BIOENVISION INC
Form 10KSB
October 13, 2005

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

Form 10-KSB

(Mark One)

X --- Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934. For the fiscal year ended June 30, 2005.

OR

--- Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period

from _____ to _____.

Commission File Number: 0-18299

BIOENVISION, INC.

(Name of Small Business Issuer in Its Charter)

Delaware	13-4025857
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
345 Park Avenue, 41st Floor New York, New York	10154
(Address of Principal Executive Offices)	(Zip Code)

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

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

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

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ____

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. [ ]

The issuer's revenues for its most recent fiscal year were $4,651,174

The aggregate market value of the voting stock held by non-affiliates computed by reference to the last price at which the stock was sold, as of August 15, 2005, was $279,101,648.

The number of shares of common stock outstanding as of October 6, 2005 was 40,760,762.

Part III incorporates information by reference from the issuer's definitive proxy statement to be filed with the Commission within 120 days after the close of the registrant's fiscal year.

Transitional Small Business Disclosure Format (check one): Yes___ No X

BIOENVISION, INC.
Annual Report on Form 10-KSB
Fiscal Year Ended June 30, 2005
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PART I

Except for historical information contained herein, this annual report on Form 10-KSB 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, "Factors that May Effect our Business", and Managements Discussion and Analysis

of Results of Operations". These forward-looking statements are identified by their use of such terms and phrases as "intends," "intend," "intended," "goal," "estimate," "estimates," "expects," "expect," "expected," "project," "projected," "projections," "plans," "anticipates," "anticipated," "should," "designed to," "foreseeable future," "believe," "believes" and "scheduled" and similar expressions. The Company's actual results or outcomes may differ materially from those anticipated. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Description of Business

Overview

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. In December 2004, the Food and Drug Administration, or FDA, approved our lead cancer product, 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 is the first new medicine initially approved in the United States, or U.S., for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and in the European Union, or E.U. Genzyme Corporation, our co-development partner, contracted with us and acquired the U.S. and Canadian marketing rights for clofarabine for certain cancer indications and Genzyme currently controls U.S. development of clofarabine in these indications. Genzyme is marketing clofarabine under the brand name Clolar(R) in the U.S. In Europe, we filed for approval of clofarabine in pediatric ALL with the European Medicines Evaluation Agency, or EMeA, in July 2004. If approved, we anticipate commencing sales in Europe during the first quarter of calendar 2006 through a dedicated European sales force.

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

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

Products and pipeline

Candidate	Indication	Status	U.S. and Canada rights	Ex-U.S. and Canada rights
Clofarabine	Relapsed or	Marketed in U.S.	Genzyme	Bioenvision

(Clolar(R))	Refractory Acute Lymphoblastic Leukemia (ALL)	(pediatric); Filed in E.U. (pediatric)		
	Acute Myelogenous Leukemia (AML)	Phase II in E.U. (adult)	Genzyme	Bioenvision
	Refractory Chronic Lymphocytic Leukemia (CLL)	Phase II in U.S. (adult)	Genzyme	Bioenvision
	Solid Tumors	Phase I (Intravenous)	Genzyme	Bioenvision
	Solid Tumors	Phase I (Oral)	Genzyme	Bioenvision
	Non-Cancer	Developmental	Bioenvision	Bioenvision
Modrenal(R)	Breast Cancer	Marketed in U.K.; Phase IV in U.K.; Phase II in U.K.	Bioenvision	Bioenvision
	Prostate Cancer	Phase II in U.S.	Bioenvision	Bioenvision
Virostat	Hepatitis C	Investigator Sponsored Phase II in Europe and Middle East	Bioenvision	Bioenvision

Our Products

Clofarabine (Clolar(R))

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

Pediatric leukemia is the most prevalent form of cancer among children up to age 19 in the U.S. It is estimated that approximately 3,400 children were diagnosed with leukemia in the U.S. in 2004, with ALL accounting for over 75% of the incidence rate. Although survival rates for childhood leukemia have improved significantly since the early 1970's, approximately 20% of pediatric patients with ALL and 60% of pediatric patients with AML do not achieve long-term survival and we believe there is a medical need for new agents to treat this population of patients. Clofarabine is approved for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two

prior regimens. The adult leukemia market represents a potentially significantly larger commercial opportunity with over 11,500 patients with AML and over 8,000 patients with CLL, diagnosed each year within the U.S. Based on population and incidence rates data, we believe that the E.U. patient population with pediatric leukemias and adult AML and CLL approximates that of the U.S.

Clofarabine is a purine nucleoside analog, which is a small molecule, that we are developing with Genzyme, our co-development partner, for the treatment of acute and chronic leukemias, lymphomas and solid tumors. Clofarabine attacks cancer cells by damaging DNA in cancer cells, preventing DNA repair by damaged cancer cells, damaging the cancer cell's important control structures, and initiating the process of programmed cell death,

or apoptosis, in cancer cells. Clofarabine appears to combine many of the favorable properties of the two most commonly used purine nucleoside analog drugs, fludarabine and cladribine, but appears to have greater potency at damaging the DNA of leukemia cells and a broader range of clinical activity.

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

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

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

Clofarabine is currently being evaluated in an IST Phase II clinical trial for refractory CLL in the U.S. In addition, commencing in Q1 2006, we intend to investigate clofarabine in European Phase II clinical trials for CLL and indolent lymphoma. In pre-clinical studies, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the lung, colon, kidney, breast, pancreas and prostate, as well as its action against leukemia cells. The initial data from the Phase I clinical trials indicate activity for clofarabine in certain solid tumor types. We believe this level of activity against solid tumors distinguishes clofarabine from other purine nucleoside

analogs. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon, pancreatic, lung, breast and prostate cancer. Currently, we anticipate the initial Phase I clinical trials for clofarabine, using both the oral and intravenous formulations, in solid tumors will be completed by end of calendar year 2005.

Pursuant to the terms of our co-development agreement with Genzyme, the successor-in-interest to ILEX Oncology, Inc., both parties are required to share promptly all information, including clinical data, generated under the co-development program and Genzyme is obligated to pay all of the U.S. and Canadian research and development costs and 50% of all approved ex-U.S. and Canada research and development costs (except for Japan and Southeast Asia 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.

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

Modrenal(R)

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

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

Modrenal(R) has been extensively studied in clinical trials in the U.S., Europe and Australia, and an analysis, known as a meta-analysis, of a series of these clinical studies, that together included 714 patients with post-menopausal advanced breast cancer who received Modrenal(R) has been conducted. Overall, a clinical benefit rate of 35% was achieved in patients with both hormone-sensitive and hormone-insensitive breast cancers. Generally, a clinical benefit is achieved when a patient's disease disappears, is decreased by greater than fifty percent or is stabilized for at least six months. In a sub-set

analysis of these clinical trial data, a clinical benefit rate of 46% was achieved for 351 patients with hormone-sensitive breast cancer who had responded to one or more prior hormonal therapies and were given Modrenal(R) upon relapse of the cancer. In one of the studies which was conducted in Australia, a clinical benefit rate of 55% was achieved for 64 patients who received Modrenal(R) having previously responded to tamoxifen and subsequently relapsed. We believe these data compare favorably to currently marketed aromatase inhibitors and other agents given as second line or subsequent therapies. Furthermore, Modrenal(R) has an acceptable side-effect profile. On the basis of these data, Modrenal(R) was granted a product license in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.

We began marketing Modrenal(R) in May 2004 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. We also intend to seek regulatory approval for Modrenal(R) in the U.S. as a therapy for hormone-sensitive breast cancers and hormone independent prostate cancers, but this strategy is dependent upon the results of the ongoing clinical trials and the resource capability of the Company. Our ongoing clinical trials in breast cancer target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as tamoxifen or any of the aromatase inhibitors. In addition, there is an ongoing Phase II clinical trial of Modrenal(R) in the U.S. that is focused on patients who have androgen independent prostate cancer and have a rising prostate specific antigen, or PSA, level.

In mid-2005 we began enrollment in a U.K., Phase IV study in post-menopausal advanced breast cancer, a Phase II study in pre-menopausal breast cancer and a Phase II study in neo-adjuvent, pre-operative breast cancer. We plan to use the data from these clinical trials to support a filing process for mutual recognition for approval of Modrenal(R) on a country-by-country basis in Europe. Each such approval, if granted, would be based upon Modrenal's(R) approval in the U.K. for post-menopausal advanced breast cancer following relapse to initial hormone therapy. The grant of any such approval is entirely within the control of the individual regulatory authorities.

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

Other Products and Technologies

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

Virostat

Virostat, especially when irradiated by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Investigator sponsored Phase II clinical trials are ongoing in Europe and the Middle East to study Virostat's use in treating hepatitis C virus infection and we announced interim results at the UBS Global Life Sciences Conference in New York on September 28, 2005. Virostat 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. Virostat 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 is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. Prior to the fourth quarter of 2005, we tested for impairment our methylene blue intangibles acquired in connection with the Pathagon acquisition and determined that, based on our assumptions, the sum of the expected future cash flows, undiscounted and pertaining solely and exclusively to approved indications, exceeded the carrying value of its long-lived assets and therefore we did not recognize an impairment. Due to the loss of an intellectual property patent suit relating to the international use of methylene blue in fresh frozen plasma we re-evaluated the intangible asset relating to methylene blue at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, again relating solely and exclusively to approved uses of methylene blue, were less than the carrying value. As a result, we recognized a non-cash impairment loss of $5,276,000, equal to the difference between the estimated future cash flows for approved uses of methylene blue, discounted at an appropriate rate, and the carrying amount of the asset. Making the impairment determination and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective.

Velostan

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

OLIGON(R) Technology

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

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

In addition, patents have been filed in Europe, Canada and Japan.

Gene Therapy Technology

Our product portfolio also includes a variety of gene therapy products that, we believe, may offer advancements in the field of cancer treatment and may have additional applications in certain non-cancer diseases such as diabetes, cystic fibrosis and other auto-immune disorders. Pursuant to a co-development agreement with the Royal Free and University College Medical School and a Canadian biotechnology company, we are developing gene vector technologies which, based on pre-clinical research and early Phase I clinical trials, we believe have potential in a wide array of clinical conditions. To date, the technology has undergone small-scale clinical testing with the 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.

