BIOENVISION INC
Form 10KSB
September 24, 2004

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, 2004.

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.)
509 Madison Avenue Suite 404 New York, New York	10022
(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 pursuant to Item 405 of Regulation S-B is 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 $3,102,214.

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 September 16, 2004, was $223,271,190. The number of shares of common stock outstanding as of September 16, 2004 was 28,597,172.

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 ____

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

Bioenvision is an emerging biopharmaceutical company. Our primary business focus is the development and distribution of drugs to treat cancer. We have a broad range of products and technologies under development, but our two lead drugs are clofarabine and Modrenal(R).

We believe that our two lead products have the following competitive advantages over existing products at market:

Modrenal(R) (emerging endocrine resistance technology)

- Novel mode of action on estrogen receptors
- Increases estrogen binding to ER(beta) resulting in decreased cancer cell proliferation
- 35% overall clinical benefit rate in multi-center clinical trial: meta-analysis of 714 patients with advanced progressive post-menopausal breast cancer
- 55% clinical benefit rate in patients who have become resistant to tamoxifen therapy
- Phase II clinical trial commenced in prostate cancer in Q3 of calendar 2004
- Phase II pre-menopausal breast cancer trial commencing Q3 of calendar 2004

Clofarabine (purine nucleoside anti-metabolite technology)

- Next generation, halogenated-purine nucleoside analogue, designed to overcome the limitations and incorporate the best qualities of both fludarabine (Fludara(R)) and cladribine (Leustatin(R)).
- Multiple Mechanisms of Action:
  - Potent inhibition of DNA synthesis and repair (active in dividing cancer cells).
  - Induces apoptotic (cell death) pathway (active in non-dividing cancer cells).
- Potent ability to kill cancer cells in a wide range of cell lines, including leukemia, non-small cell lung, colon, melanoma, ovarian, renal,

- Phase II neo-adjuvent, pre-operative breast cancer study commencing Q3 of calendar 2004
- Phase IV post-menopausal breast cancer trial commencing Q3 of calendar 2004
- Mutual recognition filings to be made in large European markets by Q2 of calendar 2005
- Product reformulation to be completed by Q1 of calendar 2005

prostate, pancreatic and breast cancer lines.

- Significant clinical benefit demonstrated in both pediatric and adult leukemias:
  - Overall response rates in relapsed/refractory pediatric acute leukemias of between 26% and 31%.
  - Overall response rates in relapsed/refractory adult acute myeloid leukemia (AML) and chronic myeloid leukemia in blast crisis (CML-BP) of between 55% and 64%.
- Solid tumor studies initiated with both the oral and intravenous formulations of clofarabine.

Products and Technologies

PRODUCT PIPELINE

CANDIDATE	TARGET	INDICATION	STATUS	MARKETING RIG U.S.
Clofarabine	DNA, Mitochondria	Hematologic Cancers	Phase II completed or ongoing	ILEX(1)
	DNA, Mitochondria	Solid Tumors	Phase I (IV)	ILEX(1)
	DNA, Mitochondria	Solid tumors	Phase I (oral)	ILEX(1)
Modrenal(R)	Estrogen receptor beta	Breast Cancer	Phase IV,II	Bioenvision
		Prostate Cancer	Phase II	Bioenvision
Velostan	Cancer cell proliferation	Bladder cancer	Phase I	Bioenvision
Virostat	Viral replication	Hepatitis C, WNV	Phase II	Bioenvision
OLIGON	Antimicrobial	Catheter related sepsis	At Market	Bioenvision, Edwards(3)
Gene Therapy	Myosin enhancer	Hypoalbuminemia, liver failure		Bioenvision

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(1) ILEX Oncology, Inc. sub-licenses marketing rights in the U.S. and Canada in cancer indications only. Bioenvision maintains the clofarabine marketing rights in the U.S. and Canada for all other

disease indications, including autoimmune diseases.

(2) Bioenvision maintains an exclusive, irrevocable option to manufacture, market and distribute clofarabine in Japan and Southeast Asia in all indications and maintains the right to manufacture, market and distribute clofarabine in all other areas of the world outside of the U.S. and Canada.

(3) Bioenvision has licensed the marketing rights for certain vascular access catheters to Edwards Lifesciences.

Anti-Cancer Product Portfolio

Our anti-cancer product portfolio includes: three products, Modrenal(R) (trilostane), clofarabine and Velostan(R) (l-gossypol), which are used or which may have clinical utility in a wide variety of cancers; and one Gene Therapy technology platform, which may be useful in several indications.

Clofarabine

We have the exclusive right to manufacture, market and distribute clofarabine for all human applications in all areas of the world except Japan and Southeast Asia. We have an exclusive, irrevocable option to manufacture, market and distribute clofarabine in Japan and Southeast Asia. In the U.S. and Canadian cancer market, we sublicensed the right to manufacture, market and distribute clofarabine to ILEX Oncology, Inc. We maintain the right to manufacture, market and distribute clofarabine in the U.S. and Canada in all non-cancer indications, including auto-immune diseases, e.g. multiple sclerosis. We maintain our exclusive rights until the last to expire of the patents used or useful in our development and marketing efforts, which we expect to occur in March 2021.

Currently, a New Drug Application (NDA) has been filed with FDA for approval of clofarabine in the U.S. in pediatric acute leukemias. Further, we submitted a Common Technical Document, the European equivalent of a NDA, with European Medicines Evaluation Agency (EMEA) in July 2004 for European approval of clofarabine in pediatric acute leukemias. Because clofarabine received "fast track" designation by FDA, an FDA opinion is expected by the end of Q4 calendar 2004 or early January 2005. Further, we expect an opinion from the

EMEA by Q2 of calendar 2005. As indicated in the previous paragraph, ILEX has the rights to market clofarabine in the cancer market in the U.S. and Canada and we would receive a royalty on U.S. and Canadian annual net sales.

In Europe, we facilitated an Investigator Sponsored Trial (IST) of clofarabine, as first line therapy for older adult patients with Acute Myeloid Leukemia (AML). The IST was closed to recruitment in August 2004 ahead of schedule due to the studies' objective response rates having been exceeded. Building upon these results, the European, Pivotal Phase II study of clofarabine, as a first-line treatment for older adult patients, newly diagnosed with AML, has been initiated and we expect to complete the Pivotal Phase II trial by mid 2005.

Additionally, clofarabine is currently being evaluated in several Phase II clinical trials for a range of hematological cancers. Both the intravenous and oral formulations are also being evaluated in Phase I clinical trials for a

variety of solid tumors.

Clofarabine has received orphan drug status 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 August 2004, FDA granted a six-month extension of the marketing exclusivity for clofarabine in the pediatric acute leukemia indication (ALL and AML) as an incentive to increase therapeutic research in children.

ILEX is obligated to pay us royalties on U.S. and Canadian annual net sales of clofarabine on a sliding scale from 5.25% to 11.25%. The minimum royalty of 5.25% applies to annual net sales of up to $30 million per year and the maximum 11.25% royalty rate applies to annual net sales at or above $500 million per year. SRI receives royalties on the same scale of US and Canadian annual net sales from 3.5% to 7.5% from each of Bioenvision and ILEX. We pay royalties on our European annual net sales to each of SRI and ILEX in the amount of 3.5% to 7.5% on the same scale as applies to the ILEX royalty payment obligations noted above. ILEX also is responsible for 50% of our research and development costs associated with clofarabine development in the Territory (worldwide outside of Japan and Southeast Asia) other than the US and Canada. We are entitled to offset any royalties otherwise due to ILEX if ILEX fails to reimburse us for all of its 50% share of clofarabine research and development costs outside the U.S. and Canada.

Under the terms of the agreement with Southern Research Institute, we were granted the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology in all human applications for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by us and by Southern Research Institute from the technology. The current projected expiration date of the license is March 2021. Together with ILEX, we currently are developing clofarabine for the treatment of leukemia, lymphoma and solid tumors.

In August 2003, SRI granted us an irrevocable, exclusive option to make, use and sell 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.

