares of our common stock. The *Trombley* lawsuit alleges that our then directors breached their fiduciary duties to our stockholders in connection with the tender offer and that Genzyme aided and abetted such alleged breach of our directors' fiduciary duties. Based on these allegations, the *Trombley* lawsuit seeks, among other relief, injunctive relief preliminarily and permanently enjoining each of us, our directors, Genzyme and Wichita Bio from consummating the merger, directing our directors to exercise their fiduciary duties to obtain a transaction that is in the best interests of our stockholders, and rescinding, to the extent already implemented, the merger or any of the terms thereof. Our board of directors and we believe the allegations in the *Trombley* lawsuit are without merit.

On June 8, 2007 and June 13, 2007, we were named as a defendant in two purported class action lawsuits filed in the Court of Chancery in the State of Delaware, New Castle County, against us, each of our directors, Genzyme and Wichita Bio. These actions are docketed as *Ortsman v. Wood, et al.*, Civ. A. No. 3009 and *Gerstle v. Bioenvision, Inc., et al.*, Civ. A. No. 3019. Both the *Ortsman* lawsuit and the *Gerstle* lawsuit purport to be brought individually and on behalf of all holders of our common stock. Both lawsuits also allege that our then directors breached their fiduciary duties to our stockholders in connection with the tender offer and that Genzyme aided and abetted such alleged breach of our directors' fiduciary duties. Based on these allegations, the *Ortsman* lawsuit and the *Gerstle* lawsuit seek, among other relief, injunctive relief preliminarily and permanently enjoining each us, our directors, Genzyme and Wichita Bio from consummating the merger, awarding damages, and rescinding, to the extent already implemented, the merger or any of the terms thereof. We and our board of directors believe the allegations in the *Ortsman* lawsuit and the *Gerstle* lawsuit are without merit.

In addition, on June 13, 2007, the plaintiff in the *Trombley* lawsuit filed an amended complaint, which expands upon the allegations made in that plaintiff's original complaint filed on June 7, 2007. On June 13, 2007, this purported stockholder also filed a preliminary injunction motion, seeking to enjoin the merger in advance of the

date it is scheduled to close, and an expedited proceedings motion, seeking to proceed with discovery on an expedited basis and to set June 28, 2007 as the date for hearing plaintiff's application for a preliminary injunction.

On June 14, 2007, a purported stockholder of Bioenvision filed a purported class action lawsuit in the Court of Chancery in the State of Delaware, New Castle County against us, each of our directors, Genzyme and Wichita Bio: *Albstein v. Bioenvision, Inc., et al.*, Civ. A. No. 3025. The *Albstein* lawsuit purports to be brought individually and on behalf of all holders of our common stock. The lawsuit alleges that our then directors breached their fiduciary duties to our stockholders in connection with the tender offer and that Genzyme aided and abetted such alleged breach of our directors' fiduciary duties. Based on these allegations, the *Albstein* lawsuit seeks, among other relief, injunctive relief preliminarily and permanently enjoining each of us, our directors, Genzyme and Wichita Bio from consummating the merger, directing the director defendants to exercise their fiduciary duties to obtain a transaction that is in the best interests of our stockholders, and rescinding, to the extent already implemented, the merger or any of the terms thereof. We and our board of directors believe the allegations in the *Albstein* lawsuit are without merit.

On June 20, 2007, a purported stockholder of Bioenvision filed a purported class action lawsuit in the Court of Chancery in the State of Delaware, New Castle County against us, each of our directors, Genzyme and Wichita Bio: *Oppenheim Asset Management, et al. v. Bioenvision, Inc., et al.*, Civ. A. No. 3040-VCP. The *Oppenheim Asset Management* lawsuit purports to be brought individually and on behalf of all holders of our common stock. The lawsuit alleges that our then directors breached their fiduciary duties to our stockholders in connection with the tender offer and that Genzyme aided and abetted such alleged breach of our directors' fiduciary duties. Based on these allegations, the *Oppenheim Asset Management* lawsuit seeks, among other relief, injunctive relief enjoining each of us, our directors, Genzyme and Wichita Bio from consummating the merger, rescinding, to the extent already implemented, the merger or any of the terms thereof, declaring that the defendants have committed or participated in a breach of their fiduciary duty to the purported stockholder and other members of the class, and awarding plaintiff the costs and disbursements of this *Oppenheim Asset Management* lawsuit including a reasonable allowance for plaintiff's attorneys and experts' fees. The purported stockholder also filed an expedited proceedings motion, seeking to proceed with discovery on an expedited basis. We and our board of directors believe the allegations in the *Oppenheim Asset Management* lawsuit are without merit.

On June 20, 2007, the Court of Chancery in the State of Delaware, New Castle County entered an order that consolidated all Delaware actions filed as of that date into the *Trombley* proceeding (*Brian Trombley et al. v. Bioenvision, Inc. et al.*, Consolidated Civ. A. 3008-VCP). On June 26, 2007, in connection with this consolidated proceeding, plaintiffs voluntarily withdrew their motion for a preliminary injunction and removed the hearing thereon scheduled for June 28, 2007 from the calendar of the Court of Chancery. Plaintiffs' claims remain pending before the Court of Chancery.

On June 22, 2007, we were served with a purported class action lawsuit filed on June 7, 2007 by a purported stockholder of Bioenvision in the Supreme Court of the State of New York, New York County: *Bert Vladimir v. Bioenvision, Inc. et al.*, Index No. 650163-2007. The *Vladimir* lawsuit purports to be brought individually and on behalf of all holders of our common stock against us and each of our then directors. The lawsuit alleges that our directors breached their fiduciary duties to our stockholders in connection with the tender offer. Based on these allegations, the *Vladimir* lawsuit seeks, among other relief, injunctive relief preliminarily and permanently enjoining us and our directors from consummating the merger, rescinding, to the extent already implemented, the merger or any of the terms thereof, declaring that the defendants have committed a breach of their fiduciary duties to the purported stockholder and other members of the class, and awarding plaintiff the costs and disbursements of the *Vladimir* lawsuit including a reasonable allowance for plaintiff's attorneys and experts' fees. The purported stockholder also filed an expedited discovery proceedings motion, seeking to proceed with discovery on an expedited basis, and a memorandum of law in support of expedited discovery proceedings. We and our board of directors believe the allegations in the *Vladimir* lawsuit are without merit.

On or about August 22, 2007, David P. Luci, our former General Counsel, filed an action in New York State Supreme Court, New York County purporting to assert claims against us, our Chief Financial Officer and certain of our current and former Directors. The Complaint purports to allege, among other things, that we breached contractual and other obligations allegedly owed to him in connection with the termination of his employment with us, and purports to demand damages, in the aggregate, of \$108,400,000. We believe that the action is without merit and intend to mount a vigorous defense. The action is entitled *David P. Luci v. Bioenvision, Inc., Joseph Cooper, Michael Kauffman, James Scibetta, Steven A. Elms, Andrew N. Schiff and Thomas Scott Nelson* (Index No. 07/111478).

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

None

**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 Global 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
<b>Fiscal year ended June 30, 2006</b>		
First Quarter	\$ 9.18	\$ 6.60
Second Quarter	8.22	5.42
Third Quarter	8.95	6.35
Fourth Quarter	7.55	4.76
<b>Fiscal year ended June 30, 2007</b>		
First Quarter	\$ 6.41	\$ 4.08
Second Quarter	6.11	4.30
Third Quarter	5.24	3.91
Fourth Quarter	5.99	3.23

The last reported sale price of our common stock on the NASDAQ Global Market on September 5, 2007 was \$5.38.

As of September 5, 2007 there were approximately 128 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.

27

*Equity Compensation Plan Information*

The following table provides information about the securities authorized for issuance under our equity compensation plans as of June 30, 2007:

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options (a)</b>	<b>Weighted-average exercise price of outstanding options (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation plans approved by security holders	4,457,250	\$ 5.39	1,449,417
Equity compensation plans not approved by security holders(1)	1,500,000	\$ 1.25	—
<b>Total</b>	<b>5,957,250</b>	<b>—</b>	<b>1,449,417</b>

(1) These 1,500,000 options were issued to Dr. Wood in April of 2001 as a retention grant before we had an approved stock incentive plan.

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 6,750,000 shares reserved for grants of options and rights under the plan and at June 30, 2007, 5,300,583 of these options and rights had been issued.

*Issuer Purchases of Equity Securities*

None.

*Performance Graph*

The following line graph compares cumulative total stockholder returns for the last five fiscal years, from June 30, 2002 through June 30, 2007 for (1) our common stock; (2) the NASDAQ Composite Index; and (3) a peer group consisting of the following publicly traded companies within our industry: Enzon Pharmaceuticals Inc., Genzyme Corp. and Vion Pharmaceuticals Inc. ( Peer Group ). The graph assumes an investment of \$100 on June 30, 2002 and includes the reinvestment of dividends, if any. The performance shown is not necessarily indicative of future performance.



	6/02	6/03	6/04	6/05	6/06	6/07
<b>Bioenvision Inc</b>	<b>100.00</b>	<b>111.00</b>	<b>438.00</b>	<b>364.00</b>	<b>266.50</b>	<b>289.00</b>
<b>NASDAQ Composite</b>	<b>100.00</b>	<b>108.54</b>	<b>139.90</b>	<b>140.79</b>	<b>151.46</b>	<b>182.66</b>
<b>Peer Group</b>	<b>100.00</b>	<b>183.03</b>	<b>207.02</b>	<b>252.07</b>	<b>255.95</b>	<b>269.47</b>

28

**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, 2007, 2006 and 2005, the Consolidated Balance Sheets as of June 30, 2007 and 2006 and the Consolidated Statements of Cash Flows Data for the years ended June 30, 2007, 2006 and 2005 are derived 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, 2004 and 2003, the Consolidated Balance Sheets as of June 30, 2005, 2004 and 2003 and the Consolidated Statements of Cash Flows Data for the years ended June 30, 2004 and 2003 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.

<b>Consolidated Statement of Operations Data</b>	<b>Year ended June 30, 2007</b>	<b>Year ended June 30, 2006</b>	<b>Year ended June 30, 2005</b>	<b>Year ended June 30, 2004</b>	<b>Year ended June 30, 2003</b>
Revenue	\$ 19,069,597	\$ 5,309,072	\$ 4,651,174	\$ 3,102,214	\$ 504,857
Cost of products sold	3,450,279	1,662,975	921,262		
Operating expenses					
Research and development	21,065,263	11,726,981	10,894,925	4,882,574	1,689,278
Selling, general and administrative	27,701,740	16,562,770	10,181,711	9,082,420	4,567,413
Depreciation and amortization	1,021,427	974,440	1,438,517	1,348,064	1,344,969
Provision for bad debts	160,740	24,564	869,220		
Loss on impairment	3,310,905		5,276,162		
Total operating expenses	56,710,354	30,951,730	29,581,797	15,313,058	7,601,660
Loss from operations	(37,640,757)	(25,642,658)	(24,930,623)	(12,210,844)	(7,096,803)
Other income (expense), net	1,736,176	1,743,895	667,838	99,763	(186,426)
Loss before income taxes	(35,904,581)	(23,898,763)	(24,262,785)	(12,111,081)	(7,283,229)
Income tax benefit				1,459,814	2,117,103
Net Loss	(35,904,581)	(23,898,763)	(24,262,785)	(10,651,267)	(5,166,126)
Cumulative preferred stock dividend	(337,500)	(337,500)	(404,079)	(856,776)	(877,818)
Net loss applicable to common stockholders	\$ (36,242,081)	\$ (24,236,263)	\$ (24,666,864)	\$ (11,508,043)	\$ (6,043,944)
Basic and diluted common shares outstanding	45,033,991	40,865,384	34,042,391	20,257,482	16,920,939
Basic and diluted net loss applicable to common stockholders per share	\$ (0.80)	\$ (0.59)	\$ (0.72)	\$ (0.57)	\$ (0.36)
<b>Consolidated Balance Sheet Data</b>	<b>Year ended June 30, 2007</b>	<b>Year ended June 30, 2006</b>	<b>Year ended June 30, 2005</b>	<b>Year ended June 30, 2004</b>	<b>Year ended June 30, 2003</b>
Cash and cash equivalents	\$ 43,682,624	\$ 3,377,937	\$ 31,407,533	\$ 18,875,675	\$ 7,929,686
Short-term investments	5,488,646	41,637,106	32,746,948		
Intangible assets, net	3,355,992	7,549,520	8,252,936	14,563,660	15,779,399
Total assets	69,793,349	62,250,464	80,790,135	42,170,844	26,173,132
Total current liabilities	13,228,368	8,592,018	6,738,722	3,460,419	2,264,896
Total stockholders' equity	50,007,929	46,587,721	66,613,815	30,800,827	21,323,737
<b>Consolidated Statement of Cash Flows Data</b>	<b>Year ended June 30, 2007</b>	<b>Year ended June 30, 2006</b>	<b>Year ended June 30, 2005</b>	<b>Year ended June 30, 2004</b>	<b>Year ended June 30, 2003</b>
Net cash used in operating activities	\$ (32,150,510)	\$ (20,794,013)	\$ (13,417,438)	\$ (4,641,193)	\$ (4,411,581)
Net cash provided by (used in) investing activities	36,929,061	(7,463,820)	(33,384,403)	(130,917)	(541,254)
Net cash provided by financing activities	35,564,621	433,370	59,296,122	15,730,847	



**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**

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, 2007 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*

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.