Animal Health Products

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

Ltd., the exclusive right to market the drug in the U.S. for $5.5 million of total consideration (including milestone payments) and a royalty of 2%-4% of annual net sales.

Patents and Proprietary Rights

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

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

Sales and Marketing

Currently we have an arrangement in place with Genzyme for the co-development and marketing of one of our lead products, clofarabine, and another arrangement with Edwards Lifesciences for the marketing of short-term vascular access catheters using the OLIGON(R) technology. We have also engaged in our own marketing and sales efforts in connection with the marketing and sale of Modrenal(R) in the U.K. If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of

five other key regions within the E.U. However, in order to market any of our products effectively, we would need to establish a much more integrated marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces.

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

Manufacturing

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

Research and Development

In developing new products, we consider a variety of factors including: (i) existing or potential marketing opportunities for these products; (ii) our capability to arrange for these products to be manufactured on a commercial scale; (iii) whether or not these products complement our existing products; (iv) the opportunities to leverage these products with the development of additional products; and (v) the ability to develop co-marketing relationships with pharmaceutical and/or other companies with respect to the products. We intend to fund future research and development activities at a number of medical and scientific centers in Europe and the United States. Costs related to these activities are expected to include: clinical trial expenses; drug production costs; salaries and benefits of scientific, clinical and other personnel; patent protection costs; analytical and other testing costs; professional fees; and insurance and other administrative expenses. We have spent approximately $10,895,000 and $4,883,000 on research and development activities for the fiscal years ended June 30, 2005 and 2004 respectively.

Government Regulation

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

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

- pre-clinical laboratory and animal tests;

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

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

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

- FDA review and approval of the new drug application.

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

Pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about

the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. There is no certainty that pre-clinical trials will result in the submission of an IND or that submission of an IND will result in FDA authorization to commence clinical trials.

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

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

PHASE I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion;
PHASE II: Studies are conducted in a limited patient population to identify possible short term adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage;
PHASE III: Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites. Phase III or IIb/III trials are often referred to as pivotal trials, as they are used for the final approval of

a product.

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

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

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

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

unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

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

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

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

Competition

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

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

Employees

As of August 15, 2005, we had 27 full-time employees based in New York, New York, and Edinburgh, Scotland. Of these, 3 are in management, 4 are in legal/accounting, 10 are in sales/marketing, 5 are in administration and 5 are in research and development. We believe our relationships with our employees are satisfactory.

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.

Information included or referred to on our website is not incorporated by reference in or otherwise a part of this prospectus. Our website address is included in this annual report as an inactive textual reference only.

Factors that May Affect Our Business

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-KSB. These risks may adversely affect our business, financial condition or operating results. If any of the events we have identified occur, the trading price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

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

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

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

To date, we have incurred significant net losses, including net losses of approximately $24,263,000 for the fiscal year ended June 30, 2005. At June 30, 2005, we had an accumulated deficit of approximately $62,331,000. We anticipate that we may continue to incur significant operating losses for the foreseeable future. We may never generate material revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

Clinical trials for our products are expensive and time consuming, and may not

result in any viable products.

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

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

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

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

- lack of efficacy during the clinical trials; or
- government or regulatory delays.

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

Our ancillary products include OLIGON, an anti-microbial compound, and Virostat, an anti-viral agent, respectively, which we acquired in February 2002 in the Pathagon acquisition. At June 30, 2005, due to the loss of an intellectual property patent suit relating to the international use of Virostat in fresh frozen plasma, we re-evaluated the fair value of the intangible assets relating to Virostat. At that date, we estimated that our undiscounted future cash flows pertaining solely and exclusively to approved uses of Virostat were less than the carrying value of our long-lived asset. As a result, we recognized

a non-cash impairment loss of $5,276,000, equal to the difference between the estimated future cash flows related solely to approved uses of Virostat, discounted at an appropriate rate, and the carrying amount of the asset. Making the determinations of impairment and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows of the assets. At June 30, 2005, subsequent to the recognition of the impairment, the net intangible assets associated with these products amounted to approximately $7.7 million and constituted approximately 9% of our total assets and approximately 11% of our stockholders' equity.

We do not currently devote any significant time or resources to the research and development of OLIGON and only intend to do so if, and to the extent, we successfully commercialize our lead drugs, clofarabine and Modrenal(R), over the next two years. Historically, we have not devoted significant time or resource to the research and development of Virostat but our management and board of directors is currently considering the appropriate level of time and resource to be devoted to Virostat over the next two years. Based on the estimated useful life of these assets of approximately 13 years and market considerations, no assurance can be given that there will not be a further impairment of these assets in the future, which could result in a material impact on our future results of operations. Changes in events or circumstances that may affect long-lived assets, particularly in the pharmaceutical industry, makes judgments and assumptions with respect to the future cash flows highly subjective and may include, but are not limited to, cancellations or terminations of license agreements or the risk of competition that could render our products noncompetitive or obsolete.

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

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

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

flow from the sale of clofarabine.

If delays in completion constitute a breach by Genzyme or there are certain other breaches of the co-development agreement by Genzyme, then, at our discretion, the primary responsibility for completion would

revert to us, but there is no assurance that we would have the financial, managerial or technical resources to complete such tasks in timely fashion or at all.

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

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. We are developing clofarabine with Genzyme, our U.S. co-development partner since its acquisition of ILEX Oncology, which occurred on December 21, 2004. No assurance can be given that the operational and managerial relations with Genzyme will proceed favorably or that the timeline for development of clofarabine will not be elongated now that Genzyme has replaced ILEX as our U.S. cancer marketing partner. If the U.S. regulatory timeline is elongated, this could materially and adversely affect the European regulatory timeline for the approval of clofarabine.

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

Generally, most products resulting from our or our collaborative partners' product development efforts are not expected to be available for sale for at least several years, if at all. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

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

Most of the existing and future products and technologies developed by us will require extensive additional development, including pre-clinical testing

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

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

Regulation in General. Virtually all aspects of our business are regulated by federal, 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Because many of our competitors have substantially greater capabilities and

resources than us, they may be able to develop products before us or develop more effective products or market them more effectively, which would adversely affect our ability to generate revenue and cash flow.

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

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

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

The pharmaceutical industry is characterized by rapid and significant technological change. We expect that pharmaceutical technology will continue to develop rapidly, and our future success will depend on our ability to develop and maintain a competitive position. Technological development by others may result in products developed by us, branded or generic, becoming obsolete before they are marketed or before we recover a significant portion of the development and commercialization expenses incurred with respect to these products.

Alternative therapies or new medical treatments could alter existing treatment regimes, and thereby reduce the need for one or more of the products developed by us, which would adversely affect our revenue and cash flow. See also "--Generic products which third parties may develop may render our products noncompetitive or obsolete" above.

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

We do not currently have any internal product testing capabilities. Our

inability to retain third parties for the clinical testing of products on acceptable terms would adversely affect our ability to develop products. Any failures by third parties to adequately perform their responsibilities may delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position. Our dependence on third parties for the development of products may adversely affect our potential profit margins and our ability to develop and deliver products on a timely basis.

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

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

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

The creation of infrastructure to commercialize oncology products is a difficult, expensive and time-consuming process. We may not be able to establish direct or indirect sales and distribution capabilities outside of the UK or be successful in gaining market acceptance for proprietary products or for other products. We currently have very limited sales and marketing capabilities outside of the UK. We currently employ eight full-time sales employees and two full-time marketing employees. To market any products directly, we will need to develop a more fulsome marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. To the extent that we enter into co-promotion or other licensing arrangements, any revenues to be received by us will be dependent on the efforts of third parties. The efforts of third parties may not be successful. Our failure to establish marketing and distribution capabilities or to enter into marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

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

We are highly dependent on our Chief Executive Officer to develop our lead drug. Dr. Wood has an employment agreement with us, dated December 31, 2002, for an initial term of one year which automatically extends for additional one year periods until either party gives the other written notice of termination at least 90 days prior to the end of the current term. Dr. Wood is not near

retirement age and he does not, to our knowledge, plan on leaving us in the near future. Dr. Wood is one of our founders and he is intimately familiar with the science that underlies our lead drugs and ancillary technologies. He also maintains a position on the clofarabine management team that is responsible for all drug development activities relating to that lead drug, and has been instrumental in the development and maintenance of our key relationships within the scientific research and medical communities, and those with our vendors, inventors, co-development partners and licensors. If Dr. Wood was no longer employed by us, the development of our drugs would be significantly delayed and otherwise would be adversely impacted, and we may be unable to maintain and develop these important relationships.

In addition, we will be required to hire additional qualified scientific and technical personnel, as well as personnel with expertise in clinical testing and government regulation to expand our research and development

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

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

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

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

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend on our ability to obtain and enforce protection for products that we develop under U.S. and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the

technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. Several of the original patents to Modrenal(R) have expired in the U.S. and foreign countries. Thus, we and our licensor, Stegram Pharmaceutical Ltd., are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal(R). We cannot guarantee that such applications will result in issued patents or that such patents if issued will provide adequate protection against competitors. Patents may not be issued from these applications and issued patents may not give us adequate protection or a competitive advantage. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain U.S. or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from SRI. The current projected expiration date of the license is March 2021. These patents cover pharmaceutical compositions and methods of using clofarabine. We cannot guarantee that these patents would survive an attack on their validity or that they will 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 marketing of clofarabine for treatment of chronic lymphocytic leukemia will not infringe any of the claims of this U.S. patent. If this patent is asserted against us, even though we may be successful in defending against such an assertion, our defense would require substantial financial and human resources. In addition, we may need a license to this patent to use the claimed dose in the treatment of CML. However, we do not know if such a license is available at commercially reasonable terms, if at all.

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

and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more products.

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

We require our employees, consultants, members of the scientific advisory board and parties to collaborative agreements to execute confidentiality

agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information.

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

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

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

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

We do not engage in forward currency transactions which means we are susceptible to fluctuations in the U.S. dollar against foreign currencies such as the pound sterling. Accordingly, as the value of the dollar becomes weaker against the pound sterling, ongoing services provided by our UK employees, 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, 2005, we had stockholders' equity of approximately $66,614,000 and net working capital of approximately $60,112,000. However, we may need additional financing to continue to fund the research and development and marketing programs for our products and to generally expand and grow our business. For example, we will need to employ a European sales force within the next twelve months to capitalize on the commercial potential for clofarabine and Modrenal(R) if and to the extent our lead drugs are at market in Europe by the end of calendar year 2005. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders would result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or

accounting methods, even though these actions would otherwise benefit our business.