In Q4 calendar 2003 and Q1 calendar 2004, we and ILEX jointly developed an oral formulation for clofarabine, the rights and related costs to which we share equally with ILEX. Clofarabine has demonstrated good oral bioavailability in clinical testing performed to date.

Pre-clinical and clinical testing of clofarabine demonstrated that the drug has anti-tumor activity against a range of human and animal cancers, including hematological malignancies and several solid tumors. Approximately 420 cancer patients have participated in clinical testing to date. Results from clinical studies indicate that clofarabine may be an effective treatment for relapsed acute leukemias in adult and pediatric patients, as well as acute leukemias in adult and pediatric patients that have become resistant, or refractory, to prior treatments. According to researchers at M.D. Anderson Cancer Center, interim Phase II study results showed that 45% of adults with acute myelogenous leukemia (AML) achieved a complete remission (CR) rate, and acute lymphocytic leukemia (ALL) patients achieved a 20% CR rate when treated with clofarabine as a single agent. Data from a separate Phase I dose-escalation study demonstrated a 25% CR rate, and an overall response rate of 40%, in children with acute leukemias who were refractory to previous therapy. Trials in pediatric acute leukemias are currently ongoing in the U.S. and in Europe.

Complete remission, in this context, means complete clearance of all leukemic cells from the blood and normalization of the blood count, sustained for a period of more than four weeks. In this context, a response, or partial response, has largely the same meaning, except that the bone marrow may still contain more than five percent but less than 25% blast cells (leukemic cells). CRp means, in this context, complete clearance of all leukemic cells from the blood in the absence of platelet recovery. In the U.S., Pivotal Phase II Clinical Trials were completed for the treatment of relapsed or refractory acute leukemia in children and a NDA was filed with the FDA in March 2004, based upon the results of 70 patients enrolled in these two trials. In August of 2004, clinical data on an additional cohort of 14 patients was submitted to the FDA and of the aggregate

ALL group (n=49), a 31% overall response rate was achieved (6 CRs, 4CRps and 5PRs) and of the aggregate AML group (n=35), a 26% overall response rate was achieved (1CRp and 8PRs).

Clofarabine appears to attack cancer cells in at least four ways:

(1) damaging DNA in cancer cells;

(2) preventing DNA repair by damaged cancer cells;

(3) damaging the cancer cell's important control structures--the mitochondria; and

(4) initiating the process of programmed cell death (apoptosis) in cancer cells.

Clofarabine combines many of the favorable properties of the two most commonly used nucleoside analog drugs, fludarabine(R) and cladribine(R), but has several-fold greater potency, when compared to fludarabine(R), at damaging the DNA of leukemia cells. Clofarabine appears to achieve this greater potency by a process of breaking DNA chains and inhibiting an important enzyme, ribonucleotide reductase. Clofarabine distinguishes itself from other drugs by its broader activity; in particular, the manner in which it damages the cells mitochondria and initiates the process of (apoptosis). (See Blood 2000; volume 96, page 3537).

Purine Nucleoside--Solid Tumor. In pre-clinical and Phase I clinical tests, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the colon, kidney and prostate, as well as its action against leukemic cells. This activity against solid tumors distinguishes clofarabine from other drugs in its class which have shown relatively little activity against solid tumors. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon and prostate cancer. The development strategy for clofarabine as a solid tumor agent will run in conjunction with the program for hematological cancers, but is expected to take longer to complete clinical trials and will require a different marketing approach. Currently, we anticipate the initial Phase I clinical trials for clofarabine in solid tumors will be completed by end of Q4 calendar 2004.

Cancer of the colon is one of the most common cancers in the Western world with approximately 200,000 new cases in the United States each year. Surgery is the most successful treatment for the primary tumor. Once the cancer has spread the results of chemotherapy are disappointing and long-term survival

figures have changed very little in the past 50 years. There is a great need for an effective chemotherapeutic agent to treat this disease, and a huge market potential exists for any drug that can induce tumor regression in patients with metastatic colon cancer. Prostate cancer affects 181,000 new patients in the United States each year. Initial treatment is directed at hormonal control of the disease, but in the event control is not achieved, chemotherapy usually is required. We intend to develop clofarabine, or a derivative of clofarabine, as a potential drug for the treatment of advanced colon and prostate cancer.

Modrenal(R)

We have the exclusive right to market and distribute Modrenal(R) (trilostane) throughout the world for all human applications. 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.

Modrenal(R) is currently at market in the United Kingdom for the treatment of women with advanced, post menopausal breast cancer who have relapsed on prior endocrine therapy. We currently have a small commercial team selling and marketing Modrenal(R) in the United Kingdom, and we record revenues accordingly. In the U.S., Modrenal(R) is in Phase II clinical studies in prostate cancer, and in Q4 calendar 2004, we intend to commence a Phase IV study in post-menopausal breast cancer, a Phase II study in pre-menopausal breast cancer and a neo-adjuvent, pre-operative breast cancer study, in each case, in the U.K. In Europe, in the large commercial markets outside of the U.K., we intend to file for mutual recognition for approval of Modrenal(R) on a country-by-country basis by Q2 of calendar 2005. Each such approval, if granted, would be based upon Modrenal's(R) approval in the U.K. for advanced post-menopausal breast cancer. The Company anticipates such approval would be granted within nine to twelve months following each such filing, but grant of such approval is entirely within the control of the individual regulatory authorities.

Modrenal(R) has been extensively studied in controlled trials in the United States, Europe and Australia, and almost 800 patients with breast cancer have been treated with Modrenal(R). Of these 800 patients, 87 of them

were given the drug in the United States as part of an FDA-approved trial. Its anti-tumor activity has been well documented and the drug has been shown to produce tumor response rates (i.e. arrest the growth of the tumor) of up to 55% in women with hormone-sensitive breast cancer. In a sub-set analysis of the clinical trial data, patients with hormone-sensitive breast cancer who had responded to one or more hormonal therapies were given Modrenal(R) upon relapse of the cancer. The response rate was above 40% in this group of patients. This compares very favorably to currently marketed aromatase inhibitors and other agents, such as herceptin, given as second line therapy. Furthermore, Modrenal(R) has an acceptable side-effect profile. On the basis of these data, Modrena(R)l was granted a product license in the United Kingdom for the treatment of post-menopausal breast cancer. Modrenal(R) is currently manufactured by third-party contractors in accordance with good manufacturing practices. We have no plans to establish our own manufacturing facility for Modrenal(R), but will continue to use third-party contractors.

Our marketing launch for Modrenal(R) occurred in May 2003 in the United Kingdom for use in the treatment of advanced post-menopausal breast cancer. We

also intend to seek regulatory approval for Modrenal(R) in the United States as salvage 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. The ongoing clinical trials in breast cancer with Modrenal target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as Tamoxifen(R) or any of the aromatase inhibitors. The results of 11 clinical trails to date, with a total of 783 patients tested, in the United States, Europe and Australia with Modrenal(R) show that it is at least as effective in second line or third line treatment of advanced breast cancer as the currently available hormonal treatments, such as the selective estrogen receptor modulators, or SERMs, and aromatase inhibitors. In the view of several clinicians and investigators familiar with Modrenal's(R) mode of action, Modrenal(R) is most effective in certain specific patient types, such as those who have become Tamoxifen(R)-refractory. The ongoing Phase II clinical trial of Modrenal in prostate cancer in the U.S. targets patients who have become androgen independent and have a rising PSA level.

Non-Cancer Product Portfolio

Our non-cancer product portfolio is as follows:

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 to 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.

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

Methylene Blue Technology

We have licensed from Oklahoma Medical Research Foundation the rights to use a range of thiazine dyes, the most well known of which is methylene blue, for the in vitro and in vivo inactivation of pathogens in biological fluids. Methylene blue, especially when irradiated by light, acts by preventing

replication of nucleic acid (DNA and RNA) in pathogens. Currently, we do not derive any revenues from its commercial use.

Blood transfusions are required to treat a variety of medical conditions and, to meet that need, over 90 million blood donations occur each year. Of these, approximately 39 million donations occur in North America, Western Europe and Japan. Methylene blue is currently used in several European countries to inactivate pathogens in fresh frozen plasma (FFP). We intend to work closely with international blood collection agencies to maximize the value of our intellectual property position.

