BIOENVISION INC
Form 10KSB/A
April 02, 2004

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-KSB/A

(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, 2003.

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:

Title of Each Class:
Common Stock, $0.001 par value

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

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

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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 $504,857.

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 March 23, 2004, was $193,797,505. The number of shares of common stock outstanding as of March 23, 2004 was 22,934,616.

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 acquisition, 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
- Possible synergistic combination therapy with tamoxifen

- Phase II clinical trial commencing in prostate cancer Q2 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, prostate, 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 25% and 36% achieved.
  - Overall response rates in relapsed/refractory adult acute myeloid leukaemia (AML) and chronic myeloid leukaemia in blast crisis (CML-BP) of between 55% and 64% achieved.
- Solid tumor studies initiated with both the oral and intravenous formulations of clofarabine.

Anti-Cancer Product Portfolio

Our anti-cancer product portfolio includes three products, Modrenal(R), Clofarabine, Gossypol, used or which may be useful in eight indications and one technology, Gene Therapy, which may be useful in two indications.

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 to expire of our underlying patents will be 2020.

Modrenal(R) is currently at market in the United Kingdom for the treatment of women with advanced post menopausal breast cancer. We have a very small

marketing team that markets Modrenal(R) in the United Kingdom, and we record revenues accordingly.

Modrenal is in Phase II clinical studies in prostate cancer trials, and in Q2-Q3 2004, we intend to commence a Phase IV study in postmenopausal breast cancer and a Phase II study in pre-menopausal breast cancer.

Clofarabine

We have the exclusive right to manufacture, market and distribute Clofarabine for all human applications in all areas of the world other than Japan and Southeast Asia. We sublicensed the right to manufacture, market and distribute Clofarabine in the U.S. and Canada to ILEX Oncology, Inc. solely with respect to human cancer applications. We maintain our exclusive rights until the last to expire of the patents used or useful in our development and sales efforts which we expect to occur in 2020.

Currently, Clofarabine is in pivotal Phase II Clinical Trials for the treatment of pediatric acute leukemias. The final part of a rolling NDA will be filed with the FDA by early Q2, 2004. The drug has a Fast Track Designation and therefore we expect an FDA ruling by Q3,2004. As indicated in the previous paragraph, ILEX has the rights to market Clofarabine in the U.S. and we would receive a royalty on U.S. annual net sales.

Clofarabine is also in Phase II Clinical Trials in a range of hematological cancers and Phase I clinical trials in solid tumors.

Gossypol

We have the exclusive world-wide right to manufacture and market an optical isomer of gossypol for human and veterinary applications. Currently gossypol, to which we have ascribed the provisional trade name of Velostan, is completing the manufacturing process. We have developed a novel method of separating the enantiomers of gossypol and we are seeking patent protection for the process. We expect to initiate Phase I clinical trials with the drug in Q2, 2004. The primary indication we are targeting for the drug is in bladder cancer, although the drug may show efficacy in other tumor indications

Gene Therapy

We have the exclusive world-wide right to develop products from a gene therapy platform technology. To date, we have incorporated three human genes into the proprietary technology and we have tested two of these in preliminary clinical trials, with the emphasis on the treatment of patients with end-stage liver disease. Management believes the technology may also have application in patients undergoing chemotherapy for cancer. We maintain our exclusive rights until the last to expire of the patents which we expect to occur in 2017.

Non-Cancer Product Portfolio

Our non-cancer product portfolio is as follows:

Oligon(R) and Methylene Blue

We have the exclusive world-wide right to manufacture and market an anti-infective technology for the use of thiazine dyes, including Methylene Blue, and for other anti-infective uses. With the acquisition of Pathagon in February 2002, we acquired the exclusive worldwide license to this technology and license this technology from Oklahoma Medical Research Foundation. We maintain our exclusive license until the last to expire of the underlying patents. Currently, there are six patents issued in the U.S. and additional patents have been filed in the U.S., Europe, Canada and Japan.

We have sub-licensed the right to market the technology in the U.S. to Edwards Lifesciences which is currently marketing the technology in its line of short-term vascular access catheters. Bioenvision earns a nominal royalty on annual net sales from Edwards Lifesciences.

Products and Technologies

The following is a description of our current portfolio of platform technologies.

Purine Nucleoside Technology

We have a license from Southern Research Institute, 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. These studies were conducted by MD Anderson Cancer Center on behalf of the Company, ILEX and several United States hospitals involved with ILEX clinical studies. The lead compound of these purine-based nucleosides is known as Clofarabine. To facilitate its development, we entered into a co-development agreement with Ilex Oncology, Inc. ("Ilex") in March 2001, pursuant to which we granted Ilex an option on a sub-license to make, sell and distribute Clofarabine in the United States and Canada, subject to successful completion of certain milestones. Clofarabine has successfully completed Phase I/II clinical trials at M.D. Anderson Cancer Center, Houston, Texas. Three Phase II clinical trials have begun at MD Anderson and will be extended to other leading centers in the United States and Europe. In addition, a clinical trial exemption certificate has been granted for Clofarabine in the United Kingdom and approval for a Phase I/II trial of Clofarabine in lymphoma has been obtained in Switzerland. In January 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. The drug also has been granted orphan drug status in the United States. The combination of the Phase II trials in acute leukemia at M.D. Anderson Cancer Center and other leading cancer centers in the U.S. and Europe and the encouraging results from the Phase I, early Phase II studies and current Phase II studies lead us to be enthusiastic for the prospects of Clofarabine reaching the market, possibly as soon as the third quarter of calendar year 2004. The United States Food and Drug Administration recently indicated that it would review clofarabine for the treatment of refractory or relapsed ALL in children more quickly than normal after having granted "fast track" status to clofarabine. "Fast track" status means that the FDA will start reviewing clinical trial data even before the entire New Drug Application ("NDA") is complete. The FDA could complete its review within six months rather than the normal 12 month review period. We believe the set of clinical data from the current Phase II clinical trials could serve as the basis for a marking application, which we believe could be filed as early as April 2004. Management believes that the "fast track" designation may also result in our more expeditiously gaining marketing approval for clofarabine for the treatment of refractory or relapsed ALL.

ILEX is obligated to pay us royalties on US 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 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.

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 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. We currently are developing Clofarabine for the treatment of leukemia and lymphoma and we plan 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.

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 360 people participated in this clinical testing. In addition, Clofarabine has been shown to have good oral bioavailability, and in conjunction with ILEX, we have developed and expect to complete an oral formulation for clofarabine prior to December 2003. Results from ongoing 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 are planned to commence in Europe later this calendar year. 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).

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 programmed cell death (apoptosis). (See Blood 2000; volume 96, page 3537).

Because Clofarabine is a potent inhibitor of DNA repair, we, along with our co-development partners in North America, ILEX, are exploring the potential use of Clofarabine in combination with DNA damaging agents. This strategy has already been validated through the combination of Fludarabine(R) with cyclophosphamide in the treatment of chronic lymphocytic leukemia (CLL) because Fludarabine, like clofarabine, is in the same class of compounds, known as purine nucleoside analogs, with similar mechanisms of action in that the both work by damaging DNA in a cancer cell. Public reports indicate that Fludarabine, used in combination with a cyclophosphamide agent, blocks enzymes which promote cancer cell growth. Because Clofarabine and Fludarabine are in the same class of cancer agents with similar modes of action, we believe use of Clofarabine in combination with DNA damaging agents may have the same effect as with Fludarabine.

Purine Nucleoside--Solid Tumor. In pre-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.

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.

Selective Steroid Receptor Modulation Technology

Selective steroid receptor modulation technology, the lead compound of which is currently approved by regulatory authorities in the United Kingdom for the treatment of advanced breast cancer in post-menopausal women, has also been approved by regulatory authorities in Germany, for the treatment of certain adrenal disorders, such as Cushing's Disease. The product had also received marketing approval for the treatment of Cushing's disease in certain other European countries and the United States. The lead product, trilostane, is currently approved for marketing under the names Modrenal(R) and Modrastane(R). We receive royalty payments from Dechra on sales of trilostane in the veterinary market in Europe.

Breast cancer is, in general, a hormone-dependent disease, with estrogen being the principal hormone driving cell growth. Consequently, a major part of modern treatment is directed at blocking the action of estrogen, either at the site of production in the body or at the cell's estrogen receptor. The most widely used drug in this area, Tamoxifen(R), has been very successful in improving response rates and survival in women with breast cancer. Until recently, it was believed that estrogen acted via a single receptor on the cancer cell. However, it is now known that more than one estrogen receptor exists. Recent scientific data from Professor Gavin Vinson's laboratory at Queen Mary & Westfield College, London, England (part of the University of London) have shown that trilostane has a unique and previously unrecognized mode of action. The drug inhibits estrogen binding to the classical estrogen receptor (ER(alpha)) in an indirect (allosteric) fashion and also modulates estrogen binding to the newly-described second receptor, ER(beta). This action makes trilostane the first drug in a new class of agents that specifically modulate ligand binding to ER(beta). This novel action may explain the high clinical response rates seen when the drug was given to breast cancer patients with Tamoxifen(R) resistance. Furthermore, trilostane's action is different from that of other known "hormonal agents" although its actions may be complementary to those of other drugs. Extensive clinical trials with the drug have shown that it is effective in a significant proportion of breast cancer patients, particularly those with hormone-sensitive tumors. Trilostane has no aromatase inhibitor activity, which distinguishes it from some of the competitor hormonal products currently marketed for the treatment of breast cancer. We believe that the new data presents the drug with considerable market potential, although there can be no assurance that the medical profession or the FDA will accept this new data or that the drug will be successful in the marketplace.

Trilostane 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 trilostane. 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 trilostane upon relapse of the cancer. The response rate was above 40% in this group of patients. This compares to a response rate of about 30-35% with currently marketed aromatase inhibitors and approximately 25% with herceptin given as second line therapy. Most of the patients in the sub-set had received Tamoxifen(R) as first-line therapy. Thus, trilostane given as follow-on, or salvage, therapy has a response rate in excess

of those reported for the drugs currently in use for second-line treatment in this disease. Furthermore, trilostane has an acceptable side-effect profile. On the basis of these data, trilostane was granted a product license in the United Kingdom for the treatment of post-menopausal breast cancer.