We currently sell our products to hospitals, clinical trial centers and our co-development partners. 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. We record product sales net of any allowances for sales returns. We estimate our return reserves based on our experience of return rates on historical sales. Our allowance for sales return reserves may increase in the future if our history of product returns changes.

Research and development contract revenue includes sales in our pre-commercial stage named patient program for Evoltra® 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® outside the United States.

We follow the guidance of Emerging Issues Task Force 99-19, Reporting Revenue Gross as a Principal versus Net as an Agent in the presentation of revenue and direct costs of revenue. This guidance requires us to assess whether we act as a principal in the transaction or as an agent acting on behalf of others. We record revenue transactions gross in our statements of operations if we are deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

*Research and Development*

Research and development costs are charged to expense as incurred. Research and development costs consist primarily of costs associated with determining feasibility, licensing and pre-clinical and clinical testing of our products, including salaries and related personnel costs, fees paid to consultants and outside service providers for drug development, the cost of Evoltra® sold prior to product approval through our named patient program and other expenses. Also included in research and development costs is the financial support provided to Cardiff for the AML 16 trials. This financial support is tied to the number of patients enrolled on clofarabine. We estimate our

expense for the AML 16 trials each reporting period based on data regarding patient enrollment received from Cardiff.

#### *Stock-Based Compensation*

We account for stock-based compensation in accordance with SFAS No. 123 (revised 2004), Share-Based Payment ( SFAS 123 (R) ) and 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 use historical exercise patterns as our best estimate of the expected term of the options. We utilize historical turnover rates in estimating expected forfeitures separately for executives and non-executives. The risk-free rate is based upon the U.S. Treasury yield curve in effect at the time of grant.

#### *Impairment of Long-Lived Assets*

In accordance with SFAS No. 144, we review for impairment our intangible assets that are subject to amortization 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. 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-orientated biopharmaceutical company primarily focused upon the acquisition, development, and marketing of compounds and technologies for the treatment of cancer. Our product pipeline includes Evoltra® (clofarabine) which has marketing approval in both the E.U. and U.S. for the treatment of pediatric relapsed or refractory acute lymphoblastic leukemia, Modrenal® (trilostane), which has marketing approval in the U.K. for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy, and other products.

On May 29, 2007, we entered into an Agreement and Plan of Merger (the Merger Agreement ) with Genzyme Corporation, our North American co-development partner for clofarabine ( Genzyme ) and Wichita Bio Corporation, a wholly-owned subsidiary of Genzyme ( Wichita Bio ). We are holding a special meeting of our stockholders to vote on this proposed merger, **which is currently scheduled for October 4, 2007**. The merger is the second and final step in the proposed acquisition of Bioenvision by Genzyme. The first step was the tender offer for all of the outstanding common stock and all of the outstanding preferred stock of Bioenvision, which expired on July 10, 2007. Pursuant to the tender offer, Wichita Bio purchased 8,398,098 shares of common stock, representing approximately 15.3% of the outstanding shares of our common stock as of the date hereof, and 2,250,000 shares of preferred stock, representing 100% of the outstanding shares of our preferred stock as of the date hereof. Following the tender offer and as of the date hereof, Genzyme beneficially owns approximately 22% of the outstanding shares of Bioenvision common stock on an as-converted basis, including all outstanding shares of Bioenvision preferred stock. If the merger is completed, Wichita Bio, will be merged with and into Bioenvision, we will become a wholly-owned subsidiary of Genzyme and each share of our common stock issued and outstanding immediately before the merger, other than treasury shares, shares for which appraisal rights have been perfected and shares held by Genzyme or Wichita Bio, will automatically

be canceled and will cease to exist and will be converted into the right to receive \$5.60 in cash, without interest. **See *Factors Relating to the Proposed Merger with Genzyme* beginning on page 10.**

31

---

Evoltra® is our lead product. In May 2006 the EMEA approved Evoltra® 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® has been granted orphan drug designation (ODD), providing marketing exclusivity for 10 years in Europe, which 10-year period commenced in May 2006 upon our receipt of E.U. marketing approval. We have a direct sales force in the U.K. and a dedicated sales force through Innovex, an affiliate of Quintiles Corporation, in several other countries within the E.U.. Subject to the outcome of the merger, we plan to increase either our direct sales force or our dedicated sales force through Innovex as we continue to work through reimbursement procedures and expand our marketing initiatives to exploit new commercial opportunities within the E.U.

On February 7, 2007, we announced that we filed with the EMEA to expand the Evoltra® (clofarabine) label to include the treatment of acute myeloid leukemia (AML) in patients who are greater than or equal to 65-years-old and have one or more of the following: adverse cytogenetics, secondary AML, aged greater than or equal to 70 years, or have one or more significant comorbidity. This new target indication, if approved, represents a significant increase in the size of the potential market available to Evoltra®. In addition, we have ODD in this new target indication which may provide further market exclusivity in the E.U.

On August 16, 2007, we announced that, in connection with the status of our application to the EMEA to include a new indication for clofarabine for the treatment of adult AML in elderly patients who have one or more of the following: adverse cytogenetics, secondary AML,  $\geq 70$  years old or significant co-morbidities and who are therefore not considered suitable for intensive chemotherapy, the EMEA has agreed to accept supplemental information from us by November 16, 2007. This timeframe will enable us to prepare a more comprehensive response to the EMEA, including interim data from the ongoing, multicenter AML-16 trials that have been initiated by the NCRI in the U.K. We currently anticipate that in December 2007 the Rapporteur will provide its assessment report and that in January 2008 the EMEA will either provide us with an opinion on whether or not we will be granted marketing authorization of clofarabine for this new indication or provide us with a second Request for Supplemental Information.

It should be noted that the foregoing may be subject to change and the EMEA's assessment report and opinion may require us to provide further data and/or to attend an oral explanation. The opinion of the EMEA is also required to be adopted by the European Commission as a pre-condition to the grant of marketing authorization of clofarabine for the treatment of adult AML. In addition, in relation to our variation application to include this new indication, the EMEA has requested that data from the ongoing AML-16 trials be provided. The AML-16 trials, sponsored by the NCRI, randomize clofarabine against the standard of care (low-dose cytarabine) for the treatment of elderly patients with adult AML who are not considered suitable for intensive chemotherapy. We believe we will be able to make data from these trials available to the EMEA by November 2007. There can be no assurances, however, that this data will be made available to us for its application. The AML-16 trials will not be fully enrolled at the time of submission of our response to the EMEA and there can be no assurances that interim data will be satisfactory, or that the data itself will be supportive of our application. Further, if the EMEA does not accept this data, we may have to run an additional randomized study.

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

In September 2006, we executed a License Agreement with SRI, pursuant to which we successfully licensed the manufacturing, marketing and distribution rights to clofarabine in Japan and Southeast Asia (the Japan License ). Since taking on these rights, we have organized JapanCo., and appointed a director in charge of corporate and product development for JapanCo.





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

Also, in conjunction with Genzyme clofarabine (Evoltra®) is in clinical development for the treatment of myelodysplastic syndrome (MDS), chronic lymphocytic leukemia (CLL), non-Hodgkin's lymphoma (NHL), solid tumors and as a preconditioning regimen for transplantation. Although we are currently not directly involved with these programs, Genzyme is required to share the data generated thereunder in accordance with the terms of our co-development agreement.

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

We have an exclusive worldwide license for clofarabine. We granted an exclusive sublicense to Genzyme to co-develop clofarabine for certain cancer indications in the US and Canada. Genzyme is commercializing clofarabine for certain cancer indications in the US and Canada under the brand name Clolar®. 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 under a co-development agreement dated August 31, 1998. On May 24, 2007, we entered into an amendment to that agreement, pursuant to which the parties agreed to modify and/or clarify certain of the economic terms of their arrangement including, without limitation, terms related to royalties, milestones, profit sharing and assignability provisions.

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 received Orphan Drug Designation status for clofarabine in the U.S., providing marketing exclusivity for 7½ years, expiring in 2012.

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

Pursuant to the terms of our co-development agreement with SRI, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications except for certain U.S. and Canadian cancer indications. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the development and marketing of clofarabine, which we currently expect to expire in 2021.

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

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

We anticipate that revenues derived from Evoltra® will permit us to further develop the other products currently in our product pipeline. In addition to clofarabine and Modrenal®, we have performed development work with Suvus® for the treatment of chronic hepatitis C. We have had discussions with potential product partners from time to time and plan to continue to explore the possibilities for co-development and sub-licensing in order to



implement our development plans. In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. The work to date on these compounds has been limited because of the need to concentrate on Evoltra®, but management believes these compounds have potential value.

In May 2003, we entered into a License and Sub-License Agreement with Dechra Pharmaceuticals, plc, or Dechra, pursuant to which we sub-licensed to Dechra the marketing and development rights to Vetoryl® (trilostane), solely with respect to animal health applications, in the U.S. and Canada. We received \$1,250,000 in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try and capitalize on these types of opportunities as they arise. We also own rights to OLIGON® technology. In January 2007, we entered into a licensing arrangement with Foster Corporation ( Foster ) to license out exclusive rights to manufacture, market and distribute our proprietary anti-microbial OLIGON® technology. Under the terms of the license agreement, we will have a revenue sharing arrangement on future sublicenses and a royalty on all sales by Foster, a Connecticut-based compounder of biomedical materials. Foster is required to comply with annual minimum marketing and research and development expenditures within the first three years of the term of the license.

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

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

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

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

## Results of Operations

### Year Ended June 30, 2007 Compared to Year Ended June 30, 2006

We recorded revenue for the years ended June 30, 2007 and 2006 of approximately \$19,070,000 and \$5,309,000, respectively, representing an increase of approximately \$13,761,000. This increase is primarily due to increased product sales of \$14,760,000 as a result of Evoltra® approval in Europe. Prior to the approval, all product sales through the named patient program were reflected as research and development contract revenue. License and royalty revenue also increased \$1,711,000 primarily due to increased royalties on US sales received from our co-development partner.

The cost of products sold for the years ended June 30, 2007 and 2006 were approximately \$3,450,000 and \$1,663,000, respectively, representing an increase of approximately \$1,787,000. The cost of products sold reflects the direct costs associated with our product sales and includes royalty expense of \$2,889,000 and \$1,277,000 for the years ended June 30, 2007 and 2006, respectively. All direct costs associated with clofarabine sales were expensed in periods prior to the E.U. approval.