Gene Therapy Technology

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

Cytostatic Technology

We have acquired a license to develop a distinct group of compounds that we believe could play an important role in controlling the rate of growth of cancer cells. In some cancers, such as cancer of the bladder and skin, drugs that stop cell growth (cytostatics) can be as effective as drugs that kill the cell by direct toxicity (cytotoxics). The cytostatic drugs we are developing are believed to work by blocking cell division and reversing the malignant process in the cancer cell. The first compound is a drug derived from a naturally grown plant, which has been widely tested for a variety of clinical indications. The results of this testing have been published in the medical literature. In particular, the drug has shown efficacy against certain cancers by, it is believed, preventing cell division and promoting cell differentiation. The isomer is more active and, we believe, less toxic, than the racemic compound, and the planned Phase I trial will be conducted with the optical isoform.

We plan to develop more potent analogs and to study their role in the process of cell differentiation and the prevention of the spread of cancer cells. The first compound derived from this technology is currently approved for a Phase I clinical trial at a leading United Kingdom cancer center.

Animal Health Products

We also have one animal health product, Veteryl(R), at market in the United Kingdom for the treatment of Cushing's disease in dogs. In November 2001, we granted to Arnolds Ltd., a major distributor of animal products in the United Kingdom, the right to market the drug for a six-month trial period, after which time, if the results were satisfactory to Arnolds, we would enter into a

licensing arrangement whereby Arnolds would pay royalties to us on sales from April 2002 onward. During the trial period, Arnolds posted more than $400,000 of sales of the drug. Arnolds has licensed the drug from us for sale in the United Kingdom market in consideration of a payment of a 5% royalty on sales. Separately, in May 2003, we granted to Dechra Pharmaceuticals, PLC, an affiliate of Arnolds Ltd., the exclusive right to market the drug in the United States for $5.5 million of total consideration (including milestone payments) and a royalty of 2%-4% of annual net sales.

Patents and Proprietary Rights

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

Through our current license agreements, we have acquired the right to utilize the technology covered by several issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. We evaluate the desirability of seeking patent or other forms of protection for our products in foreign markets based on the expected costs and relative benefits of

attaining this protection. There can be no assurance that any patents will be issued from any applications or that any issued patents will afford adequate protection to us. Further, there can be no assurance that any issued patents will not be challenged, invalidated, infringed or circumvented or that any rights granted thereunder will provide competitive advantages to us. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. There can be no assurance that patents now in existence or hereafter issued to others will not adversely affect the development or commercialization of our products or that our planned activities will not infringe patents owned by others.

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

We could incur substantial costs in defending ourselves in infringement suits brought against us or any of our licensors or in asserting any infringement claims that we may have against others. We could also incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors or distributors. An adverse outcome in any litigation could have a material adverse effect on our business and prospects. In addition, we could be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any of

these licenses would be made available on terms acceptable to us, or at all. If we are required to, and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more of our products.

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

It is our policy to require our employees, consultants, 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 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

We intend to establish strategic partnerships for the marketing, sales and distribution of our products in certain countries in Europe. As of the date of this annual report on Form 10-KSB, we have one such arrangement in place with Ilex for the co-development and marketing of one of our initial 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 United Kingdom and upon regulatory authorities' granting mutual recognition with which we intend to apply during calendar 2004 and 2005, throughout Europe. 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 will be to generate awareness of our products and target the two key audiences for our products - doctors and patients. Medical education will be 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. Patient education is particularly important because Modrenal(R), our first product for which we have obtained regulatory approval (in the United Kingdom) for marketing for use in a type of cancer treatment, is effective for patients with post-menopausal breast cancer, one of the most common cancers in women. In particular, the drug is approved as follow-on treatment for patients who have previously responded to hormonal therapy.

If the trials of trilostane in prostate cancer prove successful, we will have a drug for treating a cancer found in approximately 180,000 men each year in the United States. We will work with patient help organizations to inform the lay public through consumer journals and television.

Manufacturing

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

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 currently have three scientists currently working on a full-time basis who are involved in research and development activities. We have spent approximately $4,883,000 and $1,689,000 on research and development activities in 2004 and 2003, respectively.

Government Regulation

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

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

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

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

Pre-clinical tests include laboratory evaluation of the product, its

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

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

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

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

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

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

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

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application for approval

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

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

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

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

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

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

Competition

Product Development

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

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

Employees

As of June 30, 2004, we had nine full-time employees and four dedicated professionals, three of which are contracted to an academic institution. Of these, three are in management, two are in sales/marketing, four are in administration and four are in research and development. We believe our relationships with our employees are satisfactory.

Corporate History

We were incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed our name to Ascott Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998, at which time the Company merged with Bioenvision, Inc, a development stage Company primarily engaged in the research and development of products and technologies for the treatment of cancer.

On February 1, 2002, we completed the acquisition of Pathagon Inc., the successor in interest to Bridge Blood Technologies L.L.C., d/b/a Pathagon, a non-public company focused on the development of novel anti-infective products and technologies. Pathagon's principal products, OLIGON(R) and methylene blue, are ready for market. Affiliates of SCO Capital Partners LLC, formerly our financial advisor and consultant, owned 82% of Pathagon prior to the acquisition. We acquired 100% of the outstanding shares of Pathagon in exchange for 7,000,000 shares of our common stock. The acquisition has been accounted for as a purchase business combination in accordance with SFAS 141. With the acquisition, we added rights to OLIGON(R) and methylene blue to our product portfolio.

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.

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 September 16, 2004, our closing stock price has ranged from a high of $11.75 to a low of $3.00. 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.

Certain events could result in a dilution of your ownership of our common stock

As of June 30, 2004, we had 28,316,163 shares of common stock outstanding, 3,341,666 shares of Series A Convertible Preferred Stock outstanding which are currently convertible into 6,683,332 shares of common stock and common stock equivalents, including warrants and stock options, convertible or exercisable into 13,674,242 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from $0.74 to $8.25 per share. We have also reserved for issuance an aggregate of 3,000,000 shares of common stock for a stock option plan for our employees. Historically, from time to time, we have awarded our common stock to officers of the Company, in lieu of cash compensation, although we do not expect to do so in the future.

As of June 30, 2004, (i) we have 37,750,699 shares of common stock registered under the Securities Act on Form SB-2 and (ii) 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 and shares underlying stock options and warrants 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.

The provisions of our charter and Delaware law may inhibit potential acquisition bids that stockholders may believe are desirable, and the market price of our common stock may be lower as a result

Section 203 of the Delaware corporate statute

We are subject to the anti-takeover provisions of Section 203 of the Delaware corporate statute, which regulates corporate acquisitions. Section 203 may affect the ability of an "interested stockholder" to engage in certain business combinations, including mergers, consolidation or acquisitions of additional shares, for a period of three years following the time that the stockholder becomes an "interested stockholder". An "interested stockholder" is defined to include persons owning directly or indirectly 15% or more of the outstanding voting stock of a corporation. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock. As a result, these provisions may prevent our stock price from increasing substantially in response to actual or rumored takeover attempts. These provisions may also prevent changes in our management.

Issuance of Preferred Stock Without Common Stockholder Approval.

Our charter authorizes our board of director to increase the number of shares of preferred stock we may issue without approval of common stockholders. Preferred stock may be issued in one or more series, the terms of which may be determined without further action by common stockholders. These terms may include preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends, qualifications or terms or conditions of redemption. The issuance of any preferred stock could materially adversely affect the rights of holders of our common stock, and therefore could reduce its value. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The power of the board of directors to issue preferred stock could make it more difficult, delay, discourage, prevent or make it more costly to acquire or effect a change in control, thereby preserving the current stockholders' control.

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

Since our inception, 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 no relevant operating history upon which an evaluation of our performance and prospects can be made.