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

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

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

Third-party payors may attempt to control costs further by selecting exclusive providers of their pharmaceutical products. If third-party payors were to make this type of arrangement with one or more of our competitors, they would not reimburse patients for purchasing our competing products. For example, if a third-party payor in the U.K. were to pay patients for regimens of aromatase inhibitor treatment but not treatments of Modrenal(R), this would cause a decline in sales of Modrenal(R). This lack of reimbursement would diminish the market for products developed by us and would have a material adverse effect on us.

Our products may be subject to recall.

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

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

We face exposure to product liability claims if the use of our technologies or products or those we license from third parties is alleged to have resulted in adverse effects to users of such products. Product liability claims may be brought by clinical trial participants, although to date, no such claims have been brought against us. If any such claims were brought against us, the cost of defending such claims may adversely affect our business. Regulatory approval for commercial sale of our products does not mitigate product liability risks. Any

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

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity. As a result, their application in practice may evolve

over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance, internal control and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, our reputation may be harmed and our operations and revenues may be adversely affected.

We need to improve our internal controls over financial reporting.

In connection with its review of our consolidated financial statements as of and for the three and nine month periods ended March 31, 2004, Grant Thornton LLP, then our registered independent public accounting firm, advised the Audit Committee and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness, under standards established by the American Institute of Certified Public Accountants, including, inadequate staffing and supervision leading to the untimely identification and resolution of certain accounting matters, failure to perform timely reviews, substantiation and evaluation of certain general ledger account balances, lack of procedures or expertise needed to prepare all required

disclosures and evidence that employees lack the qualifications and training to fulfill their assigned functions. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes the entity's internal control from reducing to an appropriately low level the risk that material misstatements in the financial statements will not be prevented or detected on a timely basis. In response to the observations made by Grant Thornton LLP, we undertook a re-evaluation of our internal controls and procedures relating to those observations and implemented such enhancements as the review suggested were appropriate including the hiring a controller and a director of financial reporting.

As of March 31, 2005, the Company identified the following material weakness:

- Failure to ensure the correct application of SFAS 109 "Accounting for Income Taxes" with respect to purchase business combinations and failure to correct that error subsequently resulting from the lack of personnel knowledgeable in the accounting for income taxes.

As of June 30, 2005 the Company identified the following material weakness:

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

In an effort to remediate the identified material weaknesses we continue to implement a number of changes to our internal controls over financial reporting, including, improved training and education for all relevant internal personnel and the hiring of additional internal resources. If these remedial initiatives are insufficient to address these material weaknesses, or if additional material weaknesses or significant deficiencies in our internal controls are discovered in the future, we may fail to meet our future reporting obligations on a timely basis, our financial statements may contain material misstatements, and our common stock may be delisted from the Nasdaq National Market.

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

We are evaluating our internal controls systems in order to allow management to report on the effectiveness of our internal control over financial reporting and our registered independent public accounting firm to attest to this report, as required by Section 404 of the Sarbanes-Oxley Act. We are performing the system and process evaluation and testing, and implementing any necessary remediation, required in an effort to comply with the management report and public accounting firm attestation requirements and continue to incur additional expenses and devote significant management time towards completing actions required for management's evaluation. The evaluation and attestation processes required by Section 404 are new and neither public companies nor public accounting firms have significant experience in testing or complying with these requirements. While we have developed and are implementing plans to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and

remediation actions or the impact of the same on our operations since, like other public companies, we and our registered independent public accounting firm are undergoing the process for the first time in a regulatory environment where the standards to assess adequacy of compliance are under development. We cannot assure you that there may not be significant deficiencies or material weaknesses that would be required to be reported as a result of the process.

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

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

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

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

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

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

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

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

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

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

Our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms fixed by the board of directors. Stockholder approval is not necessary to issue preferred stock in this manner. Thus, our board of directors can authorize and issue shares of preferred stock with voting or conversion rights that could adversely affect the voting or other rights of holders of our common stock and thereby reduce its value. These rights could have the effect of making it more difficult for a person or group to acquire control of us, as well as prevent or frustrate any attempt by stockholders to change our direction or

management. While our board of directors has no current intention to issue any preferred stock, the issuance of these shares may deter potential acquirors.

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

Our existing principal stockholders, executive officers and directors beneficially own, in the aggregate, approximately 52% of our outstanding common stock. As a result, these stockholders will, if they so choose, be able to substantially control all matters requiring stockholder approval. These matters include the election of directors and approval of significant corporate transactions, such as a merger, consolidation, takeover or other business combination involving us. Our existing principal stockholders, executive officers and directors may have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership could also adversely affect the market price of our common stock or reduce any premium over market price that an acquirer might otherwise pay.

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

As of June 30, 2005, we had 40,558,948 shares of common stock outstanding, 2,250,000 shares of Series A Convertible Preferred Stock outstanding which are currently convertible into 4,500,000 shares of common stock and common stock equivalents, and warrants and stock options, convertible or exercisable into 11,472,413 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from $0.74 to $8.87 per share. We have also

reserved for issuance an aggregate of 4,500,000 shares of common stock for a stock option plan for our employees. Historically, from time to time, we have awarded our common stock to our officers, in lieu of cash compensation, although we do not expect to do so in the future. As of June 30, 2005, we have the sale of shares of common stock underlying 4,500,000 options are registered under the Securities Act on Form S-8. The future resale of these shares underlying stock options will result in a dilution to your percentage ownership of our common stock and could adversely affect the market price of our common stock.

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

Where You Can Find More Information

We file annual, quarterly and special reports, proxy statements and other information with the SEC. This information is available at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information about Bioenvision and other issuers that file electronically with the SEC at http://www.sec.gov.

Item 2. Description of Property

Facilities

As of the date of this report we do not own any interest in real property. We currently lease 5,549 square feet of office space at our principal executive offices at 345 Park Avenue, 41st Floor, New York, New York 10154 for base rent of approximately $26,351 per month. These facilities are the center for all of our administrative functions in the United States. Also, we rent approximately 2,437 square feet of office space in Edinburgh, Scotland for approximately GBP 14,400 per month. To date, most of our drug development programs have been conducted at scientific institutions around the world. It is our policy to continue development at leading scientific institutions in the U.S. and Europe. We do not plan to conduct laboratory research in any of our facilities in the near future, rather, we plan to conduct research through collaborative arrangements with SRI and others.

Item 3. Legal Proceedings

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the "Tessman Defendants") in the Supreme Court of the State of New York, County of New York (Index No.

03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state

court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously. Each of the parties has moved for summary judgment dismissing all but one of the claims of the other parties. Those motions have not been decided by the Court.

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

None.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters

Market Information

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

	High	Low
Fiscal year ended June 30, 2004		
First Quarter.....	$5.20	$1.70
Second Quarter.....	5.40	3.13
Third Quarter.....	10.25	3.74
Fourth Quarter.....	12.00	8.00
Fiscal year ended June 30, 2005		
First Quarter.....	$9.24	$5.90
Second Quarter.....	11.74	6.86
Third Quarter.....	9.18	5.17
Fourth Quarter	7.50	5.30

The last reported sale price of our common stock on the Nasdaq National Market on October 6, 2005 was $7.25.

As of October 6, 2005, there were approximately 162 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.

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Equity Compensation Plan Information

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

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	2,463,167	$4.56	1,543,500
Equity compensation plans not approved by security holders(1)	--	--	--
Total	2,463,167	$4.56	1,543,500

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

The Board of Directors adopted, and our stockholders approved our 2003 Stock Incentive Plan at the Annual Meeting held in January of 2004. The plan was adopted to recognize the contributions made by our employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve our ability to attract, retain and motivate individuals upon whom our growth and financial success depends. There are 4,500,000 shares reserved for grants of options under the plan and at June 30, 2005, 2,956,500 of these options had been issued.

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Item 6. Management's Discussion and Analysis or Plan 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 7 of this annual report on Form 10-KSB, which consolidated financial statements are presented beginning at page F-1.

Summary of Critical Accounting Policies

Financial Reporting Release No. 60, which was released by the SEC, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of the consolidated financial statements. In addition, Financial Reporting Release No. 61 was released by the SEC, which requires all companies to include a discussion to address, among other things, liquidity, off-balance sheet arrangements, contractual obligations and commercial commitments. The following discussion is intended to supplement the summary of significant accounting policies as described in Note 1 of the Notes To Consolidated Financial Statements for the year ended June 30, 2005 included under Item 7 in this annual report on Form 10-KSB, which are presented beginning at page F-1.

These policies were selected because they represent the 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, or SAB 104, upfront nonrefundable fees associated with research and development collaboration agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the estimated research and development period using the straight-line method. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis using the straight-line method. Continuation of certain contracts and grants are dependent upon the Company and/or its co-development partners' achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project. Upfront nonrefundable fees associated with licensing arrangements are recorded as deferred revenue and recognized over the term of the licensing arrangement using the straight line method, which approximates the life of the patent.

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

The Company currently sells its products to wholesale distributors and directly to hospitals, clinics, and retail pharmacies. Revenue from product sales is recognized when the risk of loss is passed to the customer, the sales price is fixed and determinable, and collectibility is reasonably assured. As the customer does not have the right of return the Company does not record a reserve for sales returns.

Revenue related to research and development with our corporate co-development partner is recognized as research and development contract revenue when persuasive evidence of an arrangement exists, the services are performed, and collectibility is reasonably assured. Research & development contract revenue represents payments due from our co-development partner relating to the reimbursement of 50% for certain of our ongoing research costs in the development of clofarabine outside the United States.