Research and development costs for the years ended June 30, 2007 and 2006 were approximately \$21,065,000 and \$11,727,000, respectively, representing an increase of approximately \$9,338,000. Our research and development costs include costs associated with the three products shown in the table below:

Product	June 30, 2007	June 30, 2006	Change
Evoltra® (clofarabine)	\$ 18,943,000	\$ 9,125,000	\$ 9,818,000
Modrenal® (trilostane)	2,085,000	2,283,000	(198,000 )
Suvus® (methylene blue)	37,000	319,000	(282,000 )
Total	\$ 21,065,000	\$ 11,727,000	\$ 9,338,000

Evoltra® research and development costs for the years ended June 30, 2007 and 2006 were approximately \$18,943,000 and \$9,125,000 respectively, representing an increase of approximately \$9,818,000. The increase is primarily due to an increase in our development activities and clinical trials of Evoltra® in Europe, including the process of filing for approval in our first label extension for Evoltra®, the enrollment of patients in our Phase II trial in Europe for the treatment of adult AML in elderly patients unfit for intensive chemotherapy and amounts relating to financial support provided to Cardiff University in connection with the AML-16 trials that are being conducted in Europe partially offset by a reduced rate of enrollment in the European Phase II BIOV-111 study of pediatric patients with refractory or relapsed ALL. We also recorded approximately \$4,000,000 of costs in connection with the acquisition of the Japanese and Southeast Asian rights to Evoltra® which occurred in September of 2006.

Modrenal® research and development costs for the years ended June 30, 2007 and 2006 were approximately \$2,085,000 and \$2,283,000, respectively, representing a decrease of \$198,000. This decrease is due to a reduced rate of patient enrollment in the Phase II clinical trial in pre-menopausal breast cancer and Phase IV clinical trial in patients with post-menopausal breast cancer, which are each being conducted in the U.K.

Suvus® research and development costs for the years ended June 30, 2007 and 2006 were approximately \$37,000 and \$319,000, respectively, representing a decrease of \$282,000. The decrease primarily reflects the costs associated with the investigator sponsored Phase II clinical trial conducted in Egypt in the prior period.

There were no research and development costs for OLIGON® for the years ended June 30, 2007 and 2006 due to our entering into a licensing arrangement with Foster to license out exclusive rights to manufacture, market and distribute our proprietary anti-microbial OLIGON® technology in January 2007. No additional costs are expected to be incurred by us in connection with future development of OLIGON® by Foster.

**The clinical trials and development strategy for Evoltra® and Modrenal®, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) Evoltra® research and development costs have been approximately \$42,384,000; (ii) Modrenal® research and development costs have been approximately \$10,737,000; and (iii) Suvus® research and development costs have been approximately \$545,000.**

**Selling, general and administrative expenses for the years ended June 30, 2007 and 2006 were approximately \$27,702,000 and \$16,563,000, respectively, representing an increase of \$11,139,000. This increase is primarily relating to the costs associated with the expanded sales and marketing team in Europe of approximately \$8,079,000 and consulting fees associated with the merger agreement with Genzyme of \$1,501,000. Other factors include an increase in stock-based compensation expense due to the issuance of common stock to one of our officers of the Company pursuant to the terms of his amended employment agreement and the granting of stock options to one of our officers as inducement to serve our Chief Financial Officer as well as increased legal and financial advisor fees incurred in connection with the Merger Agreement with Genzyme Corporation.**

**Depreciation and amortization expense for years ended June 30, 2007 and 2006 was approximately \$1,021,000 and \$974,000, respectively, representing an increase of \$47,000.**

Provision for bad debts for the years ended June 30, 2007 and 2006 were approximately \$161,000 and \$25,000, respectively, representing an increase of approximately \$136,000. The increase is due to our recording a valuation allowance relating to the outstanding receivable from a shareholder relating to the statutorily required withholding taxes due to the UK tax regulatory authority which is partially offset by our right of offset.

As a result of the loss of certain aspects of patent protection, we re-evaluated the alternative future uses of methylene blue in human indications. Methylene blue demonstrated effectiveness in the treatment of hepatitis-C through an Investigator Sponsored Phase II clinical trial conducted in the Middle East. In December of 2005, we submitted to the Ministry of Health a protocol for an investigator sponsored clinical trial in Egypt for refractory genotype IV hepatitis C. Concurrent with the submission of the protocol, we filed a marketing authorization with the Ministry for the use of methylene blue in hepatitis C based on the Phase II data. Our plan was to attain product approval (then anticipated to be received by the end of calendar 2006) and then commence with further investigator sponsored clinical trials in Egypt into which we would sell methylene blue at a price discounted to the current treatments available. The trials were intended to be performed whether marketing approval was received or not. At June 30, 2006, we received an independent third-party valuation of methylene blue which confirmed that such estimated future cash flows continued to be worth more than the carrying value of methylene blue. In September of 2006, the Ministry provided feedback on our filing and requested that, among other things, an Egyptian-based company be added to our distribution process. We responded to the Ministry in January of 2007. In March of 2007, we received another request from the Egyptian authorities relating again to the manufacturing process and we submitted our responses in April 2007. Separately, in February of 2007, we hired a third party to assist us in performing a strategic review of our asset portfolio which was completed during the fourth quarter of 2007. In conjunction with this analysis, our board of directors determined that we would no longer devote any further resources to the development of methylene blue, unless and until a secure revenue source could be identified as a pre-condition to the use of methylene blue in a clinical trial. As a result of our inability to obtain a secure source to fund further development of methylene blue, along with the inability to commence a clinical study into which we could sell the product, we re-evaluated the intangible asset at June 30, 2007. We recognized a non-cash impairment loss equal to its carrying value of approximately \$3,311,000.

We currently sell clofarabine to approximately 116 centers in Europe which are participating in the AML-16 trials that have been initiated by the National Cancer Research Institute (NCRI). Distribution of clofarabine to the study centers is being coordinated by a single trial center, Cardiff University ( Cardiff ) which is located in the U.K. The AML-16 studies include the phase I pilot intensive trial which commenced in December of 2005 and was completed in September of 2006, the phase II AML-16 non-intensive trial which commenced in July of 2006 and is expected

to complete recruitment in 2008 and the phase III AML-16 intensive trial which commenced in August of 2006 and is expected to complete recruitment in 2009. In order to facilitate distribution, invoicing and compiling of study reports, we have entered into research agreements with Cardiff in connection with each of these trials that, among other things, provide for the sale of clofarabine, at current market prices, through Cardiff to the study sites. During the years ended June 30, 2007 and 2006, respectively, 40% and 27% of our total revenue was attributed to the sale of clofarabine to Cardiff. During the three months ended September 30, 2006, December 31, 2006, March 31, 2007 and June 30, 2007, revenue attributable to Cardiff accounted for 52%, 48%, 41% and 30% of total revenue, respectively. We anticipate that the percentage of our total revenues derived from the sale of clofarabine into the AML-16 trials will continue to decrease. In connection with the research agreements, we are obligated to provide financial support to Cardiff which is dependent on the completion of certain milestones which are due upon the receipt of interim and final study reports. For the years ended June 30, 2007 and 2006, we recognized approximately \$7,770,000 and \$533,000, respectively, as research and development costs relating to the AML-16 trials.

#### 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®. This increase was partially offset by a decrease in research and development contract revenue of approximately \$1,910,000 as we 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® outside the United States because it determined that the criteria for recognizing such contract revenue had not been met. If and when we determine that collectibility is reasonably assured, we 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, three of which we currently devote time and resources:

Product	June 30, 2006	June 30, 2005	Change
Evoltra®	\$ 9,125,000	\$ 8,697,000	\$ 428,000
Modrenal®	2,283,000	1,972,000	311,000
Suvus®	319,000	131,000	188,000
Velostan		79,000	(79,000)
OLIGON®		16,000	(16,000)
Gene Therapy			
Total	\$ 11,727,000	\$ 10,895,000	\$ 832,000

Evoltra® 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®



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® 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® 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.

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 racemic form of the compound for use in our clinical development program in order for us to continue our development activities with this compound. No assurance can be given that we will be able to create the L-form Velostan required for the clinical development program or, if we can, the timing of such development.

OLIGON® 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® during this period.

The clinical trials and development strategy for the Evoltra® and Modrenal® projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as follows: (i) Evoltra® research and development costs have been approximately \$23,441,000; (ii) Modrenal® research and development costs have been approximately \$8,652,000; (iii) Velostan research and development costs have been approximately \$380,000; (iv) Suvus® research and development costs have been approximately \$508,000; (v) OLIGON® research and development costs have been approximately \$24,000; and (vi) Gene Therapy research and development costs have been approximately \$451,000.

Selling, general and administrative expenses for the 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:

- an increase of approximately \$3,450,000 in employee stock based compensation expense (a non-cash item) primarily due to our 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 one of our officers of the Company from five to ten years;
- an increase in sales and marketing costs of approximately \$1,200,000 related to our development of a sales and marketing force in Europe;
- an increase in payroll due to the significant increase in employee headcount in both New York and Edinburgh offices of approximately \$540,000;
- an increase of approximately \$256,000 due to an increase in insurance premiums paid by us.

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 our recording of 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 our recording of a valuation allowance relating to certain of the outstanding receivable balances from our co-development partner totaling \$869,000 in the prior year.

### **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 adequate revenue to support our cost structure or otherwise achieve profitable operations.

On April 5, 2007, we completed a secondary public offering in which we sold 8,000,000 common shares at \$3.75 per share, with net proceeds to us of approximately \$27,716,000, after deducting underwriting discounts and commissions and offering expenses.

On June 30, 2007, we had cash and cash equivalents and short-term investments of approximately \$49,171,000 and working capital of \$47,811,000. Management believes that we have sufficient cash and cash equivalents, short-term investments and working capital to continue currently planned operations through June 30, 2008.

However, depending on the outcome of the proposed Genzyme merger, 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, depending on the outcome of the Genzyme merger, we may be required to fund additional operating losses in the foreseeable future, our financial position may 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 or additional products, 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 years ended June 30, 2007 and 2006, net cash used in operating activities was approximately \$32,151,000 and \$20,794,000, respectively, representing an increase of approximately \$11,357,000. 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 our expanded sales and marketing and administrative infrastructure and costs associated with our internal build out and (iii) cash paid for insurance premiums. For the fiscal year ended June 30, 2007 and 2006, net cash provided by (used in) investing activities was approximately \$36,929,000 and \$(7,464,000), respectively, representing an increase of approximately \$44,393,000. This increase is primarily due to the redemption of the certificate of deposits that had been funded with the cash received from the proceeds from our February 2005 secondary offering. For the fiscal year ended June 30, 2007 and 2006, net cash provided by financing activities was approximately \$35,565,000 and \$433,000 representing an increase of \$35,132,000. This increase is primarily due to the completion of the secondary public offering in April 2007, which yielded net proceeds of approximately \$27,716,000 as well as certain of our warrant holders exercising their warrants pursuant to which we received proceeds of approximately \$8,146,000.

For the fiscal years 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 our internal build out and (iii) cash paid for insurance premiums. For the fiscal year ended June 30, 2006 and 2005, net cash used in investing

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

activities was approximately \$7,464,000 and \$33,384,000, respectively, representing a decrease of approximately \$25,920,000. This decrease is primarily due to us 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 respectively 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.

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

	Payments Due in Fiscal Year:				
	2008	2009	2010	2011	2012
Operating Leases	\$ 943,429	\$ 373,988	\$ 181,391	\$	\$
Contractual Obligations	750,000	250,000	250,000	500,000	4,000,000
Total	\$ 1,693,429	\$ 623,988	\$ 431,391	\$ 500,000	\$ 4,000,000

The contractual obligations relate to minimum payments due under our license agreement with SRI.