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

To date, we have incurred significant net losses, including net losses of approximately $11,574,000 for the fiscal year ended June 30, 2004. At June 30, 2004, we had an accumulated deficit of approximately $41,082,000. 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 will be expensive and may be time consuming, and their outcome is uncertain, but we must incur substantial expenses that may not result in viable products

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

Historically, the results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. 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. Clofarabine currently is at a pivotal stage of its development, but many of our other products and technologies are at various less mature stages of development including l-gossypol for which we have just commenced a Phase I clinical trial in the U.K. and gene therapy which is currently in pre-clinical and phase I clinical testing.

Completion of clinical trials for any product may take several years or more. 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.

If our development agreement with ILEX does not proceed as planned we may incur delay in the commercialization of clofarabine, which would delay our ability to generate sales and cash flow from the sale of Clofarabine

ILEX, and any third party to which ILEX may grant a sublicense or in any way transfer its obligations, has primary responsibility for conducting clinical trials and administering regulatory compliance and approval matters in the United States and Canada pursuant to the terms of our co-development agreement with ILEX. While there are target dates for completion, that agreement allows ILEX time to continue working beyond those dates under certain circumstances. For example, under the co-development agreement, ILEX 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 ILEX receives more time to complete the pivotal trials if the trials are ongoing at December 31, 2002 and progressing to completion within a reasonable time thereafter. Further, ILEX was required under the co-development agreement to have filed a New Drug Application by August 31, 2003, subject to extension if ILEX continues to use its reasonable efforts to promptly complete the filing after August 31, 2003. ILEX continued to use its reasonable efforts to complete the filing after August 31, 2003 and in October 2003, Ilex filed the first part of a "rolling NDA" with the FDA.

If ILEX 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 ILEX 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 ILEX. 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 ILEX or there are certain other breaches of the co-development agreement by ILEX, 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 ILEX Oncology, our U.S. co-development partner, but on February 26, 2004, Genzyme announced a merger pursuant to which Genzyme intends to acquire

ILEX in a merger transaction. If this transaction is consummated, 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. 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 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 Mass 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 resource 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 and state statutes and governmental agencies in the United States 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 United States 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 United States. 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 United States. 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 United States 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 United States 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, they may be able to develop products before us or develop more effective products or market them more effectively which would limit our ability to generate revenue and cash flow

Competition in our industry is intense. Potential competitors in the United States and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital

resources, marketing experience, research and development staffs and facilities than us. Potential competitors for certain indications of our lead drugs include, with respect to clofarabine, Schering AG, which markets fludarabine, and certain generic drug companies in Europe which could market fludarabine upon expiry of the patent protections held by Schering. Potential competitors with respect to Modrenal(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 fail to keep up with rapid technological change and evolving therapies, our technologies and products could become less competitive or obsolete

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 depend on others to manufacture our products and have not manufactured them in significant quantities

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 United States, 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 or be successful in gaining market acceptance for proprietary products or for other products. We currently have very limited sales and marketing capabilities. We currently employ one full-time sales employee and one full-time marketing employee. 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.

If we lose key management our business will suffer

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

Need for additional personnel

The Company 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 the Company's activities, and there can be no assurance that the Company will be able to attract and retain the qualified personnel necessary for the development of its business. The Company faces

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 the Company's 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 United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. 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 United States and foreign countries. Thus, we and our licensors 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 United States or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from Southern Research Institute. The current projected expiration date of the license is March 2021. These patents cover pharmaceutical compositions and methods of using clofarabine. We cannot guarantee that these patents would survive an attack on their validity or that they will provide a competitive advantage over our competitors. Moreover, we cannot guarantee that Southern Research Institute was the first to invent the subject matter of these patents. In addition, we are aware of a third party patent which is directed to the treatment of chronic myeloid leukemia ("CML") using specific doses of clofarabine. We do not believe that we will infringe this 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. And, 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.

Because we have international operations, we will be subject to risks of conducting 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 United States. 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, Cancer Research Organizations and other service providers become more expensive to us. No assurance can be given that the U.S. dollar will not continue to weaken which could have a material adverse effect on the costs associated with our drug development activities.

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

We consummated a private placement transaction on March 22, 2004, 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 consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Convertible Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional $3.5 million in the second trance 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. 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 mid- 2005. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders would result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or accounting methods, even though these

actions would otherwise benefit our business. As of June 30, 2004, we had stockholders' equity of approximately $27,383,000 and net working capital of approximately $18,828,000.

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.

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 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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 3,229 square feet of office space at our principal executive offices at 509 Madison Avenue, Suite 404, New York, New York 10022 for approximately $13,000 per month. These facilities are the center for all of our administrative functions in the United States. Also, we rent on a month-to-month basis approximately 1,000 square feet of office space in Edinburgh, Scotland for approximately $5,000 per month. To date, most of our drug development programs have been conducted at scientific institutions around the world. It is our policy to continue development at leading scientific institutions in the United States and Europe. We do not plan to conduct laboratory research in any of our facilities in the near future, rather, we will conduct research through collaborative arrangements with Southern Research Institute, M.D. Anderson and others.

Investment Policies

We do not currently have any investments in real estate or interests in real estate; investments or interests in real estate mortgages or in the securities of or interests in persons primarily engaged in real estate. We generally acquire our assets for the purpose of ultimately producing sales revenues from the exploitation of such assets in the development of our biopharmaceutical business. We currently invest our surplus cash in interest-bearing deposit accounts and short-term certificates of deposit.

Item 3. Legal Proceedings

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

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

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

The following represents the range of reported high and low bid sales prices for our common stock on a quarterly basis since July 1, 2002 as reported on the OTC Bulletin Board and the American Stock Exchange. Throughout this period and up to September 5, 2003, our trading symbol was "BIOV". Our trading symbol was changed to "BIV" on September 8, 2003 upon commencement of listing our shares of common stock on the American Stock Exchange. Our symbol was changed again to "BIVN" on August 20, 2004 upon commencement of listing our shares of common stock on the NASDAQ Stock Market. The quotations also reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

	High	Low
Fiscal Year Ended June 30, 2003		
First Quarter	$2.55	$1.35
Second Quarter	$2.25	$1.10
Third Quarter	$1.55	$0.39
Fourth Quarter	$2.89	$0.77
Fiscal Year Ended June 30, 2004		

First Quarter	$4.97	$1.70
Second Quarter	$5.10	$3.35
Third Quarter	$10.01	$4.09
Fourth Quarter	$12.00	$8.25

Holders

On June 30, 2004, we had 189 stockholders of record.

Dividends

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. 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. However, the Company is required to accrue for and pay a dividend of 5% in April, July, October and January, subject to certain circumstances and adjustments, on its cumulative Series A Convertible Preferred Stock. We have paid these accrued dividends on our cumulative Series A Convertible Preferred Stock in cash through July 30, 2004.

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, 2004:

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)	Numb avai un pla re
Equity compensation plans approved by security holders	2,105,000	$2.57	
Equity compensation plans not approved by security holders	5,328,624	$1.55	
Total	7,433,624	--	

Equity Compensation Plans 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 3,000,000 shares reserved for grants of options under the plan and at June 30, 2004, 2,105,000 of these options had been issued.

Equity Compensation Plans Not Approved by Security Holders.

The 5,328,624 securities to be issued upon exercise of options and warrants consist of warrants and options issued to the co-founders, early round investors and certain former consultants and advisors for services rendered to or on behalf of us.

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 Significant Accounting Policies

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

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

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

Stock Based Compensation - In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation, we apply Accounting Principles Board Opinion 25 and

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

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

Overview

We are an emerging biopharmaceutical company that develops and markets drugs to treat cancer. Our two lead drugs are clofarabine and Modrenal(R), although we have several other products and technologies under development. As of June 30, 2004, our internal staff consisted of nine full-time and four part-time employees based in New York, New York and Edinburgh, Scotland.