The Company follows the guidance of Emerging Issues Task Force, or ETIF, 99-19, "Reporting Revenue Gross as a Principal versus Net as an Agent" in the presentation of revenues and direct costs of revenues. This guidance requires the Company to assess whether it acts as a principal in the transaction or as an agent acting on behalf of others. The Company records revenue transactions gross in its statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

Stock Based Compensation

In accordance with the provisions of SFAS No. 123, "Accounting for Stock Based Compensation," or SFAS 123, the Company accounts for stock based compensation arrangements with employees in accordance with provisions of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees, " or APB 25. Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. The Company accounts for

equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services," or EITF 96-18. 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 an employee option. The Black-Scholes model is a trading options-pricing model that neither considers the non-traded nature of employee stock options, nor the restrictions on such trading, the lack of transferability or the ability of employees to forfeit the options prior to expiry. If the model adequately permitted consideration of the unique characteristics of employee stock options, the resulting estimate of the fair value of the stock options could be different. Our estimates of employee stock option values rely on estimates of factors we input into the Black-Scholes model. The key factors involve an estimate of future uncertain events. We determine expected volatility based on historical activity. We believe that these market-based inputs provide a better estimate of our future stock price movements. We also use historical exercise patterns as our best estimate of future exercise patterns.

Impairment of Long-Lived Assets

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

Overview and Company Status

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. In December 2004, the FDA approved our lead cancer product,

clofarabine, for the treatment of ALL in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine is the first new medicine initially approved in the United States for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and the E.U. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for certain cancer indications and currently controls U.S. development of clofarabine in these indications. Genzyme is marketing clofarabine under the brand name Clolar(R) in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL with the EMeA. If approved, we anticipate commencing sales in Europe during the first quarter of calendar 2006 through a dedicated European sales force.

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

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

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

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this early stage of our operations. Our management believes that we have the opportunity to become a leading oncology-focused pharmaceutical company

in the next four years if we successfully bring clofarabine to market in Europe and successfully develop certain of our other product candidates.

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

In May 2003, we entered into a License and Sub-License Agreement with

Dechra Pharmaceuticals, plc, or Dechra, pursuant to which we sub-licensed the marketing and development rights to Vetoryl(R) (trilostane), solely with respect to animal health applications, in the U.S. and Canada, to Dechra. We received $1.25 million in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try and capitalize on these types of opportunities as they arise. The Company also owns rights to OLIGON(R) technology and we have had discussions with potential product licensing partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans.

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

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

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

Results of Operations

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

We reported revenues of approximately $4,651,000 and $3,102,000 for the years ended June 30, 2005 and 2004, respectively, representing an increase of approximately $1,549,000. This increase primarily was due to an increase

in license and royalty revenue from milestone payments and royalties received from certain of our co-development partners in the amount of approximately $450,000, an increase in research and development contract revenue due to

increased sales in the Named Patient Program, increased reimbursements from Genzyme related to clofarabine research and development expenses, in the amount of approximately $488,000, and revenue from the sale of Modrenal(R) of approximately $611,000.

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

Research and development costs for the years ended June 30, 2005 and 2004 were approximately $10,895,000 and $4,883,000 respectively, representing an increase of $6,012,000.

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

Product	2005	2004	Change from prior year
	(in thousands)		
Clofarabine	$8,697	$2,650	$6,047
Modrenal	$1,972	$2,026	$(54)
Virostat	$131	$48	$83
Velostan	$79	$152	$(73)
OLIGON	$16	$6	$10
Gene Therapy	-	-	-

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

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

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

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

OLIGON research and development costs for the years ended June 30, 2005 and 2004 were $16,000 and $6,000, respectively, representing an increase of $10,000. The increase primarily reflects pre-development costs incurred in connection with continuing co-partnering discussions.

There were no research and development costs associated with Gene Therapy

for the years ended June 30, 2005 and 2004 due to the Company's focus on clofarabine during this period.

The clinical trials and development strategy for the clofarabine and Modrenal(R) projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of our projects is as

follows: (i) clofarabine research and development costs have been approximately $14,315,000; (ii) Modrenal(R) research and development costs have been approximately $6,369,000; (iii) Velostan research and development costs have been approximately $380,000; (iv) Virostat research and development costs have been approximately $189,000; (v) OLIGON research and development costs have been approximately $25,000; and (vi) Gene Therapy research and development costs have been approximately $451,000.

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

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

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

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

Provision for bad debts for the years ended June 30, 2005 and 2004 were approximately $869,000 and $0, respectively. The increase is due to the Company recording a valuation allowance relating to certain of the outstanding receivable balances from our co-development partner totaling $869,000 in the

current year. Management believes the amounts billed to its co-development partner and previously recorded as revenue through March 31, 2005 are supportable and continues to actively pursue collection of the outstanding balances. During its quarterly closing process the Company further evaluated the collectibility of such amounts and concluded that based upon the available information a valuation allowance was required. Additionally, based on the delay in payment from our co-development partner and other information, management concluded that collectibility was no longer reasonably assured and therefore, did not recognize revenue on amounts billed in the quarter ended June 30, 2005.

Prior to the fourth quarter of 2005, we tested for impairment our methylene blue intangibles acquired in connection with the Pathagon acquisition and determined that, based on our assumptions, the sum of the expected future cash flows, undiscounted and pertaining solely and exclusively to approved indications, exceeded the carrying value of its long-lived assets and therefore we did not recognize an impairment. Due to the loss of an intellectual property patent suit relating to the international use of methylene blue in fresh frozen plasma, we re-evaluated the intangible asset relating to methylene blue at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, again relating solely and exclusively to approved uses of methylene blue, were less than the carrying value. As a result, we recognized a non-cash impairment loss of $5,276,000, equal to the difference between the estimated future cash flows for approved uses of methylene blue, discounted at an appropriate rate, and the carrying amount of the asset. Making the impairment determination and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective.

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

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

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

Our research and development costs include costs associated with six projects of which the Company devotes significant time and resource. Clofarabine research and development costs for the year ended June 30, 2004 and 2003 were approximately $2,651,000 and $871,000, respectively, representing an increase of approximately

$1,780,000. The increase primarily reflects costs which are associated with our increased development activities and clinical trials being conducted in Europe.

Modrenal(R) research and development costs for the year ended June 30, 2004 and 2003 were approximately $2,026,000 and $913,000, respectively, representing an increase of $1,113,000. The increase primarily reflects increased development

activities associated with the Modrenal(R) development plan, including costs associated with the U.S. prostate cancer trial which is ongoing.

Velostan research and development costs were approximately $152,000 and $30,000, respectively, representing an increase of $122,000. The increase primarily reflects preparation of a protocol and other preparatory activities in advance of the Phase I Clinical Trial which has not yet commenced to date.

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

The clinical trials and development strategy for the clofarabine and Modrenal(R) projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Total costs to date for each of these four projects is as follows: (i) clofarabine research and development costs have been approximately $5,600,000; (ii) Modrenal(R) research and development costs have been approximately $4,400,000; (iii) Velostan research and development costs have been approximately $302,000; and (iv) Gene Therapy research and development costs have been approximately $450,000. Our other two research and development projects involve our two ancillary technologies; OLIGON and Virostat. We do not currently devote any significant time or resources to these research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, clofarabine and Modrenal(R), over the next two years.

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

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

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

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

Liquidity and Capital Resources

We anticipate that we may continue to incur significant operating losses

for the foreseeable future. There can be no assurance as to whether or when we will generate material revenues or achieve profitable operations.

On June 30, 2005, we had cash and cash equivalents of approximately $31,408,000, short-term securities of $32,747,000 and working capital of $60,112,000. Management believes the Company has sufficient cash and cash equivalents and working capital to continue currently planned operations over the next 12 months. Although we do not currently plan to acquire or obtain licenses for new technologies, if any such opportunity arises and we deem

it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

On February 8, 2005, we completed a secondary public offering in which we sold 7,500,000 common shares at $8.00 per share, with net proceeds to the Company of approximately $55.7 million, after deducting underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds for further development of our lead products, for sales and marketing expenses related to the commercial launch of our lead products, for working capital and other general corporate purposes.

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

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

The Company received a nonrefundable upfront payment of $1.35 million when it entered into the co-development agreement with Genzyme and received an additional $3.5 million in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application for clofarabine with FDA, the Company received an additional (i) $2 million in April 2004 and (ii) $2 million in September 2004. The Company

deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related royalty period, through March 2021. For the years ended June 30, 2005 and 2004, the Company recognized revenues of approximately $438,000 and $161,000 respectively, in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Genzyme. The Company defers payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with research and development costs including approximately $219,000 and $81,000 for the years ended June 30, 2005 and 2004, respectively, related to such charges.

The Company received a nonrefundable upfront payment of $1.25 million when it entered into the License and Sublicense Agreement with Dechra in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related royalty period, currently through September 2022. The Company recognized revenues of approximately $87,000 and $114,000 in connection with the upfront payment from Dechra for the years ended June 30, 2005 and 2004, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers 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 $17,400 and $23,000 for the years ended June 30, 2005 and 2004, respectively.

Restatement

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

On May 24, 2005, the Company received a notice from the Nasdaq staff indicating that the Company was not in compliance with Nasdaq's requirements for the continued listing due to its failure to timely file its Form 10-QSB for the period ended March 31, 2005, as required under Marketplace Rule 4310(c)(14) and that therefore its common stock was subject to delisting from The Nasdaq Stock Market. The notice does not by itself result in immediate delisting of the common stock, although Nasdaq stated that unless the Company timely requested a hearing, the Company's securities would be delisted from The Nasdaq Stock Market at the opening of business on June 2, 2005. The Company made a timely request for a hearing with the Nasdaq Listing Qualifications Panel to review the Nasdaq staff's determination which stayed the delisting pending the hearing and a

determination by the Nasdaq Listing Qualifications Panel. On June 29, 2005, the Nasdaq Listings Qualifications Panel approved Bioenvision's request for continued listing on the Nasdaq National Market and the fifth character "E" was removed from Bioenvision's trading symbol on the opening of trading on Friday, July 1, 2005.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS, No. 123 (R), a revision of SFAS 123. SFAS 123 (R) supersedes APB 25 and amends SFAS No. 95 "Statement of Cash Flows". SFAS 123(R) is similar to the approach described in SFAS 123 except that SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated statements of income, in lieu of pro-forma disclosure as provided above. SFAS 123 (R) is effective for fiscal years beginning after June 15, 2005. The Company has adopted the provisions of SFAS 123 (R) as of July 1, 2005, the first day of fiscal 2006, and applied the modified-prospective method using the Black-Scholes model for estimating the fair value of equity compensation.