### *Off-balance sheet arrangements*

We have no off-balance sheet arrangements.

### *Subsequent Events*

As disclosed in the our current report on Form 8-K, filed on July 16, 2007, On July 13, 2007, we announced that Dr. Andrew N. Schiff and Mr. Steven A. Elms resigned from the Board of Directors, effective as of July 13, 2007. Their resignations as board members were not the result of any disputes or disagreements relating to the operations, policies or practices of Bioenvision.

As disclosed in our current report on Form 8-K, filed on July 27, 2007, effective as of July 27, 2007, the Company terminated the employment of David P. Luci, Bioenvision, Inc.'s Executive Vice President, General Counsel and Secretary effective as of July 27, 2007.

As disclosed in our current report on Form 8-K, filed on August 16, 2007, On August 16, 2007, we announced that, in connection with the status of our application to the EMEA to include a new indication for clofarabine for the treatment of adult AML in elderly patients who have one or more of the following: adverse cytogenetics, secondary AML,  $\geq 70$  years old or significant co-morbidities and who are therefore not considered suitable for intensive chemotherapy, the EMEA has agreed to accept supplemental information from us by November 16, 2007. This timeframe will enable us to prepare a more comprehensive response to the EMEA, including interim data from the ongoing, multicenter AML-16 trials that have been initiated by the National Cancer Research Institute ( NCRI ) in the U.K. We currently anticipate that in December 2007 the EMEA will provide its assessment report and that in January 2008 the EMEA will either provide us with an opinion on whether or not we will be granted marketing authorization of clofarabine for this new indication or provide us with a second RSI. It should be noted that the foregoing may be subject to change and the EMEA's assessment report and opinion may require us to provide further data and/or to attend an oral explanation. The opinion of the EMEA is also required to be adopted by the European Commission as a pre-condition to the grant of marketing authorization of clofarabine for the treatment of adult AML. In addition, in relation to our variation application to include this new indication, the EMEA has requested that data from the ongoing AML-16 trials be provided. The AML-16 trials, sponsored by the NCRI, randomize clofarabine against the standard of care (low-dose cytarabine) for the treatment of elderly patients with adult AML who are not considered suitable for intensive chemotherapy. We believe we will be able to make data from these trials available to the EMEA by November 2007. There can be no assurances, however, that this data will be made available to us for its application. The AML-16 trials will not be

fully enrolled at the time of submission of our response to the EMEA and there can be no assurances that interim data will be satisfactory, or that the data itself will be supportive of our application. Further, if the EMEA does not accept this data, we may have to run an additional randomized study.

As disclosed in our current report on Form 8-K, filed on August 16, 2007, on August 31, 2007, we announced that, on or about August 22, 2007, David P. Luci, our former General Counsel, filed an action in New York State Supreme Court, New York County purporting to assert claims against us, our Chief Financial Officer and certain current and former Directors of Bioenvision. The Complaint purports to allege, among other things, that we breached contractual and other obligations allegedly owed to him in connection with the termination of his employment with us, and purports to demand damages, in the aggregate, of \$108,400,000. We believe that the action is without merit and intend to mount a vigorous defense.

On September 7, 2007, we filed a definitive proxy statement on Schedule 14A, whereby we announced that a Special Meeting of our stockholders is currently scheduled for October 4, 2007, to vote on the proposed merger with Genzyme.

#### ***Recent Accounting Pronouncements***

In June 2007, the Emerging Issues Task Force ( EITF ) issued EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ( EITF 07-3 ). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity must defer and capitalize non-refundable advance payments made for research and development activities and expenses these amounts as the related goods are delivered or the related services are performed. EITF 07-3 is effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007. We are currently evaluating the impact of adopting EITF 07-03 on its financial statements and results of operations.

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

In December 2006, the FASB issued a FASB Staff Position ( FSP ) Emerging Issues Task Force ( EITF ) Issue No. 00-19-2 Accounting for Registration Payment Arrangements ( FSP 00-19-2 ) which addresses an issuer s accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No.5 Accounting for Contingencies . The guidance in FSP 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities , and FASB Statement No.150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity , and FASB Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of this FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We have analyzed the provisions of FSP 00-19-2 and determined that it will not have a material effect on our consolidated financial statements.

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

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

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 are currently evaluating the impact, if any, of the provisions of FIN 48.

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

Our excess cash is invested in money market accounts and 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, 2007, we do not have any outstanding debt. Accordingly, due to the maturity and credit quality of our investments, we are not subjected to any substantial risk arising from changes in interest rates, currency exchange rates and commodity and equity prices. However, we do have some exposure to foreign currency rate fluctuations arising from maintaining an office for our U.K. based, wholly-owned subsidiary which transacts business in the local functional currency, as well some exposure to foreign currency rate fluctuations arising from maintaining an office for our Japan based wholly-owned subsidiary which transacts business in the local currency. Management periodically reviews such foreign currency risk and to date has not undertaken any foreign currency hedges through the use of forward exchange contracts or options and does not foresee doing so in the near future.

#### **Item 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**

None

#### **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

42

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 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.

*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, 2007, 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, 2007, in that they ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, and (2) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

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.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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, 2007, 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, 2007, 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, 2007, 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 June 30, 2007 consolidated balance sheet and related consolidated statements of operations, stockholders' equity, comprehensive loss and cash flows of Bioenvision and our report dated August 31, 2007 expressed an unqualified opinion on those statements.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
August 31, 2007

*Changes in Internal Controls*

There have not been any changes in our internal control over financial reporting during the fiscal quarter ended June 30, 2007 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**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, 2007 in connection with our 2007 Annual Meeting of Stockholders.

**Item 11. Executive Compensation**

See Item 10.

**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.

45

---



## PART IV

**Item 15. Exhibits, Financial Statement Schedules**

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

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 Bioenvision for each of the years ended June 30, 2007, 2006 and 2005, 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 Bioenvision.

	<b>Page Number</b>
Schedule II Valuation and Qualifying Accounts	S-2

(3) *Exhibits:*

<b>Exhibit Number</b>	<b>Description</b>
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (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.)
2.2	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. (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.)
2.3	Agreement and Plan of Merger, dated as of May 29, 2007, by and among Genzyme Corporation, a Massachusetts corporation, Wichita Bio Corporation, a Delaware corporation, and Bioenvision, Inc., a Delaware corporation. (Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 29, 2007.)
2.4	Amendment #1 to Agreement and Plan of Merger, dated as of August 8, 2007, by and among Genzyme Corporation, a Massachusetts corporation, Wichita Bio Corporation, a Delaware corporation, and Bioenvision, Inc., a Delaware corporation. (filed herewith.)
3.1	Certificate of Incorporation of Registrant. (filed herewith.)
3.1(a)	Amendment to Certificate of Incorporation filed January 29, 1999. (Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.)
3.1(b)	Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002. (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.)
3.1(c)	Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002. (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.)
3.1(d)	Certificate of Designations, Preferences and Rights of Series A Preferred. (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.)
3.1(e)	Certificate of Amendment to the Certificate of Incorporation, filed January 14, 2004. (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.)
3.2	Amended and Restated By-Laws of the Registrant. (Incorporated by reference and filed as an

46



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

- 4.1 Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.)  
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. (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.)
- 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. (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.)
- 4.3 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (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.)
- 4.4 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (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.)
- 4.5 Form of Warrant. (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.)
- 4.6 Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC. (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.)
- 4.7 Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC. (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.)
- 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. (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.)
- 4.9 Registration Rights Agreement, dated March 22, 2004, by and between Bioenvision, Inc. and the Investors set forth on Schedule I thereto. (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.)
- 4.10 Form of Warrant. (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.)
- 4.11 Bioenvision, Inc. 2003 Stock Incentive Plan. (Registrant's definitive proxy statement on Schedule 14-A, filed in connection with the annual meeting held on January 14, 2004.)
- 4.12 Form of Tender and Voting Agreement, by and among Genzyme Corporation, Wichita Bio Corporation and certain stockholders of Bioenvision, Inc. (Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 29, 2007.)
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc. (Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the fiscal year ended June 30, 2003.)
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc. (Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the fiscal year ended June 30, 2003.)
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. And Bioenvision, Inc. dated July 15, 1998. (Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.)
- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (Incorporated by reference and filed as an Exhibit to Registrant's Form

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

- 10-KSB/A filed with the SEC on October 18, 1999.)
- 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc. (Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the fiscal year ended June 30, 2003.)
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002. (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.)
- 10.8 Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003. (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.)
- 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (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.)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (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.)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (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.)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (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.)
- 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. (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.)
- 10.15 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (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.)
- 10.16 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (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.)
- 10.17 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (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.)
- 10.18 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (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.)
- 10.19 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999. (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.)
- 10.20 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (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.)
- 10.21 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (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.)
- 10.22 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among

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

- 10.23 Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (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.)  
Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC. (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.)
- 10.24 Employment Agreement between Bioenvision Limited and Hugh Griffith, effective as of October 23, 2002. (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.)
- 10.25 Employment Agreement between Bioenvision Limited and Ian Abercrombie, effective as of January 6, 2003. (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.)
- 10.26 Amendment # 2 to the Co-Development Agreement between Bioenvision and ILEX Oncology, Inc. dated December 30, 2003. (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.)
- 10.27 Amendment to the Co-Development Agreement between Bioenvision, Inc. and SRI, dated as of March 12, 2001. (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.)
- 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. (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.)
- 10.29 Joinder made by Bioenvision, Inc., dated February 26, 2004. (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.)
- 10.30 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Sterling SNIFF, dated as of August 12, 2005. (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.)
- 10.31 Supply Agreement-Trilostane, by and among, Stegram Pharmaceuticals, Bioenvision, Inc., Dechra Ltd. and Steroid SpA, dated as of August 12, 2005. (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.)
- 10.32 Amendment to Employment Agreement, by and between Bioenvision and David P. Luci, dated February 6, 2006. (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.)
- 10.33 Clofarabine Marketing and Development Agreement, by and between Bioenvision Inc. and Mayne Pharma Limited, dated March 24, 2006. (Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q, for the three month period ended March 31, 2006.)
- 10.34 License Agreement by and between Southern Research Institute and Bioenvision, Inc., dated September 12, 2006. (Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q, for the three month period ended September 30, 2006.)
- 10.35 Employment Agreement by and between the Company and James S. Scibetta, dated November 27, 2006. (Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on November 30, 2006.)
- 10.36 Amendment to Clofarabine Marketing and Development Agreement, by and between Bioenvision Inc. and Mayne Pharma Limited, dated November 2, 2006. (Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-Q, for the three month period ended December 31, 2006.)
- 10.37 Entrustment Agreement, by and between Bioenvision JapanCo Ltd. and Yoshimaru Yamamoto, dated January 31, 2007. (Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on February 6, 2007.)

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

- 10.38 Compromise Agreement by and between Bioenvision Limited and Dr. Andrew Saunders, dated April 20, 2007. (Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on April 26, 2007.)
- 10.39 Second Amendment to Co-Development Agreement, dated as of May 24, 2007, by and between the Company and Southern Research Institute. (Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on May 25, 2007.)
- 10.40 Amendment No. 1 to Rights Agreement, dated as of May 30, 2007, by and between American Stock Transfer & Trust Company, a New York banking corporation, and Bioenvision, Inc., a Delaware corporation. (Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on May 30, 2007.)
- 10.41\* Research Agreement for Investigator Sponsored Clinical Trial, dated as of July 12, 2006, by and between Bioenvision Limited and Cardiff University. (filed herewith.)
- 10.42\* Research Agreement for Investigator Sponsored Clinical Trial, dated as of August 11, 2006, by and between Bioenvision Limited and Cardiff University. (filed herewith.)
- 14.1 Bioenvision Inc.'s Code of Business Conduct and Ethics. (Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the year ended June 30, 2004.)
- 16.1 Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (Incorporated by reference and filed as an Exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.)
- 16.2 Letter from Ernst & Young LLP Letter from Ernst & Young to the Securities and Exchange Commission, dated July 6, 2001. (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.)
- 16.3 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (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.)
- 16.4 Letter from Grant Thornton LLP to the Securities and Exchange Commission, dated April 7, 2005. (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.)
- 16.5 Letter from Deloitte & Touche LLP to the Securities and Exchange Commission, dated January 19, 2006. (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.)
- 21.1 Subsidiaries of the registrant (filed herewith.)
- 23.1 Consent of Independent Registered Public Accounting Firm (filed herewith.)
- 23.2 Consent of Prior Independent Registered Public Accounting Firm (filed herewith.)
- 24.1 Power of Attorney (appears on Signature page)
- 31.1 Certification of Christopher B. Wood, Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (filed herewith.)
- 31.2 Certification of James S. Scibetta, Chief Accounting Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. (filed herewith.)
- 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. (filed herewith.)
- 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.