Our primary business strategy relates to our two lead drugs, clofarabine and Modrenal(R). With clofarabine, our strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory authorities to market and distribute clofarabine for the treatment of pediatric and adult acute leukemias (ALL and AML). We anticipate launching clofarabine in Europe in mid-2005, subject to our obtaining the approval of the regulatory authorities. We will continue clinical trials in other indications with the intention of

aggressively seeking label extensions after clofarabine's first approval, including our Pivotal Phase II trial of clofarabine in adults with Acute Myeloid Leukemia (AML) which commenced in August 2004 and is ongoing. Following this strategy, throughout the world, approximately two-thirds of the cancer patients dosed with clofarabine to date fall outside of the pediatric acute leukemias, which we expect to be the indication first approved by the U.S. and European regulatory authorities.

With Modrenal(R), our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to market and distribute Modrenal(R) in the major European markets. We anticipate receiving mutual recognition from major European Community member states by Q3 of calendar 2005. We intend to further U.S. development of Modrenal(R) in prostate and breast cancer indications, subject to the ongoing results of our clinical trials we are currently conducting in the U.S. and Europe.

Our secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from clofarabine and Modrenal(R) and milestone payments and royalties from the ancillary products will permit us to further develop our portfolio of ancillary

products and technologies.

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.

Clofarabine is a small molecule, purine nucleoside analogue, which we believe is effective in the treatment of leukemia, based upon our own clinical studies and studies conducted by others on our behalf. Clofarabine may also be an effective agent to treat patients with solid tumors, based on preclinical studies and Phase I clinical trials performed to date.

In July 2004, we filed for approval of clofarabine in Europe to treat children with pediatric acute leukemia (ALL and AML). Further, we are conducting a Pivotal Phase II clinical trial of clofarabine, as first line therapy for the treatment of adults with Acute Myeloid Leukemia (AML). Also in Europe, at our direction, an Investigator Sponsored Trial of clofarabine as first-line therapy for adults with AML was completed ahead of schedule and an interim analysis indicates a 64% complete response rate observed in this patient population.

In the U.S., ILEX Oncology, Inc., our sub-licensor of U.S. and Canadian cancer marketing rights, filed a New Drug Application (NDA) in March 2004 for approval of clofarabine to treat children with acute leukemias (ALL or AML). The NDA was based upon results of two Pivotal Phase II clinical trials completed by ILEX prior to the NDA filing. In connection with the NDA, the United States Food and Drug Administration (the " FDA" has set a Prescription Drug User Fee Act (PDUFA) response date at December 30, 2004.

In January, 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for clofarabine, upon grant of marketing authorization. The drug has also been granted orphan drug status and "fast track" treatment by the FDA. Further, in July 2004, the FDA granted six months of extended market exclusivity to clofarabine under the Best Pharmaceuticals for Children Act.

In August 2003, we obtained the exclusive, irrevocable option to sell, market and distribute clofarabine in Japan and Southeast Asia from the inventor of clofarabine. These rights were not previously granted by Southern Research Institute and fall outside the scope of the Company's then current licensing and development contracts with respect to clofarabine. We originally obtained an exclusive license from Southern Research Institute to sell, market and distribute clofarabine throughout the world, except for Japan and Southeast Asia, for all human applications, pursuant to a co-development agreement, dated August 31, 1998, between the Company and Southern Research Institute. On March 12, 2001, we granted an exclusive option to sell, market and distribute clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute clofarabine for cancer indications in the U.S.

Modrenal(R) is a hormonal agent with a novel mode of action that makes it an effective agent in patients with advanced breast cancer who have acquired resistance to other hormonal agents. We launched Modrenal(R) in May 2003 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. In Q2 2005, we intend to apply for mutual recognition in another four large European

territories in an effort to gain approval for Modrenal(R) in each such territory. We anticipate receiving approval in each such territory during calendar 2005, but such approval is subject to the appropriate regulatory decisions.

In the U.S., we filed an IND to conduct Modrenal(R) clinical trials for prostate cancer in February 2004 and commenced enrolling patients in this clinical trial in July 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies.

We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.

Company Status

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

We anticipate that revenues derived from the two lead drugs will permit us to further develop the other products currently in our product pipeline. We anticipate the launch of clofarabine in Europe by mid-2005 and further anticipate reaching profitability within 12 months following the marketing launch for clofarabine in Europe.

We commenced marketing one of our lead products, Modrenal(R), in June 2003 and anticipate building out our internal infrastructure of sales and marketing professionals to sell Modrenal(R) and to conduct pre-marketing activities for clofarabine in Europe. Management believes it can create synergies through internal growth by developing a sales and marketing presence which will be in position to sell both lead drugs at lead European cancer centers across a broad range of cancer indications.

Further, we intend to continue developing our existing platform technologies with a primary business focus on drugs to treat cancer, and commercializing products derived from such technologies. As a result of the acquisition of Pathagon Inc. in February 2002, we have several anti-infective technologies. These include the OLIGON(R) technology, an advanced biomaterial that has been approved for certain indications by the FDA in the U.S., and is being sold by a product co-development partner, and the use of thiazine dyes, such as methylene blue, which are used for in vitro and in vivo inactivation of pathogens (viruses, bacteria and fungus) in biological fluids. It is not the Company's strategy to sell devices or to expand into the anti-infective market per se, but the technology obtained in the Pathagon acquisition has specific application for support of the cancer patient and oncology treatment. We have had discussions with potential product co-development partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans. In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. In May 2003, we entered into a License and Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed the marketing and development rights

to vetoryl(R) trilostane, solely with respect to animal health applications, in the United States and Canada, to Dechra. We received $1.25 million in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try and exploit these types of opportunities as they arise.

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;
- respond to industry and competitive developments; and
- attract, retain, and motivate qualified personnel.

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

Results of Operations

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, 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.

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

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

The clinical trials and development strategy for the clofarabine and Modrenal(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 $5.6 million; (ii) Modrenal(R) research and development costs have been approximately $4.4 million; (iii) Gossypol research and development costs have been approximately $302,000; and (iv) Gene Therapy research and development costs have been approximately $450,000. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these research and

development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, clofarabine and Modrenal(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.

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

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

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

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

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

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

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

The clinical trials and development strategy for the clofarabine and Modrenal(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. Estimated total costs to date for each of these four projects is as follows: (i) clofarabine research and development costs have been approximately $3.0 million; (ii) Modrenal(R) research and development costs have been approximately $2.35 million; (iii) Gossypol research and development costs have been approximately $150,000; and (iv) Gene Therapy research and development costs have been approximately $450,000. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these

research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, clofarabine and Modrenal(R), over the next two years.

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

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

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

Liquidity and Capital Resources

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

The Company received a nonrefundable upfront payment of $1.35 million when it entered into the co-development agreement with ILEX and received an additional $3.5 million in December 2003 when it converted ILEX's option to market clofarabine in the U.S. into a sublicense. The Company received an additional $2 million in April 2004 upon ILEX's filing the New Drug Application for clofarabine with FDA and the Company expects to receive an additional $2 million from ILEX in October 2004 in connection with ILEX having completed such NDA filing. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related service period, through March 2021. For the years ended June 30, 2004 and 2003, respectively, the Company recognized revenues of approximately $161,000 and $370,000 in connection with the upfront and milestone payments received to date.

Deferred costs included royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with ILEX. The Company defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis, concurrent with revenue that is recognized in

connection with the ILEX agreement. Research and Development costs include approximately $81,000 and $207,000 for the years ended June 30, 2004 and 2003, respectively, related to such charges.

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

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Stegram in May 2003. The Company defers all royalty payments made to Stegram and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with the Dechra agreement. Research and Development costs include approximately $23,000 and $2,000 for the years ended June 30, 2004 and 2003, respectively.

On May 7, 2002 we authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Preferred Stock. The Series A Convertible Preferred Stock may be converted into shares of common stock at an

initial conversion price of $1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A Convertible Preferred Stock also received, in respect of each share of Series A Convertible Preferred Stock purchased in a private placement which took place in May 2002, one warrant to purchase one share of our common stock at an initial exercise price of $2.00 subject to adjustment.