We hold an exclusive license, until the expiration of existing and new patents related to trilostane, to market trilostane in major international territories, and an agreement with a United Kingdom company to co-

develop trilostane for other therapeutic indications. Trilostane is currently manufactured by third-party contractors in accordance with good manufacturing practices. We have no plans to establish our own manufacturing facility for trilostane, but will continue to use third-party contractors.

We launched Modrenal(R) in May 2003 in the United Kingdom for use in the treatment of 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. This would target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as Tamoxifen(R) or aromatase inhibitors. We believe that the potential market for Modrenal(R), based upon the sales of currently available drugs for hormonal therapy for breast cancers, is in excess of $1.8 billion of sales per annum worldwide. 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 mode of action, Modrenal(R) is most effective in certain specific patient types, such as those who have become Tamoxifen(R)-refractory. Furthermore, our management currently intends to price Modrenal(R) in such a manner as to make treatment with Modrenal(R) compare very favorably, on a price basis, with the cost of treatment with the existing drugs used for second line or third line therapy. We believe that this pricing strategy should result in cost benefits for physicians, patients and health-care systems.

Anti-Estrogen Prostate. We have received Institutional Review Board approval from the Massachusetts General Hospital for a Phase II study of trilostane for the treatment of androgen independent prostate cancer. The study will be conducted by The Dana Faber Cancer Institute and currently is intended to commence in October 2003.

The human prostate gland is under the control of several hormones, including androgens and estrogen. Receptors for estrogen have been identified in the prostate gland, and the newly discovered "second receptor," ER(beta), has been isolated from the human prostate gland. ER(beta) is also highly expressed in uterine and ovarian tissue. Prostate cancer, in most cases, is initially hormone-dependent and treatment of the disease is usually directed toward blocking the action of the relevant hormones. Unfortunately, it is a common occurrence for the cancer cells to become resistant to the standard hormonal agents. We believe that this is probably due to the inability of currently available treatments to block all the receptors on the prostate cancer cells. The ability of trilostane to control prostate cell growth by altering hormone

binding on important receptors could expand the treatment options for patients with prostate cancer.

Since adrenal disorders are relatively uncommon in humans, our strategy is not to aggressively market trilostane for these indications, but, rather, to focus our marketing efforts on trilostane for the treatment of breast and prostate cancer, which have considerably greater market potential. We intend to file for applicable regulatory approval of trilostane for treatment of breast cancer in the United States within months after discussing the appropriate course of regulatory consideration with applicable regulators. We will, however, pursue opportunities for adrenal disorder products on a smaller scale, principally in the veterinary market, which we believe will generate modest revenues over the near term. Marketing approval for trilostane's use in the veterinary market has been granted in the United Kingdom and the drug is being distributed by a third party. Under the terms of a co-development agreement, we were granted the exclusive worldwide license, excluding Japan and South Africa, to make, use and sell products derived from this 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, in exchange for, among other things, certain royalty payments based on gross sales of products derived from the technology.

We also plan to devote our research efforts to discover new applications for trilostane and related products. The latest work has allowed new patents to be filed which, if granted, will extend broadly the commercial potential for trilostane and related products. In addition, a new analog of trilostane, which shows increased activity compared with trilostane, is being developed and is the subject of new patent filings.

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, the rate of which tripled between 1980 and 1990 and which accounts for approximately $11 billion of extra expense to the U.S. healthcare system each year. According to the U.S. Centers for Disease Control, $6.5 billion of this expense is related to infections associated with medical devices, including vascular access and urology catheters, and is unreimbursable to hospitals.

OLIGON(R) devices will be marketed as next generation products into large existing markets. Manufacturers of existing products are aware of the seriousness of device related infections, but none has been able to develop technology that imparts antimicrobial efficacy to surfaces of implanted devices over long periods of time. OLIGON(R) effectively addresses these requirements.

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 DNA vector technologies which, based on pre-clinical research and early Phase I clinical trials, we believe are capable of elevating 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 synthetic analog of 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.

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 five issued patents and six 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 clofarbine. We have also filed two United States patent applications relating to the use of clofarbine in autoimmune diseases. Although the basic 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.

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 North America and certain countries in Europe. As of the date of this annual report on From 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, 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, 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 its products. These collaborators are generally expected to be responsible for funding or reimbursing all or a portion of the development costs, including the costs of clinical testing necessary to obtain regulatory clearances and for commercial-scale manufacturing, in exchange for exclusive or semi-exclusive rights to market specific products in particular geographic territories. 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.

Raw Materials

Our raw materials (such as laboratory chemicals) and other supply items to be used in our research and development processes are available from many different suppliers and are generally available in sufficient quantities in timely fashion. We do not anticipate any significant problems in the availability of, or significant price increases for, required raw materials or other production items in the foreseeable future.

Research and Development

In developing new products, we consider a variety of factors including: (i) existing or potential marketing opportunities for these products; (ii) our capability to arrange for these products to be manufactured on a commercial scale; (iii) whether or not these products complement our existing products; (iv) the opportunities to leverage these products with the development of additional products; and (v) the ability to develop co-marketing relationships with pharmaceutical and/or other companies with respect to the products. We intend to fund future research and development activities at a number of medical and scientific centers in Europe and the United States. Costs related to these activities are expected to include: clinical trial expenses; drug production costs; salaries and benefits of scientific, clinical and other personnel; 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 $1,900,000 and $1,700,000 on research and development activities in 2002 and 2003, respectively.

Industry Overview

We believe the biopharmaceutical industry has evolved significantly since its commercial inception in the 1970s and is currently approaching a period of sustained growth. To be successful, we believe biopharmaceutical companies must have the ability to harness rapidly advancing technology, provide solutions for previously unmet therapeutic needs, ensure faster development of new drugs and allow flexibility to exploit changing market conditions. We seek to engage in this new generation of biopharmaceutical companies, linking the technological skills of doctors and scientists in Europe and North America with the U.S. and European capital markets.

The National Cancer Institute estimated in 2000 the overall costs for cancer to be $107 billion in the United States; $37 billion for direct costs, $11 billion for morbidity costs and $59 billion for mortality costs. Treatment of breast, lung and prostate cancer account for over half the direct medical costs.

The table below shows the forecast global cancer treatment market for the period 2001-2007. The overall market is forecast to grow from $29.4 billion in 2001 to $42.8bn in 2007, representing an average annual growth rate of 6.5%.

Forecast Global Cancer Treatment Market 2001 - 2007 (amounts in $ billions)

Drug Class	2001	2002	2003	2004	2005	2006
Adjunct therapies	$11,321	$11,834	$12,347	$12,860	$13,373	$13,752
Cytotoxics	8,651	9,136	9,501	9,881	10,277	10,585
Hormonals	5,720	5,841	5,950	5,952	5,856	5,688
Innovative agents	3,679	4,665	5,650	7,126	8,602	10,432
TOTALS	$29,372	$31,476	$33,448	$35,820	$38,108	$40,457

Source: Reuters, 2002

We believe that new cancer therapies increasingly will be required to be more cost-effective and allow for alternate site or in-home treatment and to improve patient quality of life during treatment.

With respect to our products and technologies within the overall cancer market, Clofarabine and Gossypol constitute cytotoxic agents and Modrenal constitutes a hormonal agent, in each case, which we believe may have significant market potential both in the U.S. and other parts of the world. Although we have received orphan drug status for Clofarabine in the U.S. and Europe in pediatric and adult acute leukemias, we continue to develop the drug, in conjunction with our U.S. co-development partner, ILEX Oncology, Inc., in other indications with broader markets including solid tumors and combination studies. If Clofarabine demonstrates efficacy in all of these indications, we believe it has potential to be a leading drug in the U.S. and Europe in hematological cancers with widespread use in solid tumors. We believe efficacy

data on the use of Gossypol in bladder cancers will be available as early as Q1 2005 upon completion of our initial clinical trial. Modrenal is an approved agent which we market for the treatment of post-menopausal women with advanced breast cancer in the United Kingdom and we anticipate receiving mutual recognition from other European Union member states in Q1 2005. Taken together, we believe this portion of our cancer drug portfolio could create a significant commercial advantage for our company and our stockholders.

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

Competition in the pharmaceutical 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. Although we seek to limit potential sources of competition by developing products that are eligible for orphan drug designation or other forms of protection, there can be no assurance that our competitors will not succeed in developing similar technologies and products more rapidly than are being or will be developed by us.

One of Bioenvision's lead drugs, Clofarabine, has been granted Orphan Drug Status in the U.S. and Europe, and is currently undergoing multi-center Phase II trials. Listed below are other Cytotoxic Agents currently at market.

Company	Brand	Generic	Class	1999 ($m)
BMS	Taxol	Paclitaxel	Other Cytotoxics	1,481
Aventis	Taxotere	Docctaxel	Other Cytotoxics	461
Lilly	Gemzar	Gemcitabine	Antimetabolite	453
BMS	Paraplatin	Carboplatin	Other Cytotoxics	600
Pharmacia	Camptosar	irinorccan	Other Cytotoxics	293
Taiho	UFT	tegafur uracil	Antimetabolite	460
Pharmacia	Pharmorubicin/Ellence	cpirubein	Cytotoxic Antibiotics	206
Ivax	Paxene	paclitaxel	Other Cytotoxics	n/a
Roche	Furtulon	doxifluridine	Antimetabolite	166
Aventis	Campro	irinotecan	Other Cytotoxics	83
Sanofi	Eloxatine	oxilaplatin	Other Cytotoxics	72
SP	Temodar	temozolomide	Alkylating agents	36
Roche	Xeloda	capecitabine	Antimetabolite	53
GSK	Hycarntin	topotecan	Other Cytotoxics	141
Schering AG	Fludara	fludarabine	Antimetabolite	79
BMS	Ifex	ifosfamide	Alkylating agents	88
Alza US	Doxil/Caelyx	liposomal/ doxorubicin	Cytotoxic Antibiotics	66
Pierre Fabre	Navelbine	vinorelbine	Vae	76
Wyeth	Novantrone	mitoxantrone	Cytotoxic Antibiotics	45
BMS	VcPesid	ctoposide	Vae	77
GSK	Navelbine	vinorelbine	Vae	67
Pharmacia	Adriamycin	doxorubicin	Cytotoxic Antibiotics	65
BMS	Hydrea	hydroxyurea	Alkylating agents	56
Others				1,824
	TOTAL			6,948

Source: Reuters, 2002

Another of Bioenvision's lead drugs, Modrenal(R) is approved in the UK for the treatment of post-menopausal patients with advanced breast cancer. In particular, the drug is approved as follow-on treatment for patients who previously have responded to hormonal therapy.