---

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

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 12, 2007, 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)

Each person whose signature appears below hereby constitutes and appoints either Christopher B. Wood, or James S. Scibetta 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
<i>/s/ Christopher B. Wood, M.D.</i> Christopher B. Wood, M.D.	Chairman, Chief Executive Officer and Director (Principal Executive Officer)	September 12, 2007
<i>/s/ James S. Scibetta</i> James S. Scibetta	Chief Financial Officer (Principal Financial Officer)	September 12, 2007
<i>/s/ Lauren Bullaro</i> Lauren Bullaro	Chief Accounting Officer (Principal Accounting Officer)	September 12, 2007
<i>/s/ Thomas S. Nelson</i> Thomas S. Nelson, C.A.	Director	September 12, 2007
<i>/s/ Michael Kauffman</i> Michael Kauffman	Director	September 12, 2007
<i>/s/ Joseph Cooper</i> Joseph Cooper	Director	September 12, 2007

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Report of Prior Independent Registered Public Accounting Firm</u>	F-3
<u>Consolidated Balance Sheets as of June 30, 2007 and 2006</u>	F-4
<u>Consolidated Statements of Operations for the years ended June 30, 2007, 2006, and 2005</u>	F-5
<u>Consolidated Statements of Stockholders' Equity for the years ended June 30, 2007, 2006, and 2005</u>	F-6
<u>Consolidated Statements of Comprehensive Loss for the years ended June 30, 2007, 2006, and 2005</u>	F-7
<u>Consolidated Statements of Cash Flows for the years ended June 30, 2007, 2006, and 2005</u>	F-8
<u>Notes to Consolidated Financial Statements</u>	F-9
<u>Report of Independent Registered Public Accounting Firm</u>	S-1
<u>Schedule II - Valuation and Qualifying Accounts</u>	S-2

F-1

---



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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

We have audited the accompanying consolidated balance sheets of Bioenvision, Inc. and Subsidiaries (the Company) as of June 30, 2007 and 2006, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. 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 audits provide 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, 2007 and 2006, and their results of operations and cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 9, the Company is a party to multiple putative purported class action lawsuits in connection with a proposed merger.

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, 2007 based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organization of the Treadway Commission (COSO) and our report dated August 31, 2007, expressed an unqualified opinion on management's assessment of internal control over financial reporting and an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ JH Cohn LLP  
Roseland, New Jersey  
August 31, 2007

F-2

---

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders of

Bioenvision, Inc.:

We have audited the accompanying consolidated statements of operations, stockholders' equity, comprehensive loss and cash flows of Bioenvision, Inc. and subsidiaries (the Company) for the year ended June 30, 2005. Our audit also included the consolidated financial statement schedule as it relates to the year ended June 30, 2005 listed in the Index at Item 15. These consolidated financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule 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, such consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of Bioenvision, Inc. and subsidiaries 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 as it relates to the year ended June 30, 2005, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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

F-3

---

## BIOENVISION, INC AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	June 30, 2007	June 30, 2006
<i>Assets</i>		
Cash and cash equivalents	\$ 43,682,624	\$ 3,377,937
Short-term investments	5,488,646	41,637,106
Accounts receivable, net of allowances of \$863,079 and \$898,714, respectively	9,074,017	2,369,446
Inventories	1,131,052	427,514
Prepays and other current assets	1,663,004	844,810
Total current assets	61,039,343	48,656,813
Property and equipment, net	320,274	273,632
Intangible assets, net	3,355,992	7,549,520
Goodwill	1,540,162	1,540,162
Other assets	255,281	706,840
Deferred costs	3,282,297	3,523,497
Total assets	69,793,349	62,250,464
<i>Liabilities and Stockholders' Equity</i>		
Liabilities:		
Accounts payable	\$ 227,198	\$ 1,557,507
Accrued expenses and other current liabilities	12,431,104	6,464,445
Accrued dividend payable	56,404	56,404
Deferred revenue	513,662	513,662
Total current liabilities	13,228,368	8,592,018
Deferred revenue	6,557,052	7,070,725
Total liabilities	19,785,420	15,662,743
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, 2007 and 2006, respectively (liquidation preference \$6,750,000)	\$ 2,250	2,250
Common stock - \$0.001 par value; 70,000,000 shares authorized; 55,035,739 and 41,456,616 shares issued and outstanding at June 30, 2007 and 2006, respectively	55,036	41,457
Additional paid-in capital	173,022,341	133,604,996
Accumulated deficit	(122,809,349)	(86,567,268)
Receivable due from shareholder		(340,606)
Accumulated other comprehensive loss	(262,349)	(153,108)
Total shareholders' equity	50,007,929	46,587,721
Total liabilities and shareholders' equity	\$ 69,793,349	\$ 62,250,464

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



## BIOENVISION, INC AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

FOR THE YEARS ENDED JUNE 30, 2007, 2006 and 2005

	2007	2006	2005
<b>Revenue</b>			
Product sales	\$ 15,429,189	\$ 668,975	\$ 611,346
License and royalty revenue	3,640,408	1,929,526	1,463,326
Research and development revenue		2,710,571	2,576,502
<b>Total revenue</b>	<b>19,069,597</b>	<b>5,309,072</b>	<b>4,651,174</b>
<b>Costs and expenses</b>			
Cost of products sold (including royalty expense of \$2,889,000, \$1,277,000 and \$525,000, respectively)	3,450,279	1,662,975	921,262
Research and development	21,065,263	11,726,981	10,894,925
Provision for bad debts	160,740	24,564	869,220
Selling, general and administrative	27,701,740	16,562,770	10,181,711
Depreciation and amortization	1,021,427	974,440	1,438,517
Loss on impairment	3,310,905		5,276,162
<b>Total costs and expenses</b>	<b>56,710,354</b>	<b>30,951,730</b>	<b>29,581,797</b>
<b>Loss from operations</b>	<b>(37,640,757 )</b>	<b>(25,642,658 )</b>	<b>(24,930,623 )</b>
<b>Interest income (expense)</b>			
Interest and finance charges	26,062	(66,762 )	(79,484 )
Interest income	1,710,114	1,810,657	747,322
<b>Net loss</b>	<b>(35,904,581 )</b>	<b>(23,898,763 )</b>	<b>(24,262,785 )</b>
<b>Cumulative preferred stock dividend</b>	<b>(337,500 )</b>	<b>(337,500 )</b>	<b>(404,079 )</b>
<b>Loss applicable to common stockholders</b>	<b>\$ (36,242,081 )</b>	<b>\$ (24,236,263 )</b>	<b>\$ (24,666,864 )</b>
<b>Basic and diluted net loss per share applicable to common stockholders</b>	<b>\$ (0.80 )</b>	<b>\$ (0.59 )</b>	<b>\$ (0.72 )</b>
<b>Weighted-average shares used in computing basic and diluted net loss per share of common stock</b>	<b>45,033,991</b>	<b>40,865,384</b>	<b>34,042,391</b>

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

## BIOENVISION, INC AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

FOR THE YEARS ENDED JUNE 30, 2007, 2006 and 2005

	Convertible Participating Preferred Stock Shares		Common Stock Shares		Additional Paid-in capital	Deferred Compen- sation	Accumulated Deficit	Accumulated Other Receivable from Stockholders	Compre- hensive Income (Loss)	Total Stockholders Equity
Balance at July 1, 2004	3,341,666	\$ 3,342	28,316,163	\$ 28,316	\$ 68,517,702	\$ (223,990 )	\$ (37,664,141 )	\$	139,598	\$ 30,800,827
Net loss							(24,262,785 )			(24,262,785 )
Cumulative preferred stock dividend							(404,079 )			(404,079 )
Currency translation adjustment								(38,658 )		(38,658 )
Deferred compensation						78,344				78,344
Preferred stock converted to common stock	(1,091,666 )	(1,092 )	2,183,332	2,183	(1,092 )					
Income related to re-pricing of options					(314,950 )					(314,950 )
Warrants issued in connection with services					524,928					524,928
Shares issued in connection with services			62,500	63	496,188					496,250
Warrants exercised for common stock			1,811,120	1,811	3,277,151					3,278,962
Options exercised for common stock			685,833	686	707,638					708,324
Shares issued in connection with public offering, net of related expenses			7,500,000	7,500	55,739,152					55,746,652
Balance at June 30, 2005	2,250,000	2,250	40,558,948	40,559	128,946,717	(145,646 )	(62,331,005 )		100,940	66,613,815
Net loss							(23,898,763 )			(23,898,763 )
Cumulative preferred stock dividend							(337,500 )			(337,500 )
Currency translation adjustment								(254,048 )		(254,048 )
Due from Stockholder								(340,606 )		(340,606 )
Employee and board of director stock-based compensation					3,684,158					3,684,158
Deferred compensation					(136,457 )	145,646				9,189
			491,196	491	390,984					391,475

Edgar Filing: BIOENVISION INC - Form 10-K

Options exercised for common stock											
Warrants exercised for common stock											
			406,472	407	719,594				720,001		
Balance at June 30, 2006											
	2,250,000	2,250	41,456,616	41,457	133,604,996	(86,567,268	)	(340,606	(153,108	)	46,587,721

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

F-6

	Convertible Participating Preferred Stock Shares	Common Stock Shares	Additional Paid-in capital	Accumulated Deficit	Accumulated Receivable from Stockholders	Other Compre- hensive Loss	Total Stockholders Equity	
Net loss				(35,904,581 )			(35,904,581 )	
Cumulative preferred stock dividend				(337,500 )			(337,500 )	
Currency translation adjustment						(109,241 )	(109,241 )	
Due from Stockholder Employee and board of director stock-based compensation			3,415,931		340,606		340,606	
Issuance of unrestricted shares	31,100	31	153,447				153,478	
Warrants exercised for common stock - cash	4,310,999	4,311	8,141,520				8,145,831	
Warrants exercised for common stock - cashless	1,237,024	1,237	(1,237 )					
Shares issued in connection with public offering, net of related expenses	8,000,000	8,000	27,707,684				27,715,684	
Balance at June 30, 2007	2,250,000	\$ 2,250	55,035,739	\$ 55,036	\$ 173,022,341	\$ (122,809,349 )	\$ (262,349 )	\$ 50,007,929

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**FOR THE YEARS ENDED JUNE 30, 2007, 2006 and 2005**

**BIOENVISION, INC AND SUBSIDIARIES**

	2007	2006	2005
Loss applicable to common stockholders	\$ (36,242,081 )	\$ (24,236,263 )	\$ (24,666,864 )
Foreign currency translation loss	(109,241 )	(254,048 )	(38,658 )
Comprehensive Loss	\$ (36,351,322 )	\$ (24,490,311 )	\$ (24,705,522 )