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

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

On June 30, 2004, we have cash and cash equivalents of approximately $19,166,000 and working capital of $18,828,000 which management believes will be sufficient to continue currently planned operations over the next 12 months. We can not ensure additional funds will not be raised during the next twelve months

because of the significant scale up of our operating activities, including clofarabine development and the launch of Modrenal(R). However, if required or desirable, there can be no assurance that suitable debt or equity financing will be available for the Company. Further, although we do not currently plan to acquire or obtain licenses for new technologies, if any such opportunity arises and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

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

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

	Payments Due in			
	Total	2005	2006	2
Employee Contracts	474,539	474,539	-	
Occupancy Lease and Automobiles	278,673	205,569	62,919	10
Total	753,212	680,108	62,919	10

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

Plan of Operation

We are an emerging biopharmaceutical company with a primary business focus on the development and distribution of drugs to treat cancer. We intend to seek approval for clofarabine as a treatment for relapsed or refractory acute leukemia in children and, subsequently, as first-line therapy for adults with Acute Myeloid Leukemia (AML). Further Phase I Clinical Trials are ongoing testing clofarabine in solid tumors and chronic leukemia and we intend to aggressively pursue label extensions in these and other areas from and after the date we receive the first license to market clofarabine.

Further, we intend to seek approval of Modrenal(R) in the largest European countries and commence marketing this drug outside of the U.K. where it is approved for treatment of advanced post-menopausal breast

cancer and to complete Phase II trials in the U.S. for prostate cancer and Phase II and IV pre-menopausal and post-menopausal breast cancer trials in the U.K. We expect our third product, gossypol, to enter Phase I Clinical Trials in the U.K. in Q4 of calendar 2004.

Our secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from clofarabine and Modrenal(R) will permit us to further develop our portfolio of

ancillary products and technologies.

Once a product is launched into the market for a particular disease indication, we plan to work with numerous collaborators, both pharmaceutical and clinical, in the oncology community to extend the permitted uses of the product to other indications. In order to market our products effectively, we intend to develop marketing alliances with strategic partners and may co-promote and/or co-market in certain territories.

We plan to continue to use a major portion of the proceeds of the March and May 2004 private placement to complete our currently conducted clinical trials for clofarabine and Modrenal(R) described above and to initiate new clinical trials for our lead drugs in Europe. Further, over the next 12 months, we intend to use such proceeds, in part, 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 plan to identify licensing partners for OLIGON(R) and to continue developing new aspects of the technology. We also plan to continue development of methylene blue and other products in our pipeline.

With respect to our gene therapy technology, we have completed laboratory research which confirms proof of principal of our gene therapy technology and has added to the pre-clinical data which will be important for any subsequent regulatory submission. This laboratory research was required to allow the Company and the research departments of the relevant universities assisting with this technology to file patents for which the Company has licensing rights. We now plan to perform additional clinical trials with the two lead products related to this technology.

Recent Accounting Pronouncements

On December 31, 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation Transition and Disclosure" ("SFAS 148"). SFAS 148 amends FASB Statement No. 123, "Accounting for Stock Based Compensation," to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure provisions of SFAS 123 and APB Opinion No. 28, "Interim Financial Reporting," to require disclosure on the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. While SFAS 148 does not amend SFAS 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS 148 are applicable to all companies with stock-based employee compensation, regardless of whether they account for the compensation using the fair value method of SFAS 123 or the intrinsic value method of APB Opinion 25. The Company adopted the required disclosure provisions of SFAS 148 as described under accounting policy footnote, "Stock Based Compensation."

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

collaborative research and/or license agreements.

Subsequent Events

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

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

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

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

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

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

None.

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, 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.

In connection with its review of the Company's consolidated financial statements for and as of the three month period ended March 31, 2004, Grant Thornton LLP ("Grant Thornton"), the Company's independent accountants, advised the Audit Committee and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness, 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. Grant Thornton indicated that they considered these deficiencies to be a material weakness as that term is defined under standards established by the American Institute of Certified Public Accountants. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes our internal control from reducing to an appropriately low level the risk that material misstatements in our financial statements will not be prevented or detected on a timely basis. The Company considered these matters in connection with the quarter end closing of accounts and preparation of related quarterly financial statements at and as of March 31, 2004 and determined that no prior period financial statements were materially affected by such matters.

In response to the observations made by Grant Thornton, the Company will proceed more expeditiously with its existing plan to enhance the Company's internal controls and procedures, which it believes addresses each of the matters raised by Grant Thornton.

Changes in Internal Controls

We enhanced our internal control procedures in March 2004 by adding a full-time dedicated accountant with more than seven years work experience to the staff in our principal executive offices in New York, New York. Our accountant works directly for our outsourced accounting firm which assists us in the preparation and finalization of our accounts on an ongoing basis. Her responsibilities include preparation of the Company's

financial statements on a quarterly and annual basis and preparation of budget-to-actual analyses on a quarterly basis. Our management intends to expand her responsibilities on our behalf to include preparation of monthly financial statements and monthly and annual budget-to-actual analyses. We believe the addition of this dedicated resource will further enhance the Company's internal control over financial reporting in the near term, which management will continue to monitor on a regular basis.

In June 2004, we hired a new employee to serve as our Vice President, Corporate Compliance and Associate General Counsel. This new employee has five years of corporate law experience with a full-service internationally based law firm in the office located in New York, New York. She has represented several public companies and is knowledgeable with respect to contract law, the requirements under the Sarbanes-Oxley Act and other areas of public disclosure. We intend to continue to streamline the responsibilities of our Chief Financial Officer and General Counsel to permit him to focus more of his time and effort, as needed, on the accounting and financial reporting needs of the Company.

Further, in July 2004, the Company adopted, and management implemented, a comprehensive set if internal accounting controls, which were approved by the audit committee.

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 2004 Annual Meeting of Stockholders.

Item 13. Exhibits and Reports on Form 10-KSB

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)
14.1	Bioenvision Inc.'s Code of Business Conduct and Ethics
16.1	Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
16.2	Letter from Ernst & Young LLP to the Securities and Exchange

	Commission, dated July 6, 2001. (10)
16.3	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
21.1	Subsidiaries of the registrant (4)
23.1	Consent Of 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.

(b) Reports on Form 8-K. No Current Reports on Form 8-K were filed by the registrant during the last quarter of the period covered by this report.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

/s/ Grant Thornton LLP

GRANT THORNTON LLP
New York, New York
September 16, 2004

Bioenvision, Inc. and Subsidiaries
CONSOLIDATED BALANCE SHEETS

	June 30, 2004
ASSETS	

Current assets	
Cash and cash equivalents	$ 18,875,675
Restricted cash	290,000
Deferred costs - current	241,824
Accounts receivable	2,627,773
Other assets	253,311
Total current assets	22,288,583
Property and equipment, net	47,857
Deferred costs - long term	3,651,471
Intangible assets, net	14,563,660
Goodwill	3,902,705
Security deposits	79,111
Other long term assets	-
Total assets	$ 44,533,387
LIABILITIES AND STOCKHOLDERS' EQUITY	
Current liabilities	
Accounts payable	$ 1,495,866
Accrued expenses	1,322,584
Accrued dividends payable	90,141
Deferred revenue - current	551,828
Total current liabilities	3,460,419
Deferred revenue - long term	7,909,598
Deferred tax liability - non-current	5,780,799
Total liabilities	17,150,816
Stockholders' equity	
Preferred stock - $0.001 par value; 20,000,000 and 5,920,000 shares authorized and 3,341,666 and 5,916,666 shares issued and outstanding at June 30, 2004 and June 30, 2003, respectively (liquidation preference $10,024,998 and $17,749,998 at June 30, 2004 and June 30, 2003, respectively)	3,342
Common stock - $0.001 par value; 70,000,000 and 50,000,000 shares authorized and 28,316,163 and 17,122,739 shares issued and outstanding at June 30, 2004 and June 30, 2003, respectively	28,316
Additional paid-in capital	68,517,702
Deferred compensation	(223,990)
Accumulated deficit	(41,082,397)
Accumulated other comprehensive income	139,598
Stockholders' equity	27,382,571
Total liabilities and stockholders' equity	$ 44,533,387