Listed below are other hormonal therapies currently at market.

Company	Brand	Generic	Class	1999 ($m)
TAP	Lupron	Leuprorelin	LHRH agonsists	775
AstraZeneca	Zoladex	Goserelin	LHRH agonsists	686
AstraZeneca	Nolvadex	Tamoxifen	Anti-estrogens	573
AstraZeneca	Casodex	Bicalulamide	Anti-estrogens	340
Takeda	Leuplin	leuprorelin	LHRH agonsists	485
Barr	Tamoxifen	Tamoxifen	Anti-estrogens	297
Pharmacia	Depo-Provera	Medroxy	Progestagens	252
AstraZeneca	Arimidex	Anastrozole	Aromatase Inhibitors	140
Abbott	Lupron	leuprorelin	LHRH agonsists	140
BMS	Megace	megestrol	Progestagens	114
Novartis	Femara	letrozole	Aromatase Inhibitors	57
Ipsen	Deccapepryl	triptorelin	LHRH agonsists	100
Aventis	Nilandron	nilutamide	Anti-androgens	72
Schering AG	Androcur	cyproterone	Anti-androgens	91
Aventis	Suprecur/ Suprefact	buserelin	LHRH agonsists	83

Company	Brand	Generic	Class	1999 ($m)
SP	Eulexin	flutamide	Anti-androgens	155
Pharmacia	Aromasin	exemestane	Aromatase Inhibitors	n/a
Nihun Kayaku	Odyne	flutamide	Anti-androgens	71
Teikoku Hormone	Prostal	chlormadinone	Progestagens	63
Novartis	Lentaron	formestane	Aromatase Inhibitors	47
Nihun Kayaku	Fareston	toremifene	Anti-estrogens	44
Novartis	Afema	tadrozole	Aromatase Inhibitors	22
Mitsui	Tasuomin	Tamoxifen	Anti-estrogens	10
Others				237

TOTAL	4,855

Source: Reuters, 2002

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.

We expect that our proposed products will compete on the basis of, among other things, safety, efficacy, reliability, price, quality of life factors (including the frequency and method of drug administration), marketing, distribution, reimbursement and effectiveness of intellectual property rights. We believe that our competitive success will be based partly on our ability to attract and retain scientific personnel, establish specialized research and development capabilities, gain access to manufacturing, marketing and distribution resources, secure licenses to external technologies and products, and obtain sufficient development capital. We intend to obtain many of these capabilities from pharmaceutical or biotechnology companies through collaborative or license arrangements. However, there is intense competition among early stage biotechnology firms to establish these arrangements. Our development products may not be of suitable potential market size or provide a compelling return on investment to attract other firms to commit resources to a collaboration. Even if collaborations can be established, there can be no assurance that we will secure financial terms that meet our commercial objectives.

Employees

As of June 30, 2003, we had seven full-time and three part-time employees. Of these, three are in management, three are in sales/marketing, one is in administration and three 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, (`Old Bioenvision') 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, 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. Although all known material risks are presented in this annual report, the Company may face other risks that are not discussed in the following description of its risk factors, either because we are unaware of such risks or because we presently believe that such risks are immaterial. These risks may also adversely affect our business, financial condition or operating results. If any of the events we have identified or those that we cannot now identify occurs, 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 March 23, 2004, our closing stock price has ranged from a high of $8.40 to a low of $0.69. 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, 2003, we had 17,122,739 shares of common stock outstanding, 5,916,666 shares of Series A preferred stock outstanding which are currently convertible into 11,833,332 shares of common stock and 15,749,543 common stock equivalents including warrants and stock options, other than the options granted under the co-development agreement with ILEX. The exercise and conversion prices of the common stock equivalents range from $0.735 to $2.00 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, 2003, (i) no shares are currently registered under the Securities Act and (iii) the sale of shares underlying options are not registered under the Securities Act, on Form S-8 or otherwise.

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 Shareholder Approval.

Our charter authorizes our board of director to increase the number of shares of preferred stock we may issue without shareholder approval. Preferred stock may be issued in one or more series, the terms of which may be determined without further action by shareholders. 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 shareholders' 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 $4,373,118 for the six-month period ended December 31, 2003 and $1,773,811 for the three month period ended December 31, 2003. At December 31, 2003, we had a deficit accumulated of $33,436,828. 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 any viable products.

Before obtaining regulatory approval for the commercial sale of a product, we must demonstrate through pre-clinical testing and clinical trials that a product candidate is safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process. We will incur substantial expense for, and devote a significant amount of time to pre-clinical testing and clinical trials. Even with Modrenal, which is approved and marketed by us in the U.K. for the treatment of advanced post-menopausal breast cancer, we are conducting a clinical trial in the U.S. in prostate cancer, 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 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 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 oblihgations, 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 March 2004, ILEX completed the filing.

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. Because we intend to make use of clinical data from the clinical trials which ILEX conducted, and is conducting, to prepare and support our regulatory applications in Europe and elsewhere, ILEX's failure to expeditiously file the New Drug Application with FDA could adversely affect the timing of European approval. 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 may fail to address risks we face as a developing business which could adversely affect the implementation of our business plan.

We are prone to all of the risks inherent in being a development stage business venture including insurance risks, risks related to the establishment of new vendor relationships to develop our lead drugs, risks related to establishing a work force of our own both in the U.K. and in the U.S., certain internal accounting control risks. Although we have addressed these risks in part based on consultation with our professional advisors, no assurance can be given that we have addressed these risks appropriately. You should consider the likelihood of our future success to be highly speculative in light of our limited operating history, as well as the limited resources, problems, expenses, risks and complications frequently encountered by similarly situated companies. To address these risks, we must, among other things,

o maintain our product portfolio;

o successfully execute our business and marketing strategy;

o continue to upgrade our existing products;

o respond to industry and competitive developments; and

o attract, retain, and motivate qualified personnel.

We may not be successful in addressing these risks. If we are unable to do so, our business prospects, financial condition and results of operations would be materially adversely affected.

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

post-menopausal breast cancer patients.

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

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

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

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

Regulation in General. Virtually all aspects of our business are regulated by federal and state statutes and governmental agencies in the 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 the same drug 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 the same drug and 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 not receive orphan drug designations and FDA marketing approval before the products under development by us.

New drug application approval of 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. Prescribing of approved drugs for unapproved uses, commonly referred to as "off label" use, could adversely affect the marketing potential of products that have received an orphan drug designation and new drug application approval. In addition, new drug application approval of a drug with an orphan drug designation does not provide any marketing exclusivity in foreign markets.

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

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

In addition to government agencies, private health/science

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

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

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

Because many of our competitors have substantially greater capabilities and resources, 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 include Astra-zeneca and Novartis, which market timoxifen and other aromitase inhibitors, which could be used by clinicians as first and second line therapies in patients with hormone sensitive advanced post-menopausal breast cancer prior to a

Modrenal regimen of treatment. No assurance can be given that the ongoing business activities of our competitors will not have a material adverse effect on our business prospects and projections going forward.

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

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 fulltime sales employee and two fulltime marketing employees. To market any products directly, we will need to develop a more fulsome marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. To the extent that we enter into co-promotion or

other licensing arrangements, any revenues to be received by us will be dependent on the efforts of third parties. The efforts of third parties may not be successful. Our failure to establish marketing and distribution capabilities or to enter into marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

We 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 trilostane 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 trilostane. 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 myelogenous 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.

If we lose key management or other personnel our business will suffer.

We are highly dependent on the principal members of our scientific and management staff. We also rely on consultants and advisors, including our scientific advisors, to assist us in formulating our research and

development strategy. Our success also depends upon retaining key management and technical personnel, as well as our ability to continue to attract and retain additional highly-qualified personnel. We face intense competition for personnel from other companies, government entities and other organizations. We may not be

successful in retaining our current personnel. We may not be successful in hiring or retaining qualified personnel in the future. If we lose the services of any of our scientific and management staff or key technical personnel, or if we fail to continue to attract qualified personnel, our ability to acquire, develop or sell products would be adversely affected.

Dr. Wood constitutes a key employee of the Company and he has an employment agreement with the Company. 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 our co-founders and, as such, is most familiar with all of our key relationships (for example, the inventors and licensors of our lead products); all of our material agreements which were negotiated at his direction and with the science which underlies our lead drugs and ancillary technologies. Dr. Wood maintains a position on the Clofarabine management team which is responsible for drug development activities. Based on the responsibilities noted above and the ongoing clinical trials we are conducting, losing Dr. Wood could materially and adversely affect the timing of our development objectives and/or the goodwill created by our management with our key business, scientific and medical contacts.

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 and Edinburgh, Scotland, respectively).

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, in territories outside of the United States. Specifically, we currently market Modrenal in the United Kingdom and upon receiving European approval for Clofarabine, we intend to market the drug throughout Europe. Further, 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.

In March 2004, we completed a $12,500,000 offering through the sale of shares of common stock and issuance of common stock purchase warrants. The common stock purchase warrants are exercisable within five years of the issuance date. However, we may need additional financing to continue to fund the research and development of our products and to generally expand and grow our business. For example, we will need to employ a European sales force within the next twelve months to capitalize on the commercial potential for Clofarabine and Modrenal if and to the extent our lead drugs are at market in Europe in the first half of 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 may 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 additional 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 December 31, 2003, we had stockholders' equity of $15,404,099 and net working capital of $3,115,285.