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



**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**FOR THE YEARS ENDED JUNE 30,**

	2007	2006	2005
<b>Cash flows from operating activities</b>			
Net loss	\$ (35,904,581 )	\$ (23,898,763 )	\$ (24,262,785 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation and amortization	1,021,427	974,440	1,438,517
Provision for bad debts	160,740	24,564	869,220
Stock-based compensation	3,569,409	3,693,347	793,761
Loss on disposal		1,654	
Loss on impairment	3,310,905		5,276,162
<b>Changes in operating assets and liabilities:</b>			
Accrued interest on investments	(904,374 )	(1,405,798 )	
Inventories	(635,307 )	(143,383 )	(286,089 )
Prepays and other current assets	(737,385 )	(484,937 )	(94,797 )
Accounts receivable	(6,227,904 )	(574,610 )	(56,596 )
Other assets	489,380	(482,026 )	(132,072 )
Deferred costs	241,200	133,301	236,497
Accounts payable, accrued expenses and other current liabilities	3,979,653	1,720,017	3,325,964
Deferred revenue	(513,673 )	(351,818 )	(525,220 )
<b>Net cash used in operating activities</b>	<b>(32,150,510 )</b>	<b>(20,794,012 )</b>	<b>(13,417,438 )</b>
<b>Cash flows from investing activities</b>			
Purchase of intangible assets		(166,926 )	(359,411 )
Capital expenditures	(179,904 )	(102,535 )	(278,044 )
Release of restricted cash		290,000	
Redemption of short-term investments	37,108,965	17,834,104	
Purchase of short-term investments		(25,318,463 )	(32,746,948 )
<b>Net cash provided by (used in) investing activities</b>	<b>36,929,061</b>	<b>(7,463,820 )</b>	<b>(33,384,403 )</b>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock, net of related expenses	27,715,684		55,746,652
Due from stockholder	40,606	(340,606 )	
Proceeds from the exercise of options and warrants	8,145,831	1,111,476	3,987,286
Dividends paid	(337,500 )	(337,500 )	(437,816 )
<b>Net cash provided by financing activities</b>	<b>35,564,621</b>	<b>433,370</b>	<b>59,296,122</b>
Effect of exchange rate changes on cash and cash equivalents	(38,485 )	(205,134 )	37,577
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>40,304,687</b>	<b>(28,029,596 )</b>	<b>12,531,858</b>
Cash and cash equivalents, beginning of year	3,377,937	31,407,533	18,875,675
Cash and cash equivalents, end of year	\$ 43,682,624	\$ 3,377,937	\$ 31,407,533

*The accompanying notes are an integral part of these consolidated 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, and marketing of compounds and technologies for the treatment of cancer. Its product pipeline includes Evoltra® (clofarabine) which has marketing approval in both the European Union ( E.U. ) and United States ( U.S. ) for the treatment of pediatric relapsed or refractory acute lymphoblastic leukemia, Modrenal® (trilostane), which has marketing approval in the United Kingdom ( U.K. ) for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy, and other products.

On May 29, 2007, the Company entered into an Agreement and Plan of Merger (the Merger Agreement ) with Genzyme Corporation, our North American co-development partner for clofarabine ( Genzyme ). We are holding a special meeting of our stockholders to vote on this proposed merger, **which is currently scheduled for October 4, 2007**. The merger is the second and final step in the proposed acquisition of Bioenvision by Genzyme. The first step was the tender offer for all of the outstanding common stock and all of the outstanding preferred stock of Bioenvision, which expired on July 10, 2007. Following the tender offer and as of the date hereof, Genzyme became a stockholder and related party of the Company. If the merger is completed, our stockholders will have the right to receive \$5.60 in cash, without interest, for each share of our common stock they own.

(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 the current presentation.

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

F-9

The Company currently sells its products to hospitals, clinical trial centers and our co-development partners. 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. We record product sales net of any allowances for sales returns. We estimate our return reserves based on our experience of return rates on historical sales. Our allowance for sales return reserves may increase or decrease in the future if our history of product returns changes.

Research and development contract revenue includes sales in our pre-commercial stage named patient program for Evoltra® 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® outside the United States. Currently, the Company has billed but not recorded approximately \$4,600,000 of revenue relating to the reimbursement from our co-development partner (Genzyme) for certain of our ongoing research costs in the development of Evoltra® outside the United States as well as an additional \$2,381,000 which we have not billed but believe is owed to us from this co-development partner. If and when the Company has determined that collectibility is reasonably assured, the Company will record the revenue. Under the co-development agreement, the Company offsets these amounts against any royalty which otherwise would be paid to Genzyme on our U.K. sales. Genzyme is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada for certain cancer indications. The Company retains the right to handle those matters in all territories outside the United States and Canada and retains the right to handle these matters in the U.S. and Canada in all non-cancer indications. The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States and Canada. Under the co-development agreement, Genzyme will have certain rights if it performs its development obligations in accordance with that agreement. Under the circumstances, the Company is required to pay Genzyme a royalty on direct sales outside the U.S., Canada, Japan and Southeast Asia. In turn, Genzyme, which would have U.S. and Canadian distribution rights in cancer indications, is paying the Company a royalty on sales in the U.S. and Canada. Under the terms of the co-development agreement, Genzyme also pays royalties to Southern Research Institute ( SRI ) based on certain milestones. The Company also is obligated to pay certain royalties to SRI with respect to Evoltra®.

The Company follows the guidance of Emerging Issues Task Force 99-19, Reporting Revenue Gross as a Principal versus 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 consist primarily of costs associated with determining feasibility, licensing and pre-clinical and clinical testing of our products, including salaries and related personnel costs, fees paid to consultants and outside service providers for drug development, the cost of Evoltra® sold prior to product approval through our named patient program and other expenses. Also included in research and development costs is the financial support provided to Cardiff for the AML 16 trials. This financial support is tied to the number of patients enrolled on clofarabine. We estimate our expense for the AML 16 trials each reporting period based on data regarding patient enrollment received from Cardiff.

(e) Stock-based Compensation:

We account for stock-based compensation in accordance with SFAS No. 123 (revised 2004), Share-Based Payment ( SFAS 123 (R) ) and 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

F-10

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 use historical exercise patterns as our best estimate of the expected term of the options. We utilize historical turnover rates in estimating expected forfeitures separately for executives and non-executives. The risk-free rate is based upon the U.S. Treasury yield curve in effect at the time of grant. We have incorporated the following assumptions into the Black Scholes model:

	June 30, 2007		June 30, 2006		June 30, 2005	
Risk-free interest rate	4.43	4.84	% 3.89	4.95	% 2.93	4.05
Expected weighted-average term (in years)	3.95		3.79		3.87	
Expected weighted-average volatility	63		% 66		% 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, 2007, 2006 and 2005 was \$2.46, \$3.63 and \$4.75, respectively.

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 Company recorded, as a component of net loss, employee stock-based compensation (expense) income of approximately \$(3,323,000), \$(3,609,000) and \$227,000 for the years ended June 30, 2007, 2006 and 2005, respectively. As of June 30, 2007, the total compensation cost related to unvested equity awards granted to employees but not yet recognized is approximately \$3,568,000. This cost will be amortized on a straight-line basis over the remaining weighted average vesting period of 1.73 years.

For the year ended June 30, 2005, 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 year ended June 30, 2005:

	June 30, 2005
Net loss applicable to common stockholders, as reported	\$ (24,666,864 )
Add: Stock-based employee compensation (income) expense as reported	(227,417 )
Deduct: Total stock-based employee compensation expense as determined under the fair-value method for all awards	(2,427,771 )
Pro forma net loss applicable to common stockholders	\$ (27,322,052 )
Loss per share	
Basic and diluted as reported	\$ (0.72 )
Basic and diluted pro forma	\$ (0.80 )

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. All options and warrants to purchase 6,739,731, 11,563,314 and 11,472,414 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2007, 2006 and 2005, respectively, as their effect would have been anti-dilutive. Additionally, convertible participating preferred shares that are convertible into 4,500,000 shares of common stock have not been included in the calculation of net loss per share for each of the years ended June 30, 2007, 2006 and 2005, respectively, as their effect would have been anti-dilutive.

(h) Comprehensive Loss:

Our comprehensive loss includes loss applicable to common stockholders and unrealized gains (losses) from foreign currency translations to the US dollar, the reporting currency of the Company.

(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. We record adjustments relating to our wholly-owned subsidiary, Bioenvision JapanCo., Ltd. ( JapanCo ), whose functional currency is the US Dollar, as transaction gains (losses) in the statement of operations. For the years ended June 30, 2007, 2006 and 2005, the net foreign currency transaction gains (losses) included in selling, general and administrative expense were approximately \$(145,000), \$(2,300) and \$27,000, respectively.

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

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 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 on a straight-line basis over the term of the contract and the amortization of these costs has been presented in research and development on the consolidated statements of operations.

(l) Accounts Receivable and Significant Customers:

The Company's accounts receivable are primarily due from hospitals, clinical trial centers 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 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. Our co-development partner comprises approximately 15%, 33% and 62% of revenues earned for the years ended June 30, 2007, 2006, and 2005. Based on our evaluation of the collectibility of the accounts receivable from this customer, we believe that the balance relating to research and development reimbursements for revenue recorded in December 2004 through March 2005 may not be collectible. Under the terms of the co-development agreement, we have exercised our right of offset against royalties which would otherwise be paid on our UK sales. During the year ended June 30, 2007, we have offset royalties due of \$194,000 against the outstanding receivable from the co-development partner and have maintained a reserve on the remaining balance of \$675,000 at June 30, 2007.

The Company currently sells clofarabine to various centers located throughout Europe which are participating in the AML-16 trials that have been initiated by the National Cancer Research Institute (NCRI). Distribution of clofarabine to the study centers is being coordinated by a single trial center, Cardiff, which is located in the U.K. The AML-16 studies include the phase I pilot intensive trial which commenced in December of 2005 and was completed in September of 2006, the phase II AML-16 non-intensive trial which commenced in July of 2006 and is expected to complete recruitment in 2008 and the phase III AML-16 intensive trial which commenced in August of 2006 and is expected to complete recruitment in 2009. In order to facilitate distribution, invoicing and compiling of study reports, the Company has entered into research agreements with Cardiff in connection with each of these trials that, among other things, provide for the sale of clofarabine, at current market prices, through Cardiff to the study sites. During the years ended June 30, 2007 and 2006, respectively, 40% and 27% of the Company's revenue was attributed to the sale of clofarabine to Cardiff. In connection with the research agreements, the Company is obligated to provide financial support to Cardiff which is dependent on the completion of certain milestones which are due upon the receipt of interim and final study reports. For the years ended June 30, 2007 and 2006, the Company recognized approximately \$7,770,000 and \$533,000, respectively, as research and development costs relating to the AML-16 trials.

(m) Inventories:

Inventories are stated at the lower of cost or market, with cost being determined under the first-in, first-out method. The Company only capitalizes inventory that is produced for commercial sale. Manufacturing costs incurred to produce clofarabine prior to approval were recorded as research and development costs. The Company periodically reviews inventory on hand. Items considered outdated or obsolete are reduced to their estimated net realizable value. Below is a break down of inventories at June 30, 2007 and 2006:

F-13

---

	June 30, 2007	June 30, 2006
Raw materials	\$	\$ 118,213
Work-in-process	713,982	180,048
Finished goods	417,070	129,253
Total inventories	\$ 1,131,052	\$ 427,514

(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. The Company recorded depreciation expense for the years ended June 30, 2007, 2006 and 2005 of approximately \$139,000, \$104,000 and \$45,000, respectively.

	June 30, 2007	June 30, 2006
Computer equipment and software	\$ 446,515	\$ 390,044
Furniture and fixtures	121,382	54,503
Leasehold improvements	41,746	
	609,643	444,547
Less: Accumulated depreciation	(289,369)	(170,915)
Total property and equipment, net	\$ 320,274	\$ 273,632

(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 investments, accounts receivable and accounts payable, 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. Intangible assets include patents and licensing rights acquired in connection with the acquisition of Pathagon completed on February 1, 2002. 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 calculate the implied fair value of each goodwill amount and record an impairment loss for the excess of book value over the implied fair value, if any.