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

F-2

Bioenvision, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF OPERATIONS

	2004
License and royalty revenue	$ 1,187,212
Research and development contract revenue	1,915,002
Total revenue	3,102,214
Costs and expenses	
Research and development	4,882,574
Selling, general and administrative (includes stock based compensation expense of $3,491,252 and $1,812,894 for the twelve months ended June 30, 2004 and 2003, respectively.)	9,082,420
Depreciation and amortization	1,348,064
Total costs and expenses	15,313,058
Loss from operations	(12,210,844)
Interest income (expense)	
Interest and finance charges	-
Interest income	99,763
Net loss before income tax benefit	(12,111,081)
Income tax benefit	536,903
Net loss	(11,574,178)
Cumulative preferred stock dividend	(856,776)
Net loss available to common stockholders	$(12,430,954)
Basic and diluted net loss per share of common stock	$ (0.61)
Weighted-average shares used in computing basic and diluted net loss per share	20,257,482

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

Bioenvision, Inc. and Subsidiaries
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Preferred Stock		Common Stock		Additional Paid In
	Shares	$	Shares	$	Capital
Balance at June 30, 2002	5,916,666	$5,917	16,887,786	$16,888	$45,491,554
Net loss for the year					
Cumulative preferred stock dividend					
Shares issued to consultants for services			234,953	235	1,258,080
Warrants issued in connection with services					182,350
Repricing of options					372,465
Balance at June 30, 2003	5,916,666	5,917	17,122,739	17,123	47,304,449
Net loss for the year					
Cumulative preferred stock dividend					
Currency translation adjustment					
Deferred compensation					
Shares issued in connection with private placement			2,602,898	2,603	16,265,495
Costs related to private placement					(1,301,035)
Preferred stock converted to common stock	(2,575,000)	(2,575)	5,150,000	5,150	(2,575)
Expense related to repricing of options					2,381,066
Cashless exercises 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	2,509,88
Balance at June 30, 2004	$3,341,666	$3,342	28,316,163	$28,316	$68,517,702

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

	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
Balance at June 30, 2002	$(21,027,299)	$152,346	$24,639,405
Net loss for the year	(6,746,326)		(6,746,326)
Cumulative preferred stock dividend	(877,818)		(877,818)
Shares issued to consultants for services			1,258,080
Warrants issued in connection with services			182,350
Repricing of options			372,465
Balance at June 30, 2003	(28,651,443)	152,346	18,828,392
Net loss for the year	(11,574,178)		(11,574,178)
Cumulative preferred stock dividend	(856,776)		(856,776)
Currency translation adjustment		(12,748)	(12,748)
Deferred compensation			(223,990)
Shares issued in connection with private placement			16,268,098
Costs related to private placement			(1,301,035)
Preferred stock converted to common stock			
Expense related to repricing of options			2,381,066
Cashless exercises of options to shares			

Warrants issued in connection with services			671,601
Shares issued to consultants for services			305,987
Shares issued to employee			28,400
Options issued in connection with services			93,987
Options issued to employees			262,601
Shares issued from warrant conversions			2,511,166
Balance at June 30, 2004	$(41,082,397)	$139,598	$27,382,571

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

Bioenvision, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF CASH FLOWS

	2004
Cash flows from operating activities	
Net loss	$(11,574,178)
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	1,348,064
Deferred tax benefit	(536,903)
Compensation costs-shares and warrants issued to non-employees	1,071,575
Compensation costs-re-pricing of options	2,381,066
Compensation costs-options issued to employees	38,611
Changes in assets and liabilities	
Deferred costs	(3,645,631)
Deferred revenue	7,223,105
Accounts payable	1,084,474
Other current assets	(147,335)
Other long term assets	126,870
Accounts receivable	(2,602,773)
Security deposits	
Other accrued expenses and liabilities	591,862
Net cash used in operating activities	(4,641,193)

Cash flows from investing activities	
Purchase of intangible assets	(112,580)
Capital expenditures	(18,337)
Restricted cash	-
Net cash used in investing activities	(130,917)
Cash flows from financing activities	
Proceeds from issuance of common stock	14,967,064
Proceeds from exercise of options, warrants and other convertible securities	2,539,565
Cash dividend paid	(1,775,782)
Net cash provided by financing activities	15,730,847
Effect of exchange rate on cash	(12,748)
Net increase (decrease) in cash and cash equivalents	10,945,989
Cash and cash equivalents, beginning of year	7,929,686
Cash and cash equivalents, end of year	$ 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, 2004 AND 2003

Note 1 - Organization and significant accounting policies

Description of business

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

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

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

Basis of presentation

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

Principles of consolidation

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

Use of estimates

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

Note 1 - Organization and significant accounting policies - continued

Revenue Recognition

In accordance with SEC Staff Accounting Bulletin No. 104, upfront nonrefundable fees associated with research and development collaboration agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the estimated research and development period using the straight-line method. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis using the straight-line method. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved. Continuation of certain contracts and grants

are dependent upon the Company and/or its co-development partners' achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project.

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

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

Research and development

Research and development costs are charged to expense as incurred.

Stock based compensation

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

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force no. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services," as amended by EITF 00-27. Under EITF No. 96-18, where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument. The Company expects to continue applying the provisions of APB 25 for equity issuances to employees.

Note 1 - Organization and significant accounting policies - continued

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

	Year Ended June 30,	
	2004	2003
Net loss available to common stockholders, as reported	$(12,430,954)	$(7,62
Add: Stock based employee compensation expense included in reported net loss, net of tax effects	2,419,677	37
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(449,936)	(1,21
Pro forma net loss available to common stockholders	$(10,461,213)	$(8,46
Loss per share		
Basic and diluted - as reported	$(0.61)	$(0.
Basic and diluted - pro forma	$(0.52)	$(0.

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

	2004	2003
Expected average life (years)	4.00	4.00
Risk free interest rate	3.00%	3.00%
Expected volatility	80%	80%
Expected dividend yield	0.00	0.00

Income taxes

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

Net loss per share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options and warrants to purchase 13,674,242 and 15,749,543 shares of common stock have not been included in the

calculation of net loss per share for the years ended June 30, 2004 and 2003, respectively, as their effect would have been anti-dilutive.

Note 1 - Organization and significant accounting policies - continued

Foreign currency translation

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

Cash and cash equivalents

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

Accounts Receivable

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

Advertising costs

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

Deferred costs

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

Property and equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Property and equipment are depreciated on a straight-line basis

over their estimated useful lives, which range from 3 to 7 years.

Fair Value of Financial Instruments

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

Note 1 - Organization and significant accounting policies - continued

Goodwill and Other Intangible Assets

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

Long-Lived Assets

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

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

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2004 AND 2003

NOTE 2 - Acquisition of Pathagon

On February 1, 2002, the Company completed the acquisition of Pathagon. The acquisition was accounted for as a purchase business combination in accordance with SFAS 141. The Company issued 7,000,000 shares of common stock to complete the acquisition, which was valued at $12,600,000 based on the 5-day average trading price of the stock ($1.80) surrounding November 22, 2001, the day of the Company's announcement of the agreed upon acquisition. The acquired patents and licensing rights of OLIGON(R) and methylene blue (collectively referred to as "Purchased Technologies"), were recorded at their fair market value which was approximately $17,576,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of these assets. Since the estimated fair value of the Purchased Technologies was at least equal to the amount paid, the purchase price, net of assumed liabilities, was allocated to Purchased Technologies. The transaction qualified as a tax-free merger which resulted in a difference between the tax basis value of the assets acquired and the fair market value of the patents and licensing rights. As a result, a deferred tax liability was recorded for approximately $7,909,000. The purchase price exceeded the fair market value of the net assets acquired resulting in the recording of Goodwill of $4,704,100. The Company recorded a charge to goodwill of $801,395 for fiscal year ended June 30, 2003 as a result of a change in tax rates used to compute the deferred tax liability arising as a result of this acquisition. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro-forma financials would not be meaningful and thus are not presented.