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. Government officials and private health insurers are increasingly challenging the price of medical products and services. Significant uncertainty exists as to the pricing flexibility distributors will have with respect to, and the reimbursement status of, newly approved health care 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 aromitase inhibitor treatment but not treatments of Modrenal, this would cause sales of Modrenal to decline. This lack of reimbursement would diminish the market for products developed by us and could 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 thereof. Product liability claims may be brought by 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 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 and marketing 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://wwww.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. We also rent 250 square feet of office space at 32 Haymarket, London SW1Y 4TP for approximately $1,000 per month. This office space is used to perform certain marketing functions throughout Europe. Also, we rent on a month-to-month basis approximately 500 square feet of office space in Edinburgh, Scotland for approximately $3,000 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 alleges a breach of contract by the Company and demands 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. The Company believes that the grounds for the

complaint are meritless and intends to defend this matter vigorously. If the Company is not able to successfully defend this complaint, management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations.

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

None.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters.

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

	High	Low
Fiscal Year Ended June 30, 2001		
First Quarter	$4.25	$2.50
Second Quarter	$4.00	$1.50
Third Quarter	$2.625	$0.875
Fourth Quarter	$2.45	$0.82
Fiscal Year Ended June 30, 2002		
First Quarter	$2.50	$1.60
Second Quarter	$2.50	$1.15
Third Quarter	$3.00	$2.25
Fourth Quarter	$3.60	$1.75
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

On September 11, 2003, we had 534 stockholders of record.

We have never declared or paid cash dividends on our capital stock, and our board of directors does not intend to declare or pay any dividends on the common stock in the foreseeable future. However, the Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. We have not paid dividends on our cumulative Series A Convertible Participating Preferred Stock

since May 8, 2002 but have accrued the dividends since that time. 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.

Recent Sales of Unregistered Securities

In June 2003, in connection with that certain employment agreement, dated January 1, 2000, by and between the Company and Mr. Stuart Smith (the "Smith Employment Agreement"), we issued 19,728 shares of our common stock at fair market value to Mr. Smith in settlement of any and all obligations owing to Mr. Smith under the Smith Employment Agreement. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In May 2003, in connection with that certain consulting agreement, dated November 19, 2001 (the "Sterling Consulting Agreement"), we issued 15,225 shares of our common stock at fair market value to Mr. Sterling in settlement of all outstanding obligations under the Sterling Consulting Agreement. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In February 2003, in connection with that certain consulting agreement, dated March 1, 2002, by and between the Company and Mr. Edward W. Kelly (the "Kelly Consulting Agreement"), we issued 200,000 shares of our common stock at fair market value to Mr. Kelly in settlement of all of our outstanding obligations under the Kelly Consulting Agreement. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In January 2003, in connection with our employment of our office manager at the principal executive office, we issued options to purchase 20,000 shares of our common stock at an exercise price of $1.42 per share which approximated the fair market value of the common stock on the date of the grant. Of such options, subject to certain terms and conditions, options to purchase 10,000 shares of our common stock vested immediately and options to purchase 10,000 shares of our common stock vest on the one-year anniversary of January 9, 2003, 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, which approximated the fair market value of the common stock on the date of the grant, to its Chairman and Chief Executive Officer, Dr. Christopher B. Wood. Of these options, subject to certain circumstances, options to purchase 166,666 shares of common stock vest on each of the first, second and third anniversary of the grant date.

On December 31, 2002 the Company issued options to purchase 200,000

shares of common stock at an exercise price of $2.00 per share, which approximated the fair market value of the common stock on the date of the grant, to a consultant to the Company who performs European regulatory services for the Company. Of these options, options to purchase 66,666 shares of common stock vest on each of the first, second and third anniversary of the grant date. Compensation expense of $24,333 was recorded as consulting fees for the year ended June 30, 2003.

In October 2002, in connection with our employment of Ian Abercrombie as our Sales Manager (Europe), we issued options to purchase 50,000 shares of our common stock at an exercise price of $1.45 per share, which approximated the fair market value of the common stock on the date of the grant. Of these options, subject to certain terms and conditions, options to purchase 25,000 shares of common stock vest on each of the first and second anniversaries of October 23, 2002, the grant date.

In October 2002, in connection with our employment of Hugh Griffith as our Commercial Director (Europe), we issued options to purchase 300,000 shares of our common stock at an exercise price of $1.45 per share, which approximated the fair market value of the common stock on the date of the grant. Of these options, subject to certain terms and conditions, options to purchase 100,000 shares of common stock vest on each of the first, second and third anniversaries of October 23, 2002, the grant date.

In July 2002, in connection with our employment of David P. Luci as our Director of Finance and General Counsel, we issued options to purchase 380,000 shares of our common stock at an exercise price of $1.95 per share, which approximated the fair market value of the common stock on the date of the grant. In connection with our entering into an employment agreement with Mr. Luci, dated March 31, 2003, we cancelled these options and issued options to purchase 500,000 shares of common stock, which are exercisable at $0.735 per share, which approximated the fair market value of the common stock on the date of the grant. Of these options, subject to certain terms and conditions, options to purchase 170,000 shares of common stock vested on March 31, 2003 (the grant date), and options to purchase 110,000 shares of common stock vest on each of the first, second and third anniversaries of March 31, 2003.

In May 2002, Bioenvision issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for $3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock to seventeen accredited investors, as defined under Regulation D of the Securities Act. The issuance of these shares and warrants was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

On February 1, 2002, Bioenvision issued 7,000,000 shares of common stock to the former stockholders of Pathagon in connection with the consummation of the Pathagon transaction. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

On November 16, 2001, we entered into an engagement letter with SCO Capital, pursuant to which SCO Capital 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. 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 issuance of these shares and warrants were exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In October 2001, we issued 134,035 shares of common stock to three officers as payment for salaries accrued to September 30, 2001, each of which were accredited investors, as defined under the Securities Act of 1933. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In August 2001 in connection with outstanding deferred salaries, we issued 208,333 shares of common stock at the rate of $1.25 per share as follows: Christopher Wood 98,684 shares; Thomas Nelson, 27,412 shares; and Stuart Smith, 82,237 shares. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In addition, in August 2001, we granted 150,000 options to purchase shares of our common stock at an exercise price of $1.25 per share. The options were issued to two consultants in exchange for certain services rendered. The options expire in August 2004 and are immediately vested. Those issuances of options were exempt from registration under Regulation S promulgated under the Securities Act or Section 4(2) of the Securities Act. In August 2001, we cancelled these options and replaced them with 150,000 shares.

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 in this annual report on Form 10-KSB, which consolidated financial statements are presented beginning at page F-1, for further details.

Summary of Significant Accounting Policies

Financial Reporting Release No. 60, which was recently 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 recently 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, 2002 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. 101, 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. We have several products and technologies under development, but our two lead drugs are Clofarabine and Modrenal(R).

Clofarabine is a purine nucleoside analogue, or a small molecule, which, based on our own clinical studies and studies conducted by others on our behalf, we believe is effective in the treatment of leukemia. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I/II clinical trials performed to date. In the United Kingdom, we are currently conducting clinical trials with Clofarabine for the treatment of pediatric and adult acute leukemias. In the U.S., Clofarabine is currently in Pivotal Phase II clinical trials for pediatric acute leukemias. 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. The drug has also been granted orphan drug status and "fast track" treatment by the United States Food and Drug Administration (the "FDA"). Further, 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 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 the first half of 2004, 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 in the first half of calendar year 2005. Further, we filed an IND for prostate cancer clinical trials in the US in February 2004 and intend to commence our first US clinical trial in the second quarter of calendar year 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.

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. We anticipate receiving approval early in 2005, subject to our obtaining approval of the regulatory authorities. We will continue clinical trials in other indications with the intention of seeking label extensions after Clofarabine's first approval. With Modrenal, our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to sell Modrenal(R) throughout Europe. We anticipate receiving mutual recognition from major European Community member states by mid-2005. 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.

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 five years if we successfully bring our two lead drugs to market. We anticipate that revenues derived from the two lead drugs will permit us to further develop the twelve other products and potential products currently in our development portfolio. We currently plan to have as

many as twelve products at market by the end of 2006. We have commenced marketing one of our lead products, Modrenal(R), and 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. A key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. 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 vivos 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 anit-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 Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed the marketing and development rights to modrestane, 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, 2003 Compared to Year Ended June 30, 2002

We reported revenues of $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, $12,000 was recognized from Dechra, pursuant to the Sub-License Agreement, dated May 13, 2003.

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

Our research and development costs include costs associated with four projects for which the Company devotes significant time and resource. Clofarabine research and development costs for the year ended June 30, 2003 and 2002 were $871,000 and $596,000, respectively, representing an increase of $275,000. The increase primarily reflects the costs associated with our having commenced clinical trials in Europe to develop Clofarabine. Modrenal research and development costs for the year ended June 30, 2003 and 2002 were $913,000 and $923,000, respectively, representing a decrease of $10,000. Gossypol research and development costs were $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 $(130,000) and $303,000, respectively, representing a decrease of $433,000. The decrease primarily reflects an accrued expense in the year ended 2002 of $200,000 which was determined to be less than originally estimated by the Company in the year ended June 30, 2003. The clinical trials and development strategy for the Clofarabine and Modrenal projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable.

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

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

Depreciation and amortization expense totaled $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.

Year Ended June 30, 2002 Compared to Year Ended June 30, 2001

We reported revenues of $803,000 and $245,000 for the years ended June 30, 2002 and 2001, respectively. Revenues reflect our agreements with our co-development partners and/or licensees in connection with our platform of drugs and technologies.

Research and development costs for the years ended June 30, 2002 and 2001 were $1,912,000 and $1,566,000, respectively, representing an increase of approximately $346,000. This increase primarily is attributable to a full year amortization of deferred royalties, which represent advance royalties paid to SRI that are being amortized over the same period that related revenue is being recognized.