In accordance with SFAS No. 144, we review for impairment our intangible assets that are subject to amortization 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 2). 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.

(q) Accrued Expenses and Other Current Liabilities:

Below is a breakdown of our accrued expenses and other current liabilities at June 30, 2007 and 2006. Accrued research and development expenses include amounts relating to clinical trials, pre-clinical operating costs and amounts due on the license to develop, manufacture, market, distribute and sell Evoltra® in Japan and Southeast Asia. Other accrued expenses include inventories, royalties due on product sales and other operating expense accruals.

	June 30, 2007	June 30, 2006
Accrued research and development	\$ 6,716,903	\$ 4,389,951
Accrued sales and marketing	2,717,273	199,615
Accrued professional fees	698,016	493,924
Accrued compensation costs	789,699	702,097
Accrued other	1,509,213	678,858
<b>Total accrued expenses and other current liabilities</b>	<b>\$ 12,431,104</b>	<b>\$ 6,464,445</b>

(r) Recent Accounting Pronouncements:

In June 2007, the Emerging Issues Task Force ( EITF ) issued EITF 07-3, Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ( EITF 07-3 ). EITF 07-3 addresses the diversity that exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. The EITF concluded that an entity must defer and capitalize non-refundable advance payments made for research and development activities and expenses these amounts as the related goods are delivered or the related services are performed. EITF 07-3 is effective for interim or annual reporting periods in fiscal years beginning after December 15, 2007. The Company is currently evaluating the impact of adopting EITF 07-03 on its financial statements and results of operations.



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

In December 2006, the FASB issued a FASB Staff Position ( FSP ) Emerging Issues Task Force ( EITF ) Issue No. 00-19-2 Accounting for Registration Payment Arrangements ( FSP 00-19-2 ) which addresses an issuer 's accounting for registration payment arrangements. FSP 00-19-2 specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as a separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No.5 Accounting for Contingencies . The guidance in FSP 00-19-2 amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities , and FASB Statement No.150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity , and FASB Interpretation No. 45, Guarantor 's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others to include scope exceptions for registration payment arrangements. FSP 00-19-2 is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issue of this FSP 00-19-2. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of FSP 00-19-2, this is effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. The Company has analyzed the provisions of FSP 00-19-2 and determined that it will not have a material effect on the Company 's consolidated financial statements.

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

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

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

F-16

---

statements.

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

## Note 2 Intangible Assets

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

	June 30, 2007	June 30, 2006
Patents and licensing rights	\$ 5,218,953	\$ 9,382,450
Other intangible assets	298,505	298,505
	5,517,458	9,680,955
Less: Accumulated amortization	(2,161,466 )	(2,131,435 )
Total intangible assets, net	\$ 3,355,992	\$ 7,549,520

Amortization of patents, licensing rights and other intangible assets amounted to approximately \$883,000, \$870,000 and \$1,394,000 for the years ended June 30, 2007, 2006 and 2005, respectively, and are amortized over periods generally ranging from 1-20 years. Amortization for each of the next five fiscal years will amount to approximately \$260,000 annually. The weighted average remaining life of our intangibles at June 30, 2007 is approximately twelve years.

In connection with the Pathagon acquisition in February 2002, the Company acquired patents and licensing rights of OLIGON® and 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 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.

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.

F-17

As a result of the loss of certain aspects of patent protection, the Company re-evaluated the alternative future uses of methylene blue in human indications. Methylene blue demonstrated effectiveness in the treatment of hepatitis-C through an Investigator Sponsored Phase II clinical trial conducted in the Middle East. In December of 2005, the Company submitted to the Egyptian Ministry of Health ( Ministry ) a protocol for an investigator sponsored clinical trial in Egypt for refractory genotype IV hepatitis C. Concurrent with the submission of the protocol, the Company filed a marketing authorization with the Ministry for the use of methylene blue in hepatitis C based on the Phase II data. The Company's plan was to attain product approval (then anticipated to be received by the end of calendar 2006) and commence with further investigator sponsored clinical trials in Egypt into which we would sell methylene blue at a price discounted to the current treatments available. The trials were intended to be performed whether marketing approval was received or not.

At June 30, 2006, we completed an analysis of methylene blue which confirmed that such estimated future cash flows continued to be worth more than the carrying value of methylene blue. In September of 2006, the Ministry provided feedback on our filing and requested that, among other things, an Egyptian-based company be added to our distribution process. We responded to the Ministry in January of 2007. In March of 2007, the Company received another request from the Egyptian authorities relating again to the manufacturing process and we submitted our responses in April 2007. Separately, in February of 2007, the Company hired a third party to assist us in performing a strategic review of our asset portfolio which was completed during the fourth quarter of fiscal 2007. In conjunction with this analysis, our board of directors determined that the Company would no longer devote any further resources to the development of methylene blue, unless and until a secure revenue source could be identified as a pre-condition to the use of methylene blue in a clinical trial. As a result of our inability to obtain a secure source to fund further development of methylene blue, along with the continual delays from the Ministry, the Company re-evaluated the intangible asset at June 30, 2007. We recognized a non-cash impairment loss equal to its carrying value of approximately \$3,311,000.

The OLIGON® 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. At the time of acquisition, OLIGON® 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® technology to Edwards Lifescience for its use in short-term central venous catheters and pulmonary catheters. In January 2007, the Company entered into a licensing arrangement with Foster Corporation ( Foster ), a Connecticut-based compounder of biomedical materials, to license out exclusive rights to manufacture, market and distribute the Company's proprietary anti-microbial OLIGON® technology. Under the terms of the license agreement, Bioenvision will have a revenue sharing arrangement on future sublicenses and a royalty on all sales by Foster. At June 30, 2007, we estimate that our undiscounted cash flows relating to the OLIGON® technology are greater than the carrying value of our long-lived asset, and therefore, no impairment was deemed necessary for OLIGON® related intangibles.

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.

#### *Clofarabine (Evoltra®)*

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®). The Company received regulatory approval for Evoltra® from the

**Note 3 License and Co-Development Agreements**

European Medicines Agency on May 31, 2006 under the centralized approval process for treatment of acute lymphoblastic leukemia, or ALL, in pediatric patients who have relapsed or are refractory to at least two prior regimens of treatment.

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

In March 2001, to facilitate the development of Evoltra®, the Company entered into a co-development agreement with ILEX Oncology, Inc. our sub-licensor until it was acquired by Genzyme on December 21, 2004, for the development of Evoltra® 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® in cancer indications. Currently, the Company has billed but not recorded as a receivable approximately \$4,600,000 of revenue relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of Evoltra® outside the United States as well as an additional \$2,381,000 which we have not billed but believe is owed to us from this co-development partner. If and when the Company has determined that collectibility is reasonably assured, the Company will record the revenue. Under the co-development agreement, the Company offsets these amounts against any royalty which otherwise would be paid to Genzyme on our U.K. sales. Genzyme is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada for certain cancer indications. The Company retains the right to handle those matters in all territories outside the United States and Canada and retains the right to handle these matters in the U.S. and Canada in all non-cancer indications. The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States and Canada. Under the co-development agreement, Genzyme will have certain rights if it performs its development obligations in accordance with that agreement. Under the circumstances, the Company is required to pay Genzyme a royalty on direct sales outside the U.S., Canada, Japan and Southeast Asia. In turn, Genzyme, which would have U.S. and Canadian distribution rights in cancer indications, is paying the Company a royalty on sales in the U.S. and Canada. Under the terms of the co-development agreement, Genzyme also pays royalties to SRI based on certain milestones. The Company also is obligated to pay certain royalties to SRI with respect to Evoltra®.

The Company received a nonrefundable upfront payment of \$1,350,000 when it entered into the co-development agreement with Genzyme and received an additional \$3,500,000 in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application for clofarabine with the FDA, the Company received an additional (i) \$2,000,000 in April 2004 and (ii) \$2,000,000 in September 2004. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight-line basis over the related service period, through March 2021. For each of the years ended June 30, 2007, 2006 and 2005, the Company recognized revenues of approximately \$438,000 in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Genzyme. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis over the related service period, concurrent with the revenue that is recognized in connection with these research and development costs through 2021. The Company recognized expense of approximately \$219,000 for each of the years ended June 30, 2007, 2006 and 2005.

F-19

In September 2006, the Company obtained the exclusive license to develop, manufacture, market, distribute and sell Evoltra® in Japan and Southeast Asia. We made an initial payment of \$2,500,000 to SRI upon execution of this agreement and are obligated to pay SRI additional milestone payments and royalties during the term of this agreement. Since taking on these rights, the Company has organized Bioenvision JapanCo., Ltd., a wholly-owned subsidiary of the Company ( JapanCo ) and established an office in Tokyo.

#### *Modrenal®*

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

The Company received a nonrefundable upfront payment of \$1,250,000 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, \$60,000 and \$87,000, respectively, in connection with the upfront payment from Dechra for the years ended June 30, 2007, 2006 and 2005, 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 \$12,000 and \$17,000 for the years ended June 30, 2007, 2006 and 2005, respectively.

#### *OLIGON®*

In January 2007, the Company entered into a licensing arrangement with Foster, a Connecticut-based compounder of biomedical materials, to license out exclusive rights to manufacture, market and distribute the Company's proprietary anti-microbial OLIGON® technology. Under the terms of the license agreement, Bioenvision will have a revenue sharing arrangement on future sublicenses and a royalty on all sales by Foster. Foster is required to comply with annual minimum marketing and research and development expenditures within the first five years of the term of the license.

### **Note 4 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® 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®, 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 5 Income Taxes**

The domestic and foreign components of loss before income taxes for the years ended June 30, 2007, 2006, and 2005 are as follows:

F-20

---

Edgar Filing: BIOENVISION INC - Form 10-K

	2007	2006	2005
Domestic	\$ (24,850,000 )	\$ (19,333,000 )	\$ (22,601,000 )
Foreign	(11,055,000 )	(4,566,000 )	(1,662,000 )
Loss before income tax benefit	\$ (35,905,000 )	\$ (23,899,000 )	\$ (24,263,000 )

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, 2007, 2006 and 2005:

	June 30, 2007	June 30, 2006	June 30, 2005
Consolidated tax benefit at federal statutory rate	(34.0 )%	(34.0 )%	(34.0 )%
Other non-deductible expenses	0.9 %	1.3 %	(0.3 )%
State income tax benefit, net of federal provision	(4.4 )%	(5.1 )%	(6.1 )%
Valuation allowance	36.4 %	36.9 %	40.1 %
Foreign rate differential	1.2 %	0.7 %	0.3 %
Other, net	(0.1 )%	0.2 %	0.0 %
Effective tax rate	0.0 %	0.0 %	0.0 %

Significant components of the Company's deferred tax assets and liabilities at June 30, 2007 and 2006 are as follows:

	June 30, 2007	June 30, 2006
<b>Deferred tax liabilities</b>		
Acquired intangibles	\$ (1,119,000 )	\$ (2,780,000 )
Deferred costs	(1,329,000 )	(1,427,000 )
Amortization	(169,000 )	(203,000 )
Depreciation	(39,000 )	(16,000 )
Other	(3,000 )	(3,000 )
Total deferred tax liabilities	(2,659,000 )	(4,429,000 )
<b>Deferred tax assets</b>		
Net operating loss	35,064,000	23,966,000
Options, warrants and shares issued to non-employees	273,000	273,000
Options and shares issued to employees	2,586,000	1,081,000
Deferred revenue	2,864,000	3,072,000
Provision for bad debts	474,000	352,000
Accrued expenses	312,000	303,000
Other	14,000	13,000
Total deferred tax assets	41,587,000	29,060,000
Valuation allowance for deferred tax assets	(38,928,000 )	(24,631,000 )
Net deferred tax assets	2,659,000	4,429,000
Total deferred tax assets, net	\$	\$



At June 30, 2007, the Company had estimated \$72,805,000 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 \$29,486,000. At June 30, 2007, the Company also had estimated \$18,592,000 of net operating loss carryforwards relating to foreign operations, respectively, with no expiration date, with a tax value of \$5,577,000.