In March 2005, the SEC issued Staff Accounting Bulletin No. 107 "Share-Based Payment" ("SAB No.107"), which provides interpretive guidance related to the interaction between SFAS 123R (reivsed 2004) and certain SEC rules and regulations, as well as provides the SEC staff's views regarding the valuation of share-based payment arrangements. The Company is currently assessing the effect of SAB No. 107 on its implementation and adoption of SFAS 123R.

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

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

Item 7. Financial Statements

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 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

As more fully disclosed in Bioenvision's current report on Form 8-K filed on April 7, 2005, on April 4, 2005, Bioenvision, Inc. notified Grant Thornton LLP ("GT") of GT's dismissal in connection with its decision to engage new auditors as its independent registered public accounting firm. On that date, Bioenvision appointed Deloitte & Touche LLP ("Deloitte") as its new independent registered public accounting firm for the fiscal year ending June 30, 2005. The decision to engage Deloitte was made by the Audit Committee of Bioenvision's Board of Directors on April 4, 2005. The appointment was effective as of such date.

Item 8a. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report on Form 10-KSB. Based on this evaluation, except as set forth in this Item 8a, our principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the requisite time periods.

Changes in Internal Controls

In May 2005, the Company appointed a Director of Financial Reporting who is involved with assisting the Controller with the administration of all accounting functions including Sarbanes-Oxley compliance, preparation of all monthly, quarterly and annual financial statements and further enhancements of the Company's internal controls. Our Director of Financial Reporting most recently served as a Supervising Senior Associate in the audit department of KPMG (New York office), an internationally recognized public accounting firm. In addition, in May 2005 the Company also added an Assistant Accountant to its UK office to assist with certain basic accounting and bookkeeping responsibilities. Our Assistant Accountant most recently served as an Intercompany Accountant with Quintiles, an international pharmaceutical company.

In April 2005, the Company implemented a new accounting system to support its general ledger, accounts payable, inventory, and revenue processes. The implementation of the system has enhanced our internal controls by automating certain approval processes and strengthening our segregation of duties through limiting the performance of certain accounting functions performed by each employee in the accounting department.

Unless otherwise disclosed, we made no other change in our internal control over financial reporting during the quarter that materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Description of Material Weaknesses in Internal Controls Over Financial Reporting

(a) Restatement of the Company's 10-KSB for the fiscal year ended June 30, 2004.

In connection with the preparation and filing of our quarterly report on Form 10-QSB for the three-month period ended March 31, 2005, our internal corporate staff identified errors with respect to our tax accounting treatment associated with the acquisition of Pathagon, Inc. which was consummated in February 2002. Our initial accounting concluded that the realization of our deferred tax assets related to the net operating losses and other deductible temporary differences existing at the acquisition date, and generated after the acquisition date, did not meet the "more likely than not" criteria and, as a result, a valuation allowance was established on the deferred tax assets of the Company. The Company subsequently determined that the deferred tax liability recorded in connection with the Pathagon acquisition creates taxable income as the taxable temporary differences reverse and, therefore, a portion of the valuation allowance previously established on our deferred tax assets was not required.

Management reported its findings to the Audit Committee of the Board of Directors. After initial discussions with the Audit Committee, management reviewed these matters in further detail, and after completing its analysis on May 15, 2005, recommended to the Audit Committee that previously reported financial results be restated to reflect correction of these errors. The Audit Committee agreed with this recommendation. Pursuant to the recommendation of the Audit Committee, the Board of Directors determined at its meeting on May 15, 2005, that previously reported results be restated to correct the income tax treatment associated with the Pathagon acquisition.

In connection with the restatement, under the direction of our Chief Executive Officer and Chief Financial Officer, we reevaluated our disclosure controls and procedures. We identified the following material weakness in our internal control over financial reporting with respect to accounting for income taxes associated with a purchase business combination:

- a failure to ensure the correct application of SFAS 109 "Accounting for Income Taxes" with respect to purchase business combinations and failure to correct that error subsequently resulting from the lack of personnel knowledgeable in the accounting for income taxes.

Solely as a result of this material weakness, we concluded that our disclosure controls and procedures were not effective as of March 31, 2005.

As of June 30, 2005, we had taken the following measures to remediate the material weakness in our internal control over financial reporting with respect to accounting for income taxes that existed as of March 31, 2005. The remedial actions included:

- improving training, education and accounting reviews designed to ensure that all relevant personnel involved in income tax transactions understand and apply accounting in compliance with SFAS 109;

- hiring additional internal resources, including a Director of Financial Reporting, to perform internal control activities previously completed by outside consultants; and

- engaging an outside tax consultant to supplement our internal tax staff and enhance our internal controls over income tax accounting.

(b) In connection with this annual report on Form 10-KSB, under the direction of

our principal executive officer and principal financial officer, we have evaluated our disclosure controls and procedures as currently in effect and we have concluded that as of June 30, 2005, the following material weakness in internal control over financial reporting existed:

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

Management has discussed this material weakness with our audit committee. In an effort to remediate the identified material weakness we continue to implement a number of changes to our internal controls over financial reporting, including, improved training and education for all relevant internal personnel and the hiring of additional internal resources.

Notwithstanding the above mentioned weaknesses, we believe that the consolidated financial statements included in this report fairly present our consolidated financial position as of, and the consolidated results of operations for the year ended, June 30, 2005.

Item 8b. Other information.

Prior to the fourth quarter of 2005, we tested for impairment our Virostat intangibles acquired in connection with the Pathagon acquisition and determined that, based on our assumptions, the sum of the expected future cash flows, undiscounted and pertaining solely and exclusively to approved indications, exceeded the carrying value of its long-lived assets and therefore we did not recognize an impairment. Due to the loss of an intellectual property patent suit relating to the international use of virostat in fresh frozen plasma, we re-evaluated the intangible asset relating to Virostat at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, again relating solely and exclusively to approved uses of Virostat, were less than the carrying value. As a result, we recognized a non-cash impairment loss of $5,276,000, equal to the difference between the estimated future cash flows for approved uses of Virostat, discounted at an appropriate rate, and the carrying amount of the asset. Making the impairment determination and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective.

PART III

The information required for Part III in this Annual Report on Form 10-KSB is incorporated by reference from the Company's definitive proxy

statement for the Company's 2005 Annual Meeting of Stockholders.

Items 13. Exhibits

Exhibit Number	Description
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1)
2.2	Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)
3.1	Certificate of Incorporation of Registrant. (2)
3.1(a)	Amendment to Certificate of Incorporation filed January 29, 1999. (3)
3.1(b)	Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)
3.1(c)	Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)
3.1(d)	Certificate of Designations, Preferences and Rights of series A Preferred Stock (6)
3.1(e)	Certificate of Amendment to the Certificate of Incorporation, filed January 14, 2004 (15)
3.2	Amended and Restated By-Laws of the Registrant. (13)
4.1	Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
4.2	Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
4.3	Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
4.4	Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
4.5	Form of Warrant (6)
4.6	Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)

4.7	Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)
4.8	Common Stock and Warrant Purchase Agreement, dated as of March 22, 2004, by and among Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
4.9	Registration Rights Agreement, dated March 22, 2004, by and between Bioenvision, Inc. and the Investors set forth on Schedule I thereto (16)
4.10	Form of Warrant (16)
4.11	Bioenvision, Inc. 2003 Stock Incentive Plan (17)
10.1	Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc.
10.2	Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
10.3	Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc.
10.4	Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998. (3)
10.5	Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
10.5(a)	Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
10.6	License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc
10.7	Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
10.8	Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003 (14)
10.9	Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
10.10	Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
10.11	Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
10.12	Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)

10.13	Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
10.14	Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
10.15	License Agreement by and between Oklahoma Medical Research

	Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
10.16	Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
10.17	Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
10.18	License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
10.19	Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
10.20	Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
10.21	Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
10.22	Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
10.23	Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC(14)
10.24	Employment Agreement between Bioenvision Limited and Hugh Griffith, made effective as of October 23, 2002 (18)
10.25	Employment Agreement between Bioenvision Limited and Ian Abercrombie, made effective as of January 6, 2003 (18)
10.26	Amendment # 2 to the Co-Development Agreement between Bioenvision and ILEX Oncology, Inc. dated December 30, 2003.
10.27	Amendment to the Co-Development Agreement between Bioenvision, Inc. and SRI, dated as of March 12, 2001.
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 .

14.1	Bioenvision Inc.'s Code of Business Conduct and Ethics (19)
16.1	Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
16.2	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
16.3	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
16.4	Letter from Grant Thornton LLP to the Securities and Exchange Commission , dated April 7, 2005 (20)

21.1	Subsidiaries of the registrant (4)
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of Prior Independent Registered Public Accounting Firm
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.
31.2	Certification of David P. Luci, Chief Accounting Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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(1) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 12, 1999.

(2) Incorporated by reference and filed as an Exhibit to Registrant's Registration Statement on Form 10-12g filed with the SEC on September 3, 1998.

(3) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.

(4) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.

(5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2002.

(6) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2002.

(7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.

(8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.

(9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.

(10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.

(11) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 6, 2001.

(12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.

(13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.

(14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.

(15) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2004.

(16) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on March 24, 2004.

(17) Registrant's definitive proxy statement on Schedule 14-A, filed in connection with the annual meeting held on January 14, 2004.

(18) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three- month period ended September 30, 2003.

(19) Incorporated by reference and filed as an Exhibit to Registrant's Annual Report on Form 10-KSB for the year ended June 30, 2004.

(20) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on April 7, 2005.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of Bioenvision, Inc. and subsidiaries (the "Company") as of June 30, 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the 2005 consolidated financial statements present fairly, in all material respects, the financial position of Bioenvision, Inc. and subsidiaries as of June 30, 2005, and the results of its operations and its cash flows for the year ended June 30, 2005, in conformity with accounting principles generally accepted in the United States of America.

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

REPORT OF PRIOR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

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

As more fully described in Note 10, the June 30, 2004 financial statements have been restated.