Administrative expenses for the year ended June 30, 2002 and 2001 were $2,128,000 and $550,000, respectively, representing an increase of $1,578,000. Of this amount, (i) approximately $650,000 related to an increase in legal and other professional fees paid during the year, (ii) approximately $750,000 related to an increase in printing, investor and public relations costs and (iii) approximately $85,000 was due to an increase in travel expenses related to the Company's expansion of the internal management team.

We reported interest and finance charges of $2,173,000 and $229,000 for the years ended June 30, 2002 and 2001, respectively, representing an increase of $1,944,000. This increase reflects charges related to the issuance of warrants in connection with the Company's various financings.

Depreciation and amortization expense totaled $579,000 and $23,000 for the years ended June 30, 2002 and 2001, respectively. This increase primarily is 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 foreseeable future. There can be no assurance as to whether or when we will generate material revenues or achieve profitable operations.

We are actively seeking strategic alliances in order to develop and market our range of products. In August 2001, we obtained a $1 million unsecured line of credit facility from Jano Holdings Limited, bearing interest at 8% per

annum. In November 2001, we entered into a senior, Secured Credit Facility with SCO Capital Partners LLC. The credit facility was established for up to $1,000,000 in short term financing, in four trances of $250,000, subject to satisfaction of certain conditions, secured by the pledge of certain of our assets, and was established to bear interest on drawings at a rate of 6% per annum. In addition, our officers agreed to defer salaries, and our former outside counsel agreed to defer certain fees, until we obtained sufficient long-term funding. Deferred salaries and fees amounted to approximately $52,000 through June 30, 2002. In May 2001, our officers agreed to accept 705,954 shares of our common stock in settlement of $910,681 of the outstanding accrued salaries through June 30, 2001. The shares were issued during the quarter ended March 31, 2002. On October 17, 2001, our officers agreed to accept 134,035 shares in settlement of $154,140 of additional outstanding accrued salaries to September 30, 2001. On October 17, 2001, the board of directors approved a plan to repay certain trade debt with shares of our common stock, and a total of 146,499 shares of common stock were issued for the repayment of $168,473.

We received an initial payment from ILEX of $1,350,000 which became non-refundable in March 2001 upon execution of the agreement with ILEX to co-develop Clofarabine. That sum will be recognized as income for accounting purposes on a straight line basis over the period from March 2001, when the payment was received, through December 31, 2002, at which time ILEX was originally scheduled to complete Phase II trials of Clofarabine and make another payment to us.

We received an initial payment from Dechra of $1,250,000 on May 13, 2003 upon execution of our sub-license agreement with Dechra. This agreement expires upon expiration of the last patent related to modrenal or the completion of the last royalty obligation as set forth therein.

On May 7, 2002 we authorized the issuance and sale of up to 5,920,000 shares of Series A Preferred Stock. The Series A 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 preferred stock also received, in respect of each share of Series A 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 participating 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 June 30, 2003, we have cash and cash equivalents of $8,200,000 and working capital of $6,108,000 which management believes will be sufficient to continue currently planned operations over the next 12 months.

Although we do not currently intend to raise any additional funds for the next 12 months, we can not ensure additional funds will not be raised during such period because of the significant scale up of our operating activities, including clofarabine development and the launch of modrenal. Further, a key element of our business strategy is to continue to acquire, obtain licenses for,

and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. We are not presently considering any such transactions, and we do not presently expect to acquire any significant assets over the coming 12 month period, but 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 foreseeable future. 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, 2003:

	Payments Due in		
	Total	2004	2005
Employee Contracts	266,400	266,400	-
Occupancy Lease	369,500	161,600	166,100
Total	635,900	418,500	156,000

In management's opinion, cash flows from operations and borrowing capacity combined with cash on hand will provide adequate flexibility for funding the Company's working capital obligations for the next twelve months. However, there can be no assurance that suitable debt or equity financing will be available for the Company. The Company has a commitment under its operating lease with the New York office. The Company leases 3,299 square feet under a lease that expires on September 30, 2005. The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision, Ltd.

Plan of Operation

We are an emerging biopharmaceutical company with a primary business focus on the acquisition, development and distribution of drugs to treat cancer. We have acquired development and marketing rights to a portfolio of six platform technologies developed over the past 15 years from which a range of products have been derived and additional products may be developed in the future. Although we have commenced marketing one of our lead products, Modrenal(R), and intend to continue to develop Clofarabine, and our existing platform technologies and commercializing products derived from such technologies, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. Once a product or technology has been 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 May 2002 private placement to initiate clinical trials of Clofarabine in Europe.

The emphasis will be on the use of Clofarabine in the treatment of refractory acute leukemia in children and adults. The drug has received orphan drug designation in Europe.

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 methlylene 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.

Key Personnel, Consultants and Infrastructure

On July 22, 2002, David P. Luci commenced employment with the Company and serves as Director of Finance, General Counsel and Corporate Secretary of the Company, pursuant to terms which are memorialized in an Employment Agreement, dated March 31, 2003. See Part III, Item 9 "Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act - Employment Agreements" below.

On September 3, 2002, the Company and ILEX constituted the management team (the "Management Team") for the development of Clofarabine in the U.S., Canada and Europe. The Management Team meets regularly to plan and coordinate clofarabine drug development on an ongoing basis. The Management Team currently consists of Dr. Wood and Mr. Luci from the Company and Jeffrey Buchalter, President and Chief Executive Officer of Ilex.

On September 17, 2002, the Company announced its establishment of principal executive offices at 509 Madison Avenue, Suite 404, New York, New York 10022.

On September 24, 2002, Mr. Thomas Scott Nelson resigned his position as Chief Financial Officer of the Company. Mr. Luci has taken responsibility as the Company's principal accounting officer. Mr. Nelson continues his role as director of the Company.

On September 30, 2002, Stuart Smith resigned from his position as Senior Vice President of the Company; his employment agreement was terminated. The Company issued shares of its common stock to Mr. Smith at the then current fair market value in satisfaction of all outstanding obligations of the Company to Mr. Smith pursuant to the employment agreement.

On October 6, 2002, Mr. Hugh Griffith commenced employment with Bioenvision Ltd., a wholly owned subsidiary of the Company. Mr. Griffith serves as Commercial Director (Europe) and is responsible for Bioenvision's marketing campaign for modrenal, which is approved in the United Kingdom for the treatment of advanced post-menopausal breast cancer, and for Bioenvision's sales and marketing initiatives for all other approved products throughout Europe which, initially, includes methylene blue and OLIGON.

On November 1, 2002, the Company entered into an agreement with

Queen Mary Westfield College, University of London ("Queen Mary"), pursuant to which, in pertinent part, Queen Mary has agreed to perform certain research and development activities in connection with the development of modrenal(TM). The term of the agreement is five years, subject to certain rights of the parties to terminate prior thereto.

On December 1, 2002, the Company appointed Mr. Ian Abercrombie to serve as Sales Manager (Europe). Messrs. Abercrombie and Griffith, together, are creating a worldwide marketing strategy for the Company's products and marketing Modrenal (TM) in the United Kingdom. Further, Messrs. Abercrombie and Griffith are designing plans to expand the Company's marketing strategy throughout the European Community and to commence pre-registration marketing activities with Clofarabine worldwide, except for North America.

On December 31, 2002, the Company entered into a one-year employment agreement with Dr. Christopher B. Wood who serves as Chairman and Chief Executive Officer of the Company. See Part III, Item 9 "Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act - Employment Agreements" below.

On December 31, 2002, the Company entered into a consulting agreement with Dr. Deidre Tessman to serve as a regulatory consultant to the Company in connection with the European development of Clofarabine.

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 (TM) 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.

In April 2003, we entered into an exclusive license agreement with CLL Pharma ("CLL"), pursuant to which CLL has agreed to develop a new formulation of modrenal using proprietary patented technology of CLL. The term of the agreement is for a period of 24 months following the first delivery of reformulated drug product.

In May 2003, we entered into a Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed the marketing and development rights to modrestane, 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.

In May 2003, we entered into a Master Services Agreement with Penn Pharmaceutical Services Limited ("Penn"), pursuant to which Penn will assist the Company with labeling, packaging and distribution of Clofarabine and certain other services including regulatory and quality control, in each case, as requested by the Company on an ongoing basis. The term of the agreement is 12 months subject to automatic 12 month extensions unless earlier terminated by either party.

In June 2003, we entered into a supply agreement and a development

agreement, in each case, with Ferro Phanstiehl Laboratories, ("Ferro"), pursuant to which Ferro will manufacture and exclusively supply to us our global supply of Clofarabine and perform a scale-up of this compound for commercial use. The term of the supply agreement is five-years from the first product regulatory approval for Clofarabine, subject to certain early termination rights.

Scientific Advisory Board / Modrenal Launch

In December 2002, the Company's scientific advisory board convened at the Meeting of the American Society of Hematologists in Philadelphia, PA and reviewed the clinical trial results to date and planned future clinical trials for clofarabine.

In May 2003, the Company's scientific advisory board met to review and discuss the design and strategy for the forthcoming clinical trials for modrenal, globally, for patients with breast cancer.

In May 2003, the Company launched the marketing of modrenal in the United Kingdom for breast cancer at the Royal College of Surgeons in London, England.

Recent Accounting Pronouncements

In July 2002, the FASB Issued Statement 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Cost to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The principal difference between this Statement and Issue 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. Effective January 1, 2003, the Company adopted the provisions of SFAS 146 which did not have an impact on the results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45, "Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). FIN 45 requires that certain guarantees be initially recorded at fair value, which is different from the general current practice of recording a liability only when a loss is probable and reasonably estimable. FIN 45 also requires a guarantor to make significant new disclosures for virtually all guarantees. Effective January 1, 2003, the Company adopted the disclosure requirements under FIN 45 which did not have a material impact on the results of operations or financial position of the Company.