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

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

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

On May 7, 2002, the Company executed an amendment to the original license agreement between Oklahoma Medical Research Foundation ("OMRF") and Bridge Therapeutic Products, Inc. ("BTP"), a predecessor of Pathagon, relating to the licensing of methylene blue. Under the terms of the amendment, OMRF agreed to

the assignment of the original license agreement by BTP to Pathagon. Pursuant to the amendment, the Company paid OMRF $100,000 and issued 200,000 shares of the Company's common stock and a five-year warrant to purchase an additional 200,000 shares of common stock. The exercise price of the warrant is $2.33 per share, subject to adjustment. The Company capitalized the costs of approximately $1,145,600 related to this amendment as an intangible asset and will amortize this asset over the remaining life of the methylene blue license agreement.

NOTE 3 - Intangible Assets

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

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

NOTE 4 - License and Co-Development Agreements

Clofarabine

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

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

To facilitate the development of clofarabine, we entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX") in March 2001. Under the terms of the co-development agreement, ILEX is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia). ILEX is

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

Note 4 - License and Co-Development Agreements - continued

The Company received a nonrefundable upfront payment of $1.35 million when it entered into the co-development agreement with ILEX and received an additional $3.5 million in December 2003 when it converted ILEX's option to market clofarabine in the U.S. into a sublicense. The Company received an additional $2 million in April 2004 upon ILEX's filing the New Drug Application for clofarabine with FDA and the Company expects to receive an additional $2 million from ILEX in October 2004 in connection with the achievement of the NDA filing. The Company deferred the upfront payment and recognized revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company has deferred the milestone payments received to date and recognizes revenues ratably, on a straight line basis over the related service period, through March 2021. For the years ended June 30, 2004 and 2003, respectively, the Company recognized revenues of approximately $161,000 and $370,000 in connection with the upfront and milestone payments received to date.

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

Modrenal(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, through May 2014. The Company recognized revenues of approximately $114,000 and $12,000 in connection with the upfront payment from Dechra for the years ended June 30, 2004 and 2003, respectively.

Deferred costs include royalty payments that became due and payable to Stegram Pharmaceuticals Ltd. upon the Company's execution of the License and Sub-License Agreement with Stegram in May 2003. The Company defers all royalty payments made to Stegram and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with the Dechra agreement. Research and Development costs include approximately $23,000 and $2,000 for the years ended June 30, 2004 and 2003, respectively.

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

Operational Developments

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

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

Note 4 - License and Co-Development Agreements - continued

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

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

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

Note 5 - Income taxes

The components of the income tax benefit are as follows:

	June 30,	
	2004	2003
Current:		
Federal	$ --	$ --
State	--	--
Deferred:		
Federal	(404,000)	(404,000)
State	(133,000)	(133,000)
	(537,000)	(537,000)
Total benefit	$(537,000)	$(537,000)

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

	June 30,	
	2004	2003
Deferred tax liability		
Acquired intangibles	$(5,781,000)	$(6,318,000)

Deferred costs	(1,577,000)	(100,000)
Amortization	(20,000)	-
Total deferred tax liability	(7,378,000)	(6,418,000)
Deferred tax assets		
Net operating loss	9,431,000	5,512,000
Options, warrants and shares issued to non-employees	352,000	-
Options issued to employees	16,000	-
Deferred revenue	455,000	501,000
Amortization	-	1,000
Depreciation	10,000	11,000
Other	40,000	65,000
Total deferred tax assets	10,304,000	6,090,000
Valuation allowance for deferred tax assets	(8,707,000)	(5,990,000)
Net deferred tax asset	1,587,000	100,000
Net deferred tax liability	(5,781,000)	(6,318,000)

Note 5 - Income taxes - continued

At June 30, 2004, the Company had approximately $23,287,000 of net operating loss carryforwards for U.S. Federal and state income tax purposes that expire fiscal year ending 2019, with a tax value of $9,431,000. A full valuation allowance has been established for the deferred tax assets due to the uncertainty of the utilization of such deferred tax asset.

The Tax Reform Act of 1986 enacted a complex set of rules (Internal Revenue Code Section 382) limiting the utilization of NOLs 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 NOLs available in a given year, which could ultimately cause NOLs to expire prior to utilization.

The income tax benefit as recognized differs from the benefit that would be recognized at the Federal statutory rate on the pre-dividend net loss primarily due to certain permanent items and the valuation allowance established against the net operating loss deferred tax assets.

NOTE 6 - Stockholders' transactions

Common Stock and Securities Convertible into Common Stock

The Board of Directors adopted, and the stockholders approved the 2003 Stock Incentive Plan at the Annual Meeting held in January of 2004. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve

the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 3,000,000 shares reserved for grants of options under the plan and at June 30, 2004, options to purchase 2,105,000 shares of common stock had been issued. Stock options vest pursuant to individual stock option agreements. No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Board of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors or until expiration of the plan on November 17, 2013.

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

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

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

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

Note 6 - Stockholders' transactions - continued

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

and become exercisable on the first anniversary of the grant date and the remaining options to purchase 10,000 shares of common stock vest and become exercisable on the second anniversary of the grant date.

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

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

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

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

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

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

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

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

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

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

On March 22, 2004, the Company consummated a private placement transaction, pursuant to which it raised $12.8 million and issued 2,044,514 shares of its common stock and warrants to purchase an additional 408,903 shares of its common stock at an exercise price of $7.50 per share. The Company recorded proceeds of $12,151,240 net of all legal, professional and financing fees incurred in connection.

Note 6 - Stockholders' transactions - continued

with the offering. The Company consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Convertible Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional $3.2 million (net of all legal, professional and financial services incurred) from the second closing and issued an additional 558,384 shares of its common stock and warrants to purchase 111,677 shares of its common stock at an exercise price of $7.50 per share.

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

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

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

	No. of Shares	Weighted Avg. Exercise Price
Balance - June 30, 2002	2,200,000	1.25
Granted during 2003	1,370,000	1.19
Exercised during 2003	-	-
Forfeiture during 2003	-	-

Balance - June 30, 2003	3,570,000	$ 1.23
Granted during 2004	720,000	$ 5.02
Exercised during 2004	20,000	$ 1.42
Forfeiture during 2004	-	-
Balance - June 30, 2004	4,270,000	$ 1.87

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

NOTE 6 - Stockholders' transactions - continued

Preferred Stock

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

each holder from and after the issuance date, or (ii) the date at any time after the one year anniversary of the issuance date upon which both (x) the average of the market price for a share of common stock for thirty consecutive trading days exceeds $10.00 per share, subject to certain adjustments, and (y) the average of the trading volume for the Company's common stock during such period exceeds 150,000, subject to certain adjustments.

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

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

NOTE 7 - Related party transactions

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

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

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

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

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

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2004 AND 2003

NOTE 8 - Commitments and Contingencies

Leases

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

Year ended June 30,	
2005	$206,000
2006	63,000
2007	10,000
2008	_____
	$ 279,000

Employment Agreements

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

On October 23, 2002, we entered into an employment agreement with Hugh S. Griffith, pursuant to which he agrees to serve as our Commercial Director (Europe). The initial term of Mr. Griffith's employment agreement is one-year, with automatic six month extensions thereafter unless either party provides written notice to the contrary. If Mr. Griffith's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 0.5 multiplied by the sum of his then current annual base salary plus a payment equal to six (6) months of his then current base salary in complete satisfaction of the

Company's obligation to provide no less than six (6) months prior written notice as set forth in the employment agreement.

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

Note 8 - Commitments and Contingencies - continued

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

Litigation

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

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

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 September 24, 2004, 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	Dat
/s/ Christopher B. Wood, M.D. --- Christopher B. Wood, M.D.	Chairman and Chief Executive Officer and Director (Principal Executive Officer)	September
/s/ David P. Luci --- David P. Luci	Chief Financial Officer, General Counsel and Corporate Secretary (Principal Financial and Accounting Officer)	September
/s/ Thomas S. Nelson ---	Director	September

Thomas S. Nelson, C.A.

/s/ Michael Kaufmann Michael Kauffman	Director	September
/s/ Andrew N. Schiff --- Andrew N. Schiff	Director	September
/s/ Steven A. Elms Steven A. Elms	Director	September