/s/ Grant Thornton LLP
New York, New York
September 16, 2004 (except for paragraph 13 of Note 1 and Note 10, as to which the date is May 27, 2005)

BIOENVISION, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

Ju

ASSETS

Current assets	
Cash and cash equivalents	$ 31
Restricted cash	
Short-term securities	32
Accounts receivable (less allowances for bad debts of $869,220 and $0, respectively)	1
Inventory	
Other current assets	
Total current assets	66
Property and equipment, net	
Intangible assets, net	8
Goodwill	1
Security Deposits	
Deferred costs	3
Total assets	$ 80
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities	
Accounts payable	$ 1
Accrued expenses and other current liabilities	4
Accrued dividends payable	
Deferred revenue	
Total current liabilities	6
Deferred revenue	7
Total liabilities	14
Stockholders' equity	
Convertible Preferred stock - $0.001 par value; 20,000,000 shares authorized; 2,250,000 and 3,341,666 shares issued and outstanding at June 30, 2005 and June 30, 2004, respectively (liquidation preference $6,750,000 and $10,024,998, respectively)	
Common stock - $0.001 par value; 70,000,000 shares authorized; 40,558,948 and 28,316,163 shares issued and outstanding at June 30, 2005 and June 30, 2004, respectively	
Additional paid-in capital	128
Deferred compensation	
Accumulated deficit	(62
Accumulated other comprehensive income	
Stockholders' equity	66
Total liabilities and stockholders' equity	$ 80

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

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BIOENVISION, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended June 30,	
	2005	2004
Revenue		
License and royalty revenue	$1,463,326	$ 1,014,7
Product sales	611,346	
Research and development contract revenue	2,576,502	2,087,4
Total revenue	4,651,174	3,102,2
Costs and expenses		
Cost of products sold (including royalty expense of $524,755 for the year ended June 30, 2005)	921,262	
Research and development	10,894,925	4,882,5
Provision for bad debts	869,220	
Selling, general and administrative (includes stock based compensation expense of $793,761 and $3,491,252 for the years ended June 30, 2005 and 2004, respectively)	10,181,711	9,082,4
Depreciation and amortization	1,438,517	1,348,0
Loss on impairment	5,276,162	
Total costs and expenses	29,581,797	15,313,0
Loss from operations	(24,930,623)	(12,210,8
Interest income (expense)		
Interest and finance charges	(79,484)	
Interest income	747,322	99,7
Net loss before income tax benefit	(24,262,785)	(12,111,0
Income tax benefit	-	1,459,8
Net loss	(24,262,785)	(10,651,2
Cumulative preferred stock dividend	(404,079)	(856,7
Net loss available to common stockholders	$(24,666,864)	$(11,508,0

Basic and diluted net loss per share of common stock	$ (0.72)	$ (.
Weighted-average shares used in computing basic and diluted net loss per share of common stock	34,042,391	20,257,4

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

BIOENVISION, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Convertible Preferred Stock		Common Stock		Additional Paid In	Deferred	Accu
	Shares	$ -	Shares	$ -	Capital	Compensation	De
Balance at July 1, 2003	5,916,966	$5,917	17,122,739	$17,123	$47,304,449	$ -	$(2
Net loss for the period							(1
Cumulative preferred stock dividend for the period							
Currency translation adjustment							
Deferred compensation						(223,990)	
Shares issued in connection with private placement			2,602,898	2,603	16,265,495		
Costs related to March private placement financing					(1,301,035)		
Preferred stock converted to common stock	(2,575,300)	(2,575)	5,150,000	5,150	(2,575)		
Expense related to repricing of options					2,381,066		

Cashless exercise of options to shares			2,122,682	2,122	(2,122)		
Warrants issued in connection with services				-	671,601		
Shares issued to consultants for services			14,510	15	305,972		
Shares issued to employee			20,000	20	28,380		
Options issued in connection with services					93,987		
Options issued to employees					262,601		
Shares issued from warrant conversions			1,283,334	1,283	2,509,883		
Balance at June 30, 2004	3,341,666	$3,342	28,316,163	$28,316	$68,517,702	$(223,990)	$(3
Net loss for the period							(2
Cumulative preferred stock dividend for the period							
Currency translation adjustment							
Deferred compensation						78,344	
Options exercised to common stock			685,833	686	707,638		
Income related to repricing of options					(314,950)		
Warrants issued in connection with services					524,928		
Warrants exercised to common stock			1,811,120	1,811	3,277,151		
Shares issued in connection with services			62,500	63	496,188		
Preferred stock converted to common stock	(1,091,666)	(1,092)	2,183,332	2,183	(1,092)		
Shares issued in connection with public offering, net of related expenses			7,500,000	7,500	55,739,152		
Balance at June 30, 2005	2,250,000	$2,250	40,558,948	$40,559	$128,946,717	$(145,646)	$(6

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

BIOENVISION, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended June 30,	
	2005	2004
Cash flows from operating activities		
Net loss	$(24,262,785)	$(10,651,267
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,438,517	1,348,064
Provision for bad debts	869,220	-
Deferred tax benefit	-	(1,459,814
Stock based compensation	793,761	3,491,252
Changes in net deferred revenues and expenses	(288,723)	3,577,474
Loss on impairment	5,276,162	-
Changes in assets and liabilities		
Accounts payable	121,966	1,084,474
Inventory	(286,089)	-
Other current assets	(94,797)	(147,335
Security deposits	(132,072)	-
Accounts receivable	(56,596)	(2,602,773
Other long term assets	-	126,870
Accrued expenses and other liabilities	3,203,998	591,862
Net cash used in operating activities	(13,417,438)	(4,641,193
Cash flows from investing activities		
Purchase of intangible assets	(359,411)	(112,580
Capital expenditures	(278,044)	(18,337
Purchase of short-term securities	(32,746,948)	-
Net cash used in investing activities	(33,384,403)	(130,917
Cash flows from financing activities		
Proceeds from issuance of common stock, net of related expenses	55,746,652	14,967,064
Proceeds from exercise of options and warrants	3,987,286	2,539,565
Dividends paid	(437,816)	(1,775,782
Net cash provided by financing activities	59,296,122	15,730,847
Effect of exchange rate on cash	37,577	(12,748
Net increase in cash and cash equivalents	12,531,858	10,945,989
Cash and cash equivalents, beginning of period	18,875,675	7,929,686

Cash and cash equivalents, end of period	$ 31,407,533	$ 18,875,675

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

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2005 AND 2004

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

Description of business

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

The Company is currently selling its second product, Modrenal(R), in the United Kingdom, or U.K. Modrenal(R) is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.

We anticipate that revenues derived from our two lead drugs, clofarabine and Modrenal(R) will permit us to further develop the other products currently in our product pipeline. In addition to clofarabine and Modrenal(R), we are performing initial development work on Virostat for the treatment of Hepatitis C and Velostan, initially for the treatment of bladder cancer.

Principles of consolidation

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

Use of estimates

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

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2005 AND 2004

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

Revenue Recognition

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

Royalty revenue from product licensees is recorded as earned.

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

Research & development contract revenue represent payments due from our co-development partner relating to the reimbursement of 50% for certain of our ongoing research costs in the development of clofarabine outside the United States.

Currently, the Company has billed but not recorded approximately $1,142,000 of revenues relating to the reimbursement from our co-development partner for certain of our ongoing research costs in the development of clofarabine outside the United States. When the Company has determined that the criteria relating to revenue recognition has been met, the Company will record the revenue.

Provision for bad debts for the years ended June 30, 2005 and 2004 were approximately $869,000 and $0, respectively. The increase is due to the Company recording a valuation allowance relating to certain of the outstanding receivable balances from our co-development partner totaling $869,000 in the current year.

The Company follows the guidance of Emerging Issues Task Force 99-19, or EITF, "Reporting Revenue Gross as a Principal versus Net as an Agent" in the presentation of revenues and direct costs of revenues. This guidance requires the Company to assess whether it acts as a principal in the transaction or as an agent acting on behalf of others. The Company records revenue transactions gross in its statements of operations if it is deemed the principal in the transaction, which includes being the primary obligor and having the risks and rewards of ownership.

Research and development

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

Stock based compensation

As permitted by SFAS No. 123, "Accounting for Stock Based Compensation," or SFAS 123, the Company accounts for stock based compensation arrangements with employees in accordance with provisions of Accounting Principles Board Opinion No. 25 "Accounting for Stock Issued to Employees," or APB 25. Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. For year ended June 30, 2005, the Company recognized stock based employee compensation income of $315,000 as a result of the re-pricing of 380,000 options granted to an employee pursuant to the terms of his Employment Agreement (see Note 6). The Company also recognized a compensation expense of $88,000 for the year ended June 30, 2005 as a result of 505,000 options granted to certain employees on January 20, 2004.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services," or EITF 96-18. 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.

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

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

	Year Ended J	
	2005	
Net loss available 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 determined under fair value based method for all awards	(2,427,771)	
Pro forma net loss	$(27,322,052)	

Loss per share	
Basic and diluted - as reported	$(0. 72)
Basic and diluted - pro forma	$(0.80)

The fair value of options at the date of grant was established using the Black-Scholes model with

	2005	2004
Expected average life (years)	3.87	3.50
Risk free interest rate	3.37%	2.35%
Expected volatility	80%	80%
Expected dividend yield	0%	0%

In December 2004, FASB issued SFAS No. 123 (R), "Share-Based Payment", a revision of SFAS 123. SFAS 123 (R) supersedes APB 25 and amends SFAS No. 95 "Statement of Cash Flows". SFAS 123(R) is similar to the approach described in SFAS 123 except that SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the consolidated statements of income, in lieu of pro-forma disclosure as provided above. SFAS 123 (R) is effective for fiscal periods beginning after June 15, 2005. The Company has adopted the provisions of SFAS 123 (R) as of July 1, 2005, the first day of fiscal 2006, and applied the modified-prospective method using the Black-Scholes model for estimating the fair value of equity compensation.

As permitted by SFAS 123, through June 30, 2005 the Company accounted for share-based payments to employees using the intrinsic value method set forth in APB 25 and, as such, generally recognized no compensation cost for employee stock options. Accordingly, the adoption of the fair value method under SFAS 123(R) will have a significant impact on the Company's consolidated statements of income. However, the Company's overall cash position will not be affected by the adoption of SFAS 123(R). The actual impact of SFAS 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and other factors.