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 January 2003, the FASB issued interpretation No. 46, "Consolidation of Variable Interest Entities--An Interpretation of ARB No. 51" ("FIN 46"), which addresses consolidation of variable interest entities. FIN 46 expands the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disburse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and variable interest entities in which an enterprise obtains and interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material impact on the results of operation or financial position of the Company.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (SFAS 150"). The objective of SFAS No. 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial statements entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. The adoption of SFAS 150 is not expected to have a material impact on the results of operations or financial position of the Company.

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 August 2003, we entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, we succeeded to the U.K. marketing rights to modrenal.

In August 2003, we received notice that our application to list our shares of common stock had been approved by the American Stock Exchange under the symbol "BIV". Our shares of common stock commenced trading on the American Stock Exchange on September 8, 2003.

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.

In September 2003, we entered into a letter agreement with ILEX Oncology, Inc. pursuant to which we are working with ILEX to co-develop an oral formulation for clofarabine; the rights and related costs to which we agreed to split equally with ILEX.

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.

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

Our executive officers, directors and other significant employees and their ages and positions are as follows:

Name of Individual	Age	Position with Bioenvision and Subsidia
Christopher B. Wood, M.D.	57	Chairman of the Board and Chief Execut
David P. Luci, C.P.A., J.D.	36	Director of Finance, General Counsel a
Hugh Griffith	35	Commercial Director (Europe) (2)
Jeffrey B. Davis	40	Director (3)
Thomas Scott Nelson, C.A.	64	Director (4)
Steven A. Elms	39	Director (4)
Andrew Schiff, M.D.	38	Director (3) (4)

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(1) Mr. Luci has been employed with the Company since July 22, 2002.
(2) Mr. Griffith has been employed with Bioenvision, Ltd, a wholly-owned subsidiary of the Company, since October 6, 2002.
(3) Member of the Compensation Committee since September 5, 2002.
(4) Member of the Audit Committee since September 5, 2002.

Christopher B. Wood, M.D. has served as our Chairman of the Board and Chief Executive Officer since January 1999. From January 1997 to December 1998, Dr. Wood was Chairman of Eurobiotech, Inc. From March 1994 to January 1997, Dr. Wood was a specialist surgeon in the National Health Service, United Kingdom. From April 1979 to March 1991, Dr. Wood was a specialist surgeon at The Royal Postgraduate Medical School, London, England. He has more than 15 years experience in the European biotechnology sector. He has taken two biotechnology companies from start-up through commercialization, one of which, Medeva Plc., traded on the London Stock Exchange and the New York Stock Exchange, and is now wholly owned by Celltech Group PLC, the other being Genethics Ltd which was sold to Proteus International plc. Dr. Wood holds an M.D. from the University of Wales School of Medicine and the Fellowship of the Royal College of Surgeons of Edinburgh.

David P. Luci, C.P.A., Esq. has served as Director of Finance, General Counsel and Corporate Secretary since July 2002. From September 1994 to July 2002, Mr. Luci served as a corporate associate at Paul, Hastings, Janofsky & Walker LLP (New York office). Prior to that, Mr. Luci served as a senior auditor at Ernst & Young LLP (New York office). Mr. Luci is a certified public accountant. He holds a Bachelor of Science in Business Administration with a concentration in accounting from Bucknell University and a J.D. from Albany Law School of Union University.

Hugh S. Griffith has served as Commercial Director (Europe) of Bioenvision, Ltd., a wholly-owned sales and marketing subsidiary of the Company since October 2002. From January 2002 to October 2002, Mr. Griffith served as Executive Commercial Director of QuantaNova Ltd. From January 2000 to December 2001, Mr. Griffith served as Senior Business Unit Manager at Abbott Laboratories, Ltd. where he was responsible for strategic development, implementation and commercialization of a new neonatology business unit. This role encompassed the management of the sales force, marketing, PR, policy and healthcare liaison teams whilst also directing the clinical development programme for the neonatology portfolio. From April 1998 to January 2000, Mr. Griffith was the HIV Business Unit Manager at Abbott Laboratories Ltd where he was responsible for the profitability of the HIV franchise. Mr Griffith managed the Norvir capsule crisis including the fully comprehensive named patient programme. At Abbott Laboratories Ltd., Mr. Griffith also served as Business Development Manager (July 1997 to April 1998) and as Area Sales Manager (October 1995 to July 1997). Mr. Griffith holds a Masters of Business Administration from Cardiff Business School, a Diploma of Marketing and a Bachelor of Science in Honours Biology from University of Stirling.

Thomas Scott Nelson, C.A. was named a director in May 1998. Mr. Nelson served as our Chief Financial Officer from May 1998 to September 2002. From 1996 to 1999, Mr. Nelson served as the Director of Finance of the Management Board of the Royal & Sun Alliance Insurance Group. From 1991 to 1996, Mr. Nelson served as

Group Finance Director of the Main Board of Sun Alliance Insurance Group. He has served as Chairman of the United Kingdom insurance industry committee on European regulatory, fiscal and accounting issues. He has also worked with Deloitte in Paris and as a consultant with PA Consultants Management. Mr. Nelson is a Member of Institute of Chartered Accountants of Scotland and a Fellow of the Institute of Cost and Management Accountants. Mr. Nelson holds a B.A. degree from Cambridge University.

Jeffrey B. Davis was named a director in February 2002. Mr. Davis has extensive experience in investment banking, and corporate development and financing for development stage companies. Mr. Davis serves as President of SCO Financial Group LLC and SCO Securities LLC. He served as Senior Vice President and Chief Financial Officer of a publicly traded development stage healthcare technology company from November 1995 to April 1997. Prior to that, from June 1990 to November 1995, Mr. Davis was Vice President, Corporate Finance, at Deutsche Morgan Grenfell, both in the U.S. and Europe. Mr. Davis also served in senior marketing and product management positions at AT&T Bell Laboratories and Philips Medical Systems North America, where he was also a member of the technical staff.

Steven A. Elms was named a director in May 2002. Mr. Elms serves as a Managing Director of the Perseus-Soros BioPharmaceutical Fund. For five years prior to joining Perseus-Soros, Mr. Elms was a Principal in the Life Science Investment Banking group of Hambrecht & Quist (now J.P. Morgan H&Q). During his five years at H&Q, Mr. Elms was involved in over 60 financing and M&A transactions, helping clients raise in excess of $3.3 billion of capital. Mr. Elms' primary areas of focus were the genomics and drug discovery technology sectors.

Andrew Schiff, M.D. was named a director in May 2002. Dr. Schiff currently serves as a Managing Director of Perseus-Soros Biopharmaceutical Fund. Over the last 10 years, Schiff has practiced internal medicine at The New York Presbyterian Hospital where he maintains his position as a Clinical Assistant Professor of Medicine. In addition, he has also been a partner of a small family run investment fund, Kuhn, Loeb & Co.

Under the terms of its investment agreement, as amended in April 2001, Bioaccelerate Ltd. has the right to nominate one member to our board of directors. Bioaccelerate Ltd. has not made any such nomination at this time.

Under the terms of the merger agreement with certain former directors of Pathagon, such former directors have the right to nominate another individual to our board of directors. These former directors of Pathagon have not made any such nomination at this time.

The directors serve until the next annual meeting of stockholders and until their respective successors are elected and qualified. Officers serve at the discretion of the board of directors.

Committees of the Board of Directors

The Board of Directors currently has two committees; the Audit Committee and the Compensation Committee. The Board of Directors re-constituted membership of the Audit Committee and Compensation Committee to include non-management directors on such committees.

The Audit Committee is comprised of Messrs. Elms, Schiff and Nelson; with Mr. Elms serving as Chairman of the Audit Committee. The Audit Committee recommends the independent accountants appointed by the Board of Directors to audit our the financial statements, which includes an inspection of our books and accounts, and reviews with such accountants the scope of their audit and their report thereon, including any questions and recommendations that may arise

relating to such audit and report or our internal accounting and auditing system procedures. The Audit Committee reports to the Board of Directors.

The Compensation Committee is comprised of Messrs. Davis and Schiff; with Mr. Davis serving as Chairman of the Compensation Committee. The function of the Compensation Committee is to review and approve the compensation of executive officers and establish targets and incentive awards under our incentive compensation plans. The Compensation Committee reports to the Board of Directors.

Scientific Advisory Committee

In addition to the foregoing committees of the board of directors, the Company has a Scientific Advisory Committee. The Scientific Advisory Committee is comprised of Professor Emillio Montserrat, Nagy Habib, M.D., Ph.D., Michael Keating, M.D., Professor Cecilia Saccone, B.Sr., Professor Wafik El-Deiry, M.D., Ph.D., Professor Anthony Davies, Ph.D., D.Sr. and Professor Daniel Jaeck, M.D. The members of the Scientific Advisory

Committee are each leaders in various disciplines relating to our scientific interests. These individuals were appointed by and report to the Board of Directors and provide critical review and advice pertaining to our product research and development, and business development activities and strategies at the request of management or the Board of Directors. Members of the Scientific Advisory Committee are compensated on a case-by-case basis based on their commitment of time and other factors and are reimbursed for out-of-pocket expenses incurred in serving on the Scientific Advisory Committee. Compensation through stock options or stock purchases may be provided. To our knowledge, none of our Scientific Advisory Committee members have any conflict of interest between his or her obligations to us and his or her obligations to others.

Chief Medical Consultant

George Margetts, M.D. has served as our Chief Medical Consultant since December 1998. Since 1990, he has been Managing Director of Stegram Pharmaceutical Ltd. From 1984 to 1990, Dr. Margetts served as Executive Vice President Research/Managing Director of Sterling Winthrop Group and as its Medical Director between 1971 and 1989. Dr. Margetts holds B. Pharm. and M.Sc. degrees from the University of London and M.R.C.S., L.R.C.P., M.D. and B.S. degrees from University College Hospital Medical School, London.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires Bioenvision's directors and executive officers, and persons who own more than 10% of the outstanding equity securities of Bioenvision, to file initial reports of beneficial ownership and reports of changes in beneficial ownership of equity securities with the SEC and any national securities exchange on which equity securities are listed. These persons are required by SEC regulations to furnish Bioenvision with copies of all Section 16(a) forms they file.