At June 30, 2007 and 2006, the Company has recorded a valuation allowance of approximately \$38,928,000 and \$24,631,000, 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, 2007, 2006 and 2005 is approximately \$0 and \$3,222,000 and \$3,857,000, respectively 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 \$0, \$1,305,000 and \$1,562,000, 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 6 Stockholders Transactions**

##### *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 \$17,700,000 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.

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, 2007.

F-22



Common Stock:

On April 5, 2007, the Company completed a direct public offering in which it sold 8,000,000 common shares at \$3.75 per share, with net proceeds to the Company of approximately \$27,716,000, after deducting underwriting discounts and commissions and offering expenses.

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

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.

Stock Options:

The Board of Directors adopted, and the stockholders approved, the 2003 Stock Incentive Plan at the Annual Meeting held in January 2004. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 6,750,000 shares reserved for grants of options under the plan and, at June 30, 2007, options to purchase 5,301,000 shares of common stock had been issued. The Company's policy is to issue new shares for option exercises. Stock options vest pursuant to individual stock option agreements. No options granted under the plan are exercisable after the expiration of ten years (or lesser at the discretion of the Board of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors or until expiration of the plan on November 17, 2013.

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 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 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.

F-23

---

For the year ended June 30, 2005, the Company recorded compensation expense of approximately \$88,000 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 has recorded the compensation expense for the fair value of the stock options over the remaining vesting term.

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.

During the year ended June 30, 2007, options to purchase 81,250 of the Company's common stock at a weighted average exercise price of \$4.94 per share were granted to members serving on the Board of Directors, in which the Company recognized \$57,000 of expense relating to said options. Total expense for options granted to members of the Board of Directors was \$93,000, \$75,000 and \$60,000, respectively, for the years ended June 30, 2007, 2006 and 2005.

Options granted to employees for the year ended June 30, 2007 totaled 1,256,500. Total compensation (expense) income for options granted to employees was (\$3,323,000), (\$3,609,000) and \$227,000 for the years ended June 30, 2007, 2006 and 2005, respectively.

There were no options exercised during the year ended June 30, 2007. 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.

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

F-24

---

Edgar Filing: BIOENVISION INC - Form 10-K

	Number of Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Term	Aggregate Intrinsic Value(a)
Balance at July 1, 2004	4,270,000	\$ 1.87		
Granted	784,000	7.99		
Exercised	(885,500 )	1.08		
Cancelled				
Forfeited	(12,500 )	3.53		
Balance at June 30, 2005	4,156,000	\$ 3.18	5.30	\$ 20,306,755
Granted	1,287,000	6.49		
Exercised	(525,000 )	1.28		
Cancelled	(252,000 )	4.05		
Forfeited	(25,000 )	8.22		
Balance at June 30, 2006	4,641,000	\$ 4.24	4.44	\$ 8,916,283
Granted	1,257,000	4.78		
Exercised				
Cancelled	(4,000 )	7.14		
Forfeited	(80,000 )	6.56		
Balance at June 30, 2007	5,814,000	\$ 4.32	6.83	\$ 11,433,207
Exercisable at June 30, 2007	4,199,000	\$ 3.75	6.00	\$ 10,558,445

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

No options were exercised by employees during the year ended June 30, 2007. Options exercised by employees during the years ended June 30, 2006 and 2005 had an intrinsic value of approximately \$1,323,000, and \$5,866,000, respectively.

A summary of the Company's non-vested employee options at June 30, 2007 and changes during the year ended June 30, 2007 is presented below:

	Non-vested Number of Options	Weighted-average Fair Value at Grant Date
Balance at July 1, 2006	1,391,000	\$ 3.79
Granted	1,257,000	2.46
Vested	(953,000 )	3.30
Cancelled		
Forfeited	(80,000 )	3.41
Balance at June 30, 2007	1,615,000	\$ 3.07



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 \$0, \$9,000 and \$138,000 as consulting expense for years ended June 30, 2007, 2006 and 2005, respectively, as 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 years ended June 30, 2007 and 2006.

On June 22, 2004, the Company entered into a consulting agreement pursuant to which consultant would 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, 2007, certain warrant holders of the Company exercised their warrants to acquire 4,310,999 shares of the Company's common stock, in which the Company received proceeds of approximately \$8,146,000. 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 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 in which the Company received proceeds of approximately \$3,279,000 from the exercise of such 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 \$340,606, of which \$40,606 has been collected. The payment of these taxes was not part of the option agreement. The Company classified such note as a shareholder receivable in the equity section of the consolidated balance sheets. In December 2006, the Company reserved for the remaining balance outstanding.

**Note 7 Geographic Information**

We have one operating segment and define geographical regions as countries in which we operate. Our corporate headquarters in the United States collects licensing, royalties and research & development contract revenue from our arrangements with external customers and our co-development partners. Our wholly-owned subsidiary, Bioenvision Limited, is located in the United Kingdom and currently manages our product sales in Europe. Our wholly-owned subsidiary, Bioenvision JapanCo., Ltd, is located in Tokyo and is focused on product development in Japan and Southeast Asia. Currently, there is no sales activity in Japan. The following table reconciles our revenues by geographic region to the consolidated total:

F-26

---

	June 30, 2007	June 30, 2006	June 30, 2005
United States	\$ 3,640,408	\$ 1,929,527	\$ 3,373,547
Europe	15,234,700	3,379,545	1,277,627
Other	194,489		
<b>Total Revenue</b>	<b>\$ 19,069,597</b>	<b>\$ 5,309,072</b>	<b>\$ 4,651,174</b>

#### Note 8 Liquidity and Capital Resources

In August 2006, the Company borrowed \$1,500,000 in conjunction with a promissory note signed with a financial institution. In September 2006, the Company borrowed an additional \$3,500,000. All amounts drawn were fully repaid as of September 30, 2006.

On June 30, 2007, the Company had cash and cash equivalents and short-term investments of approximately \$49,171,000 and working capital of \$47,811,000. Management believes the Company has sufficient cash and cash equivalents, short-term investments and working capital to continue currently planned operations through June 30, 2008. However, depending on the outcome of the proposed Genzyme merger, 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, depending on the outcome of the Genzyme merger, we may be required to fund additional operating losses in the foreseeable future, our financial position may 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.

#### Note 9 Commitments and Contingencies

##### Commitments:

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. Also, we rent office space in Tokyo, Japan, under a lease that expires in February 2008. Rent expense for all three facilities in the aggregate for the years ended June 30, 2007, 2006 and 2005 was approximately \$848,000, \$680,000 and \$421,000, respectively. Further, the Company leases three vehicles under leases which expire November 29, 2008 and one which expires January 6, 2009. Lease expense was approximately \$55,000, \$49,000 and \$24,000 for the years ended June 30, 2007, 2006 and 2005, respectively. At June 30, 2007, total minimum rentals under operating leases with initial or remaining non-cancelable lease terms of more than one year as well as contractual obligations under our license agreement with SRI were approximately:

F-27

	<b>For the Year Ended June 30,</b>
2008	\$ 1,693,429
2009	623,988
2010	431,391
2011	500,000
2012	4,000,000
Thereafter	
Total	\$ 7,248,808

Litigation:

The Company is a defendant in multiple putative class action lawsuits that have been filed in connection with the proposed merger with Genzyme against the Company and its directors. Among other things, the lawsuits seek to enjoin the completion of the merger. While it is not feasible to predict the outcome of these lawsuits, their ultimate resolution could have an adverse effect upon our business, financial condition, results of operations or reputation. We have contacted the plaintiff's counsel to determine whether a settlement can be reached. If an acceptable settlement cannot be reached, we expect to contest the plaintiff's claims vigorously.

**Note 10 Quarterly Financial Data (Unaudited)**

	<b>Quarter ended September 30, 2006</b>	<b>Quarter ended December 31, 2006</b>	<b>Quarter ended March 31, 2007</b>	<b>Quarter ended June 30, 2007</b>
<b>2007</b>				
Revenue	\$ 2,864,572	\$ 4,496,640	\$ 4,957,496	\$ 6,750,889
Cost of products sold (1)	422,728	897,593	985,197	1,144,761
Loss from operations (2)	(12,538,329 )	(7,278,088 )	(7,956,019 )	(9,868,321 )
Net loss	(12,125,694 )	(6,912,408 )	(7,698,334 )	(9,168,145 )
Net loss applicable to common stockholders	(12,210,762 )	(6,997,477 )	\$ (7,781,552 )	(9,252,290 )
Basic and diluted net loss applicable to common stockholders per share	\$ (0.29 )	\$ (0.16 )	\$ (0.18 )	\$ (0.17 )

(1) The Company records royalty expense as a component of cost of products sold. For the three months ended September 30, 2006, December 31, 2006, March 31, 2007 and June 30, 2007, the Company recorded royalty expense of \$361,469, \$758,596, \$854,028, and \$914,606, respectively as a component of cost of products sold.

(2) For the three months ended June 30, 2007, the Company recorded an impairment charge on certain acquired intangible assets of \$3,310,905, which is included in Loss from operations.

	September 30, 2005	December 31, 2005	March 31, 2006	June 30, 2006
<b>2006</b>				
Revenue	\$ 670,218	\$ 1,091,307	\$ 1,741,095	\$ 1,806,452
Cost of products sold (1)	328,292	438,018	386,818	509,847
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 common stockholders	\$ (4,889,660 )	\$ (3,878,931 )	\$ (8,221,521 )	\$ (7,246,151 )
Basic and diluted net loss applicable to common stockholders per share	\$ (0.12 )	\$ (0.10 )	\$ (0.20 )	\$ (0.18 )

(1) The Company records royalty expense as a component of cost of products sold. For the three months ended September 30, 2005, December 31, 2005, March 31, 2006 and June 30, 2006, the Company recorded royalty expense of \$201,177, \$330,410, \$315,537, and \$430,287, respectively as a component of cost of products sold.

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.

#### **Note 11 Subsequent Events**

On or about August 22, 2007, David P. Luci, the Company's former General Counsel, filed an action in New York State Supreme Court, New York County purporting to assert claims against the Company, its Chief Financial Officer and certain current and former Directors of the Company. The Complaint purports to allege, among other things, that the Company breached contractual and other obligations allegedly owed to him in connection with the termination of his employment with the Company, and purports to demand damages, in the aggregate, of \$108,400,000. The Company believes that the action is without merit and intends to mount a vigorous defense.

F-29



**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 years ended June 30, 2007 and 2006, we also audited the 2007 and 2006 consolidated financial statement Schedule II. In our opinion, the 2007 and 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 31, 2007

S-1

---

## SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

Years Ended June 30, 2007, 2006 and, 2005

	Balance at Beginning of Period	Charged to Cost and Expense	Write-offs and Recoveries	Loss on Foreign Exchange	Balance at End of Period
<b><u>Allowance for doubtful accounts</u></b>					
June 30, 2007	\$ 898,714	\$ 160,740	\$ (205,455 )	(1) \$ 9,080	\$ 863,079
June 30, 2006	\$ 869,220	\$ 25,564	\$	\$ 3,930	\$ 898,714
June 30, 2005	\$	\$ 869,220	\$	\$	\$ 869,220
<b><u>Deferred tax asset valuation allowance</u></b>					
June 30, 2007	\$ 24,631,266	\$ 14,295,910	(2) \$	\$	\$ 38,927,176
June 30, 2006	\$ 14,178,975	\$ 10,452,291	(2) \$	\$	\$ 24,631,266
June 30, 2005	\$ 2,893,873	\$ 11,285,102	(2) \$	\$	\$ 14,178,975

(1) Includes \$194,241 relating to our right of offset against royalties due from our co-development partner which has been offset against the fully reserved receivable balance due from the co-development partner.

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

S-2