However, had the Company adopted SFAS 123(R) in prior periods, the impact of that standard and therefore, the disclosure of pro forma net income and earnings per share above would remain the same. SFAS 123(R) also requires that tax deductions in excess of recognized compensation cost be reported as a financing cash flow, rather than as operating cash flow. This requirement will reduce net operating cash flow

Note 1 - Description of Business and Summary of Significant Accounting Policies - continued
and increase net financing cash flow in periods after the adoption of SFAS 123(R). Estimation of the increase in net financing cash flow and decrease in net operating cash flow depends on the timing and exercise of stock options and

is difficult to predict. The amount of operating cash flow recognized in prior periods for such excess tax deductions was $0 and $890,000 for years ended June 30, 2005 and 2004, respectively.

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.

Net loss per share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options and warrants to purchase 11,472,414 and 13,674,242 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2005 and 2004, respectively, as their effect would have been anti-dilutive.

Comprehensive Loss

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

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 U.S. 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 income accounts at average rates for the period. For the year ended June 30, 2005, foreign currency transaction gains and losses included in selling, general and administrative expense were $33,000 and $6,000, respectively.

Cash and cash equivalents and Short-term securities

The Company considers all highly liquid financial instruments with a maturity of three months or less when purchased to be cash equivalents. All funds invested in a Certificate 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.

Deferred costs

Deferred costs represent payments to Southern research Institute, or SRI, and to Stegram Pharmaceutical Ltd, which directly relate to milestone payments received in connection with the Genzyme Co-Development Agreement and the Dechra Sub-License Agreement, respectively. The amortization of these costs have been presented in research and development on the statement of operations.

Credit Risk

Our accounts receivable are primarily due from wholesale distributors and our co-development partners. One customer comprises approximately 62% of revenues earned at June 30, 2005. Based on our evaluation of the collectibility of these

accounts receivable, we believe that this balance may not be collectible and therefore have reserved 100% of the balance outstanding at June 30, 2005.

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2005 AND 2004

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

Inventory

Inventories are stated at the lower of cost or market, cost being determined under the first-in, first-out method. We only capitalize inventory that is produced for commercial sale. The Company periodically reviews inventories and items considered outdated or obsolete are reduced to their estimated net realizable value. Inventories consisted of $171,000 of work-in-progress and $107,000 of finished goods at June 30, 2005.

Property and equipment

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

Asset Description	Estimated Useful Life	2005	2004
			Property a
Computer equipment and software	3 to 5 years	304,892	43,879
Furniture and fixtures	7 years	49,364	35,052
		354,256	78,931
Less: accumulated depreciation		(74,478)	(31,074)
Net Property and equipment		$ 279,778	$ 47,857

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

Fair Value of Financial Instruments

The Company has estimated the fair value of financial instruments using available market information and other valuation methodologies in accordance with SFAS No. 107, "Disclosures About Fair Value of Financial Instruments." Management of the Company believes that the fair value of financial instruments, consisting of cash, cash equivalents, short term securities, accounts receivable, accounts payable and accrued liabilities, approximates carrying

value due to the immediate or short-term maturity associated with these instruments.

Goodwill and Other Intangible Assets

Goodwill represents the excess of costs over the fair value of identifiable net assets of Pathagon. Intangible assets include patents and licensing rights acquired in connection with the acquisition of Pathagon. The Company accounts for these assets in accordance with SFAS No. 142, Goodwill and Other Intangible Assets. Goodwill is not amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 144, Accounting for Impairment or Disposal of Long-Lived Assets.

For goodwill, each year and whenever impairment indicators are present, we will calculate the implied fair value of each goodwill amount and record an impairment loss for the excess of book value over the implied fair value, if any.

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

Impairment of Long-Lived Assets

The Company adopted the provisions of SFAS No. 144 on July 1, 2003. In accordance with SFAS No. 144, long-lived assets, such as property and equipment and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset (see Note 3).

Note 2 - Acquisition of Pathagon

On February 1, 2002, the Company completed the acquisition of Pathagon. The acquisition was accounted for as a purchase business combination in accordance with SFAS 141. The Company issued 7,000,000 shares of common stock to complete the acquisition, which was valued at $12,600,000 based on the 5-day average trading price of the stock ($1.80) surrounding November 22, 2001, the day of the Company's announcement of the agreed upon acquisition. The acquired patents and licensing rights of OLIGON(R) and methylene blue (collectively referred to as "Purchased Technologies"), were recorded at their fair market value which was approximately $17,576,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of these assets. Since the estimated fair value of the Purchased Technologies was at least equal to the amount paid, the purchase price, net of assumed liabilities, was allocated to Purchased Technologies. The transaction qualified as a tax-free merger which resulted in a difference between the tax basis value of the assets acquired and the fair market value of the patents and licensing

rights. As a result, a deferred tax liability was recorded for approximately $7,909,000. The purchase price exceeded the fair market value of the net assets acquired resulting in the recording of Goodwill of $2,341,000. The Company recorded a charge to goodwill of $801,395 for fiscal year ended June 30, 2003 as a result of a change in tax rates used to compute the deferred tax liability arising as a result of this acquisition. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro-forma financials would not be meaningful and thus are not presented.

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

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

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

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

Note 3 - Intangible Assets

Intangible assets consist of the following:	As of June 30 2005	2004
Patents and licensing rights	$9,514,026	$17,757,101
Less: accumulated amortization	(1,261,090)	(3,193,441)
	$8,252,936	$14,563,660

Amortization of patents and licensing rights amounted to $1,394,000 and $1,328,000 for the years ended June 30, 2005 and June 30, 2004, respectively. Other intangible assets are recorded at cost and amortized over periods generally ranging from 10-20 years. Amortization for each of the next five fiscal years will amount to approximately $900,000 annually.

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

Note 4 - License and Co-Development Agreements

Clofarabine

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

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

To facilitate the development of clofarabine, in March 2001, the Company entered into a co-development agreement with ILEX Oncology, Inc., our sub-licensor until it was acquired by Genzyme Corporation on December 21, 2004, for the development

of clofarabine in cancer indications. Under the terms of the co-development agreement, Genzyme is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia), in each case, for the development of clofarabine in cancer indications. Genzyme is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada for certain cancer indications. The Company retains the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia) and retains the right to handle these matters in the U.S. and Canada in all non-cancer indications. The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. Under the co-development agreement, Genzyme will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay Genzyme a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. In turn, Genzyme, which would have U.S. and Canadian distribution rights in cancer

Note 4 - License and Co-Development Agreements - continued

indications, would pay the Company a royalty on sales in the U.S. and Canada. Under the terms of the co-development agreement, Genzyme also pays royalties to SRI based on certain milestones. The Company also is obligated to pay certain royalties to SRI with respect to clofarabine.

The Company received a nonrefundable upfront payment of $1.35 million when it entered into the co-development agreement with Genzyme and received an additional $3.5 million in December 2003 when it converted Genzyme's option to market clofarabine in the U.S. into a sublicense. Upon Genzyme's filing the New Drug Application for clofarabine with the FDA, the Company received an additional (i) $2 million in April 2004 and (ii) $2 million in September 2004. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related initial service period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related service period, through March 2021. For the years ended June 30, 2005 and 2004, the Company recognized revenues of approximately $438,000, and $161,000, respectively, in connection with the milestone payments received to date.

Deferred costs include royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Genzyme. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with research and development costs including approximately $219,000 and $81,000 for the years ended June 30, 2005 and 2004, respectively related to such charges.

Modrenal(R)

The Company holds an exclusive license, until the expiration of existing and new patents related to Modrenal(R), to market Modrenal(R) in major international territories, and an agreement with a United Kingdom company to co-develop Modrenal(R) for other therapeutic indications. Management believes that

Modrenal(R) currently is manufactured by third-party contractors in accordance with good manufacturing practices. The Company has no plans to establish its own manufacturing facility for Modrenal(R), but will continue to use third-party contractors.

The Company received a nonrefundable upfront payment of $1.25 million when it entered into the License and Sublicense Agreement with Dechra Pharmaceuticals in May 2003. The Company deferred the upfront payment and recognizes revenues ratably, on a straight-line basis over the related service period, currently through September 2022. The Company recognized revenues of approximately $87,000 and $114,000 in connection with the upfront payment from Dechra for the years ended June 30, 2005 and 2004, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Dechra in May 2003. The Company defers all royalty payments made to Stegram and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with the Dechra agreement. Research and development costs related to this agreement include approximately $17,400 and $23,000 for the years ended June 30, 2005 and 2004, respectively.

Note 5 - Income Taxes

The components of the income tax benefit are as follows:

	June 30, 2005	June 30, 2004
Current:		
Federal	$ --	$ --
State	--	--
Deferred:		
Federal	--	(1,099,000)
State	--	(361,000)
	--	(1,460,000)
Total benefit	$ --	$(1,460,000)

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

	June 30, 2005	June 30, 2004
Domestic	$(22,601,000)	$(10,781,000)

Foreign	(1,662,000)	(1,330,000)
Loss before taxes	$(24,263,000)	$(12,111,000)

BIOENVISION, INC. AND SUBSIDIARIES
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Note 5 - Income taxes - continued

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

	June 30,	
	2005	2004
Consolidated tax benefit at federal statutory rate	(34.0%)	(34.0%)
Non-deductible expenses	(0.3%)	6.8%
State income tax benefit, net of federal provision	(6.1%)	(4.5%)
Valuation allowance	40.1%	19.3%
Foreign rate differential	0.3%	0.4%
Other, net	0.0%	(0.1%)
Effective tax rate	0.0%	(12.1%)

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

	June 30,	
	2005	2004
Deferred tax liability		
Acquired intangibles	$(2,923,000)	$(5,781,000)
Deferred costs	(1,481,000)	(1,577,000)
Amortization	(115,000)	(43,000)
Depreciation	(33,000)	(30,000)
Other	(3,000)	(3,000)
Total deferred tax liability	(4,555,000)	(7,434,000)
Deferred tax assets		
Net operating loss	14,344,000	6,384,000
Options, warrants and shares		

issued to non-employees	534,000	345,000
Options issued to employees	164,000	104,000
Deferred revenue	3,214,000	3,427,000
Provision for bad debts	352,000	-
Accrued expenses	126,000	68,000
Total deferred tax assets	18,734,000	10,328,000
Valuation allowance for deferred tax assets	(14,179,000)	(2,894,000)
Net deferred tax asset	4,555,000	7,434,000
Net deferred tax liability	$ -	$ -

Note 5 - Income Taxes - continued

At June 30, 2005 and 2004, the Company had approximately $32,524,000 and $14,087,000 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 $13,172,000 and $5,705,000, respectively. At June 30, 2005 and 2004, the Company also had approximately $3,906,000 and $2,263,000 of net operating loss carryforwards relating to foreign operations, respectively, with no expiration date, with a tax value of $1,172,000 and $679,000, respectively.