Based upon filings made with the SEC and Bioenvision's records, Bioenvision believes that certain of its directors, executive officers or holders of more than 10% of the outstanding shares of common stock have not filed on a timely basis the reports required by Section 16(a) of the Exchange Act during, or with respect to, the year ended June 30, 2003.

Item 10. Executive Compensation.

The following table sets forth information for each of the fiscal years ended June 30, 2003, 2002 and 2001 concerning the compensation paid and awarded to all individuals serving as (a) our chief executive officer, (b) each of our four other most highly compensated executive officers (other than our chief executive officer) at the end of our fiscal year ended June 30, 2003 whose total annual salary and bonus exceeded $100,000 for these periods, and (c) up to two additional individuals, if any, for whom disclosure would have been provided pursuant to (b) except that the individual(s) were not serving as our executive officers at the end of our fiscal year ended June 30, 2003:

Summary Compensation Table

		Annual compensation			Long term compens		
					Awards		
Name & Principal Position	Year	Salary $	Bonus $	Other Annual Comp-ensation $	Restricted Stock Awards $	Securities underlying options/SARs	LTI
Christopher B. Wood (1)	2003	225,000	-				
	2002	225,000	-				
	2001	180,000	-				
David P. Luci (2)	2003	205,200	57,000(3)				
	2002	-	-				
	2001	-	-				
Hugh Griffith (4)	2003	180,000	20,000				
	2002	-	-				
	2001	-	-				
Stuart Smith (5)	2002	150,000	-				
	2001	150,000	-				
	2000	150,000	-				

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(1) On April 30, 2001, Dr. Wood was granted options to purchase 1,500,000 shares of our common stock. The options are immediately exercisable and originally expired on April 30, 2004 but have been extended to April 30, 2006. On December 31, 2002, Dr. Wood was granted options to

purchase 500,000 shares of our common stock which vest and become exercisable in equal amounts on the first, second and third anniversaries of the December 31, 2002 grant date.

(2) On July 22, 2002, Mr. Luci was granted options to purchase 380,000 shares of our common stock. On March 31, 2003, in connection with the execution of an employment agreement between the Company and Mr. Luci, these options were cancelled and the Company issued options to purchase 500,000 shares of common stock at a then-current fair market value. Of these options, options to purchase 170,000 shares of our common stock are immediately exercisable and, subject to certain circumstances, options to purchase 110,000 shares of common stock vest and become exercisable on each of the first, second and third anniversaries of March 31, 2003, the grant date.

(3) This annual bonus was prorated for the portion of calendar year 2002 within which Mr. Luci was employed by the Company. The net amount of the bonus paid to Mr. Luci after such pro-ration was equal to $25,000.

(4) On October 23, 2002, Mr. Griffith was granted options to purchase 300,000 shares of our common stock at a then-current fair market value. Of these options, options to purchase 100,000 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of October 22, 2002, the grant date.

(5) On April 30, 2001, Mr. Smith was granted options to purchase 500,000 shares of our common stock. The options are immediately exercisable and originally expired on April 30, 2004 but have been extended to April 30, 2006.

Stock Options

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Eligibility and Administration.

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

Shares Available for Issuance Under the Plan

The stock subject to options granted under the plan are shares of the Company's authorized but unissued or reacquired shares of Common Stock. On

March 23, 2004, the closing price of the common stock on the American Stock Exchange of the Common Stock was $8.45 per share. There are 3,000,000 shares reserved for grants of options under the plan. On the same date, there were 22,934,616 shares of Common Stock outstanding.

Grant, Exercise and other Terms of Awards.

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

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

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

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

Cause (as such term is defined in the Amended Award Plan) or if the participant becomes an employee, director or consultant of an entity that the Administrator determines is in direct competition with the Company.

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

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

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

Adjustment of Awards Upon Certain Events.

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

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

performance units, an award of performance units of the surviving or acquiring corporation, or (ii) (a) permit participants with restricted shares to receive unrestricted shares immediately prior to the effective date of any transaction, (b) permit participants with performance units to receive cash with respect to the value of any performance units immediately before the effective date of the transaction and (c) provide participants with options the choice of exercising the option prior to the consummation of the transaction or receiving a replacement option.

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

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

Transfer of Awards.

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

Amendment and Termination.

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

The following table sets forth information concerning option/SAR grants in our fiscal year ended June 30, 2003 to all individuals serving as (a) our chief executive officer, (b) each of our four other most highly compensated executive officers (other than our chief executive officer) at the end of our

fiscal year ended June 30, 2003 whose total annual salary and bonus exceeded $100,000 for these periods, and (c) up to two additional individuals, if any, for whom disclosure would have been provided pursuant to (b) except that the individual(s) were not serving as our executive officers at the end of our fiscal year ended June 30, 2003:

Option/SAR Grants in Last Fiscal Year
Individual Grants

Name	Number of securities underlying options/SARs granted (#)	Percent of total options/SARs granted to employees in fiscal year	Exercise or base price ($/Share)
Christopher B. Wood	500,000	35.84%	$1.45
David P. Luci	500,000	35.84%	$.74
Hugh Griffith	300,000	21.51%	$1.45
All Executive Officers	1,300,000	93.19%	n/a

Employment Agreements

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

On September 1, 1999, we entered into an employment agreement with Christopher B. Wood, M.D. under which he serves as our Chairman and Chief Executive Officer. The initial term of Dr. Wood's employment agreement is two years with automatic one-year extensions thereafter unless either party gives

written notice to the contrary. On December 31, 2002, we entered into a new employment agreement with Dr. Wood, under which he continues to serve as our Chairman and Chief Executive Officer. Under this contract, the term is one year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. Dr. Wood's new employment agreement provides for an initial base salary of $225,000, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to 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 January 1, 2000, we entered into an employment agreement with Stuart Smith under which he serves as our Senior Vice President. The initial term of Mr. Smith's employment agreement is two years, with automatic one-year extensions thereafter unless either party gives written notice to the contrary. Mr. Smith's agreement provides for an initial base salary of $150,000, a bonus as determined by the board of directors, life insurance benefits equal to his annual salary, health insurance and other benefits currently or in the future provided to our key employees. On September 30, 2002, Mr. Smith resigned from his position as Senior Vice President of the Company; his employment agreement was terminated and the Company agreed to issue shares of its common stock to Mr. Smith at the then current fair market value in satisfaction of all outstanding obligations of the Company to Mr. Smith pursuant to the employment agreement.

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

Director Compensation

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

Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information regarding the beneficial ownership of common stock, as of September 15, 2003, by (i) each person whom we know to beneficially own 5% or more of the common stock, (ii) each of our directors, (iii) each person listed on the Summary Compensation Table set forth under "Executive Compensation" and (iv) all of our directors and executive officers. The number of shares of common stock beneficially owned by each stockholder is determined in accordance with the rules of the Commission and does not necessarily indicate beneficial ownership for any other purpose. Under these rules, beneficial ownership includes those shares of common stock over which the stockholder exercises sole or shared voting or investment power. The percentage ownership of the common stock, however, is based on the assumption, expressly required by the rules of the Commission, that only the

person or entity whose ownership is being reported has converted or exercised common stock equivalents into shares of common stock; that is, shares underlying common stock equivalents are not included in calculations in the table below for any other purpose, including for the purpose of calculating the number of shares outstanding generally. The table below does not reflect the right of ILEX to purchase from us $1.0 million of our common stock at the then applicable market price within 30 days of the completion of the Phase II trial for Clofarabine, and an additional $2.0 million of our common stock at the then applicable market price within 30 days of submittal to the FDA of the NDA for Clofarabine.

NAME	BENEFICIAL OWNERSHIP OF STOCK
Perseus-Soros Biopharmaceutical Fund, LP (2) 888 Seventh Avenue, 29th Floor New York, New York 10106	9,000,000
OrbiMed Advisors Inc. (3) 767 Third Avenue, 30th Floor New York, New York 10017	3,000,000
Merlin Biomed Private Equity Fund LP (4) 230 Park Avenue, Suite 928 New York, New York 10169	1,000,002
DWS Investment GmbH (5) Gruneburgweg M3-M5 60323 Frankfurt Germany	1,299,999
SCO Capital Partners LLC (6) 1285 Avenue of the Americas, 35th Floor New York, New York 10019	7,409,946
Kevin Leech (7) The Old Chapel Sacre Couer Rouge Boullion St Helier Jersey, Channel Islands	1,900,000
Lifescience Ventures Limited (8) Suite F8 International Commercial Centre Gibraltar	887,500
Estate of David Chester (9)	887,500
Bioaccelerate, Inc. (10) PO Box 3175 Road Town Tortolla British Virgin Islands	2,181,816

Christopher B. Wood, M.D. (11) c/o Bioenvision, Inc. 509 Madison Avenue, Suite 404 New York, New York 10022.....	4,457,342
Stuart Smith (12) c/o Bioenvision, Inc. 509 Madison Avenue, Suite 404 New York, New York 10022.....	700,000
David P. Luci (13) c/o Bioenvision, Inc. 509 Madison Avenue, Suite 404 New York, New York 10022.....	170,000
Hugh Griffith c/o Bioenvision, Inc. 509 Madison Avenue, Suite 404	

NAME	BENEFICIAL OWNERSHIP OF STOCK
New York, New York 10022	0
Thomas Scott Nelson (14) c/o Bioenvision, Inc. 509 Madison Avenue, Suite 404 New York, New York 10022.....	287,523
Jeffrey B. Davis (15) 1285 Avenue of the Americas, 35th Floor New York, New York 10019.....	749,243
Steven A. Elms 888 Seventh Avenue, 29th Floor New York, New York 10106.....	0
Andrew N. Schiff, M.D. 888 Seventh Avenue, 29th Floor New York, New York 10106.....	0
All Executive Officers and Directors as a group (six persons) (16).....	6,364,108

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

(1) Based on a total of 17,417,739 shares of common stock outstanding as of September 15, 2002.