At June 30, 2005 and 2004, the Company has recorded a valuation allowance of $14,179,000 and $2,894,000 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. Of these amounts, a valuation allowance of $650,000 was recorded at June 30, 2005 and 2004 for certain US deferred tax assets which will be recognized after the period in which the Pathagon deferred tax liability reverses. The remaining allowance relates to the net operating loss of the foreign operations due to the uncertainty that the Company will realize taxable income in the foreign jurisdiction to utilize the net operating loss carryforward.

Included in the June 30, 2005 and 2004 net operating loss is $3,857,000 and $415,000, 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. When the valuation allowance is removed, the tax affected benefit of $1,562,000 and $168,000, respectively, related to this loss will be credited to equity.

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

Note 6 - Stockholders' Transactions

Stock Options

The Board of Directors adopted, and the stockholders approved the 2003 Stock Incentive Plan at the Annual Meeting held in January of 2004. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 4,500,000 shares reserved for grants of options under the plan and at June 30, 2005, options to purchase 2,956,500 shares of common stock had been issued. Stock options vest pursuant to individual stock option agreements. No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Board of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors or until expiration of the plan on November 17, 2013.

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

Note 6 - Stockholders' Transactions - continued

expense based on changes in the stock price. Stock based compensation income (expense) recognized as a result of this re-pricing amounted to $315,000 and $(2,381,000) for the years ended June 30, 2005 and 2004, respectively.

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

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

On January 20, 2004, the Company granted 25,000 options to a member of the Board of Directors, for serving as a member of the Board of Directors, at an exercise

price of $4.55 per share which vest ratably on the first and second anniversaries of the grant date. The Company recognized $47,000 and $21,000 as consulting expenses for the years ended June 30, 2005 and June 30, 2004, respectively.

The Company recorded a compensation expense of $88,000 and $38,611 for the years ended June 30, 2005 and June 30, 2004, respectively, as a result of 505,000 options granted to certain employees on January 20, 2004 at a strike price that was lower than the exercise price.

On January 6, 2005, the Company granted 7,500 options to a board member for serving as a member of the Board of Directors, at an exercise price of $8.17 per share which 1,875 vest immediately on the grant date and the remaining 5,625 vest ratably on the first, second and third anniversaries of the grant date. The Company recognized approximately $13,000 as consulting expense for the year ended June 30, 2005.

BIOENVISION, INC. AND SUBSIDIARIES
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Note 6 - Stockholders' Transactions - continued

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

	Number of Shares	Weighted Average Exercise Price
Balance - June 30, 2003	3,570,000	$ 1.23
Granted during 2004	720,000	$ 5.02
Exercised during 2004	20,000	$ 1.42
Balance - June 30, 2004	4,270,000	$ 1.87
Granted during 2005	784,000	$ 7.99
Exercised during 2005	885,500	$ 1.08
Forfeiture during 2005	12,500	$ 3.53
Balance - June 30, 2005	4,156,000	$ 3.18

	Stock Options Outstanding			Options Exercisa	
Exercise Price Range	Weighted Average Exercise price	Number of Options	Weighted Average Remaining Contractual Life	Number of Stock Options Exercisable	Wei Ave Exe Pri

$0.74 - $1.45	$ 1.29	2,685,000	3.21	2,283,000	$
$4.05 - $4.05	$ 4.05	497,000	8.56	166,000	$
$5.44 - $6.50	$ 5.93	111,000	9.26	29,000	$
$7.87 - $8.87	$ 8.21	863,000	9.41	243,000	$
$0.74 - $8.87	$ 3.18	4,156,000	5.30	2,721,000	$

The weighted-average grant date fair value of options granted for the periods ended June 30, 2005 and 2004 was $4.75 and $3.13, respectively

Convertible Preferred Stock

On May 7, 2002 the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Preferred Stock, par value $0.001 per share ("Series A Preferred Stock"). Series A Preferred Stock may be converted into two shares of common stock at an initial conversion price of $1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. In May 2002, the Company consummated a Private Placement of Series A Preferred Stock and received gross proceeds of $17.7 million. Holders of Series A Preferred Stock also received, in respect of each share of Series A Preferred Stock purchased in the May 2002 Private Placement by the Company, one warrant to purchase one share of the Company's common stock at an initial exercise price of $2.00, subject to adjustment. The purchasers of Series A Preferred Stock also received certain registration rights. The preferred stock generally carries rights to vote with the holders of common stock as one class on a two-for-one basis. The preferred stock is convertible into the Company's common stock, 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

Note 6 - Stockholders' Transactions - continued

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.

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Preferred Stock. The Company has paid the dividend in cash to holders of Series A Convertible Preferred Stock through July 30, 2005.

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.

During the year ended June 30, 2005, certain holders of 1,091,666 shares of the Company's preferred stock converted such shares into 2,183,332 shares of the Company's common stock. In addition, during the year ended June 30, 2005, certain warrant holders of the Company exercised their warrants to acquire 1,598,411 shares of the Company's common stock. The Company received proceeds of approximately $3,278,963 during the year ended June 30, 2005 from the exercise of these warrants.

Common Stock

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.

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 $55.7 million, after deducting underwriting discounts and commissions and offering expenses.

Warrants

On June 22, 2004 the Company entered into a consulting agreement pursuant to which consultant will provide certain investor relation services on behalf of the Company. In connection therewith, the Company issued a warrant to said consultant pursuant to which said consultant has the right to purchase 50,000 shares of Company's common stock at a price of $8.25 per share upon the completion of certain milestones, as set forth in such agreement. The Company recognized approximately $243,000 as a consulting expense for the year ended June 30, 2005.

On August 4, 2004, the Company issued a warrant to a consultant pursuant to which said consultant has the right to purchase 40,000 shares of the Company's common stock at a price of $7.22 per share upon satisfaction of certain milestones included in the warrant. The Company recognized approximately $75,000 as consulting expense for the year ended June 30, 2005, relating to said 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 $138,000 as consulting expense for year ended June 30, 2005 relating to said warrants.

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, located in the United Kingdom manages our product sales (including the named patient program). The following table reconciles our revenues by geographic region to the consolidated total:

	Year ended June 30, 2005	2004
Region		
United States	$ 3,373,547	$ 2,929,719
United Kingdom	1,277,627	172,495
	$ 4,651,174	$ 3,102,214

Note 8 - Related Party Transactions

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

Note 9 - Commitments and Contingencies

Leases

The Company leases 5,549 square feet of office space for its New York, New York headquarters under a non-cancelable operating lease expiring on December 29, 2009 and approximately 2,437 square feet in Edinburgh, Scotland under a lease agreement for its subsidiary Bioenvision Ltd. which expires February 28, 2006. Rent expense for both facilities in the aggregate for the year ended June 30, 2005, was approximately $421,000. Further, the Company leases two vehicles under leases which expire November 29, 2005 and February 28, 2007. Lease expense was approximately $34,000 and $37,000 for the years ended June 30, 2005 and June 30, 2004, respectively. At June 30, 2005, total minimum rentals under operating leases with initial or remaining non-cancelable lease terms of more than one year were approximately:

Year ended June 30,	
2006	$773,000
2007	546,000
2008	316,000
2009	316,000
2010	159,000
	$ 2,110,000

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2005 AND 2004

Note 9 - Commitments and Contingencies - continued

Litigation

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the "Tessman Defendants") in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously. Each of the parties has moved for summary judgment dismissing all but one of the claims of the other parties. Those motions have not been decided by the Court.

Note 10 - Restatements

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

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

As a result of the above, the Company previously restated its consolidated

financial statements as of June 30, 2004 in its Form 10-KSB/A. The following is a summary of the effects of the income tax accounting corrections on the Company's consolidated financial statements for the years ended June 30, 2004 and 2003.

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2005 AND 2004

Note 10 - Restatements - continued

June 30	2004		2003	
	As Reported	As Restated	As Reported	As
Consolidated Balance Sheets:				
Goodwill	$ 3,902,705	$ 1,540,162	$ 3,902,705	$
Total assets	44,533,387	42,170,844	28,535,675	
Deferred tax liability	5,780,799	-	6,317,702	
Total liabilities	17,150,816	11,370,017	9,707,283	
Accumulated deficit	(41,082,397)	(37,664,141)	(28,651,443)	(
Total shareholders' equity	27,382,571	30,800,827	18,828,392	

Year Ended June 30	2004		2003	
	As Reported	As Restated	As Reported	As
Consolidated Statements of Operations:				
Income tax benefit	$ 536,903	$ 1,459,814	$ 536,903	$
Net loss	(11,574,178)	(10,651,267)	(6,746,326)	
Net loss available to common stockholders	(12,430,954)	(11,508,043)	(7,624,144)	
Basic and diluted net loss per share of common stock	$ (0.61)	$ (0.57)	$ (0.45)	$

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

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

SIGNATURES

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 October 13, 2005, thereunto duly authorized.

BIOENVISION, INC.

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

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

By /s/ David P. Luci

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

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

Signature	Title	Date
/s/ Christopher B. Wood, M.D. --- Christopher B. Wood, M.D.	Chairman and Chief Executive Officer and Director (Principal Executive Officer)	October 13, 2005
/s/ David P. Luci --- David P. Luci	Chief Financial Officer, General Counsel and Corporate Secretary (Principal Financial and Accounting Officer)	October 13, 2005
/s/ Thomas S. Nelson --- Thomas S. Nelson, C.A.	Director	October 13, 2005
/s/ Michael Kauffman --- Michael Kauffman	Director	October 13, 2005

/s/ Andrew N. Schiff --- Andrew N. Schiff	Director	October 13, 2005
/s/ Steven A. Elms --- Steven A. Elms	Director	October 13, 2005