(2) Includes 3,000,000 shares of Series A Preferred Stock currently convertible into 6,000,000 shares of common stock at a conversion price of $1.50 and a warrant to purchase 3,000,000 shares of common stock exercisable at $2.00 per share for five years from May 8, 2002. Based upon information contained in its report on Schedule 13D filed with the Commission on May 20, 2002, Perseus-Soros BioPharmaceutical Fund, L.P. reported that Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners may be deemed to have sole power to direct the voting and disposition of the 9,000,000 shares of common stock. By virtue of the relationships between and among Perseus-Soros BioPharmaceutical Fund, L.P., Perseus-Soros Partners, LLC, Perseus BioTech Fund Partners, LLC, SFM Participation, L.P., SFM AH, Inc., Frank H. Pearl, George Soros, Soros Fund Management LLC, Perseus EC, LLC, Perseuspur, LLC, each of such Perseus entities, other than Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners, may be deemed to share the power to direct the voting and disposition of the 9,000,000 shares of common stock.

(3) Includes 669,964 shares of Series A Preferred Stock currently convertible into 1,339,928 shares of common stock at a conversion price of $1.50 and a warrant to purchase 669,964 shares of common stock exercisable at $2.00 per share for five years from May 16, 2002, both of which are held by Caduceus Private Investments, LP; 13,945 shares of Series A Preferred Stock currently convertible into 27,980 shares of common stock at a conversion price of $1.50 and a warrant to purchase 13,945 shares of common stock exercisable at $2.00 per share for five years from May 16, 2002, both of which are held by OrbiMed Associates LLC; and 316,091 shares of Series A Preferred Stock currently convertible into 632,182 shares of common stock at a conversion price of $1.50 and a warrant to purchase 316,091 shares of common stock exercisable at $2.00 per share for five years from May 16, 2002, both of which are held by PW Juniper Crossover Fund, L.L.C. Based upon information contained in its report on Schedule 13G filed with the Commission on June 21, 2002, OrbiMed Advisors Inc., OrbiMed Advisors LLC, OrbiMed Capital LLC and Samuel D. Isaly reported that they share the power to direct the voting and disposition of the 3,000,000 shares of common stock.

(4) Includes 333,334 shares of Series A Preferred Stock currently convertible into 666,668 shares of common stock at a conversion price of $1.50 and a warrant to purchase 333,334 shares of common stock exercisable at $2.00 per share for five years from May 8, 2002. Based upon information contained in its report on Schedule 13G filed with the Commission on June 28, 2002, Merlin BioMed Private Equity Fund, L.P. reported that it shares the power to direct the voting and disposition of the 1,000,002 shares of common stock with Merlin

BioMed Private Equity, LLC, its general partner and Dominique Semon, who is the sole managing member of the general partner.

(5) Includes 433,333 shares of Series A Preferred Stock currently convertible into 866,666 shares of common stock at a conversion price of $1.50 and a warrant to purchase 433,333 shares of common stock exercisable at $2.00 per share for five years from May 14, 2002. Deutsche Bank AG has sole voting and investment power with respect to these shares.

(6) Includes a warrant to purchase 1,200,000 shares of common stock exercisable at $1.25 per share for five years from November 16, 2001; a warrant to purchase 688,333 shares of common stock exercisable at $1.50 per share for five years from May 8, 2002; a warrant to purchase 100,000 shares of common

stock exercisable at $1.25 per share Financial Group LLC for five years from November 16, 2001 held by SCO; a warrant to purchase 70,000 shares of common stock exercisable at $1.50 per share for five years from May 8, 2002 held by SCO Financial Group LLC; a warrant to purchase 150,000 shares of common stock exercisable at $1.25 per share for five years from November 16, 2001 held by the Sophie C. Rouhandeh Trust; and a warrant to purchase 150,000 shares of common stock exercisable at $1.25 per share for five years from November 16, 2001 held by the Chloe H. Rouhandeh Trust. Steven H. Rouhandeh, in his capacity as President of SCO Capital Partners LLC, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.

(7) These shares are owned of record by Phoenix Ventures Limited, a Channel Islands (Jersey) corporation, which, to our knowledge, is wholly-owned by Kevin Leech. These shares include 500,000 options which are exercisable at $1.25 per share for the benefit of Phoenix.

(8) Lifescience Ventures is a Gibraltar limited company owned of record by a Gibraltar trust. Lee J. Cole, in his capacity as the trustee of the trust, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.

(9) These shares are owned of record by General Capital Limited, a Bermuda corporation which, to our knowledge, is wholly-owned by the Estate of David Chester, a private investor.

(10) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors and includes options to acquire 1,454,544 shares of the common stock which are exercisable at $1.25 per share for five years from April 30, 2001. Barbara Platts, in her capacity as Managing Director of Bioaccelerate, Inc., has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.

(11) Includes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest, and 1,500,000 options which are exercisable at $1.25 for five years from April 30, 2001. Also includes 500,000 options which are exercisable at $1.45 from December 31, 2002.

(12) Includes options to acquire 500,000 shares of the common stock which are exercisable at $1.25 per share for five years from April 30, 2001.

(13) Includes options to acquire 170,000 shares of common stock which are exercisable at $0.735 per share from March 31, 2003.

(14) Includes options to acquire 200,000 shares of the common stock which are exercisable at $1.25 per share for five years from April 30, 2001.

(15) Includes a warrant to purchase 250,000 shares of common stock exercisable at $1.50 per share for five years from May 8, 2002. Mr. Davis is the President of SCO Financial Group LLC, an affiliate of SCO Capital Partners LLC. Mr. Davis disclaims beneficial ownership of all shares of common stock deemed beneficially owned by SCO Capital Partners LLC.

(16) Includes shares of common stock owned by Christopher B. Wood, Stuart Smith, Thomas Nelson, Jeffrey Davis, Steven A. Elms and Andrew Schiff, M.D. Also includes (a) 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest, (b) Christopher Wood's options to acquire 1,500,000 shares of common stock, (c) Stuart Smith's options to acquire 500,000 shares of common stock, (d) David Luci's options to acquire 50,000 shares of common stock, (e) Thomas

Nelson's options to acquire 200,000 shares of common stock and (e) Jeffrey B. Davis' warrant to purchase 250,000 shares of common stock.

Item 12. Certain Relationships and Related Transactions.

In August 2001 Bioenvision issued 208,333 shares at the rate of $1.25 per share as follows: Christopher B. Wood, 98,684 shares; Thomas Nelson, 27,412 shares; and Stuart Smith, 82,237 shares.

In August 2001, we obtained a $1 million line of credit facility, which expires in September 2002, from Jano Holdings Limited, one of our shareholders. This credit facility was terminated in May 2002.

In October 2001, we issued 134,035 shares of common stock to officers as payment for salaries accrued to September 30, 2001.

On November 16, 2001, we entered into an engagement letter with SCO Capital, 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. Pursuant to this engagement letter, among other things, SCO Capital performs investor relations services for the Company and earns a monthly fee of $9,000 per month in connection therewith.

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.

On February 5, 2002, we completed the acquisition of Pathagon Inc. 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, we completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for $3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock. An affiliate of SCO Capital Partners LLC, one of our stockholders, served as financial advisor to the Company in connection with this financing and earned a placement fee of approximately $1,200,000 in connection therewith. This affiliate of SCO Capital Partners LLC continues to serve as a financial advisor to the Company.

Item 13. Exhibits, List 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)
3.2	Amended and Restated By-Laws of the Registrant. (13)
3.2(a)	Amendment to Bylaws, effective April 30, 2002 (6)
4.1	Certificate of Designation (6)
4.2	Form of Warrant (6)
4.3	Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
4.4	Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)
10.1	Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc.
10.2	Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
10.3	Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc.
10.4	Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998. (3)
10.5	Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
10.5(a)	Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
10.6	License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc

10.7	Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
10.8	Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003 (14)
10.9	Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
10.10	Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
10.11	Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
10.12	Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
10.13	Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)

10.14	Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
10.15	Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Chirstopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
10.16	Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
10.17	Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
10.18	Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
10.19	License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
10.20	Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
10.21	Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)

10.22	License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
10.23	Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
10.24	Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
10.25	Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
10.26	Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
10.27	Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC(14)
16.1	Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
16.2	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
16.3	Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)

21.1	Subsidiaries of the registrant (4)
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.

(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.

Item 14. Controls and Procedures.

(a) Certificate of Chief Executive Officer.

I, Christopher B. Wood, certify that:

1. I have reviewed this annual report on Form 10-KSB/A of Bioenvision, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements

were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14 for the registrant and have:

a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 1, 2004

/s/ Christopher B. Wood

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

(b) Certificate of Director of Finance.

I, David P. Luci, certify that:

7. I have reviewed this annual report on Form 10-KSB/A of Bioenvision, Inc.;

8. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

9. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

10. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14 for the registrant and have:

a. designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b. evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c. presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

11. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

12. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: April 1, 2004

/s/ David P. Luci

David P. Luci
Director of Finance, General Counsel and
Corporate Secretary
(Principal Accounting Officer)

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REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

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, 2003 and 2002 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 auditing standards generally accepted in the United States of America. 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, 2003 and 2002, 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 22, 2003

Bioenvision, Inc. and Subsidiaries
CONSOLIDATED BALANCE SHEETS

	June 30, 2003	June 30, 2002
ASSETS		
Current assets		
Cash and cash equivalents	$ 7,929,686	$ 12,882,521
Restricted cash	290,000	
Deferred costs - current	22,727	184,091
Accounts receivable	25,000	50,000
Other assets	105,976	
Total current assets	8,373,389	13,116,612
Property and equipment, net	49,265	587
Deferred costs - long term	224,937	
Intangible assets, net	15,779,399	16,921,792
Goodwill	3,902,705	4,704,100
Security deposits	79,111	
Other Long term assets	126,869	
Total assets	$ 28,535,675	$ 34,743,091
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 411,392	$ 434,316
Accrued expenses	730,722	1,513,859
Accrued dividends payable	1,009,146	131,328
Deferred revenue - current	113,636	368,182
Total current liabilities	2,264,896	2,447,685
Deferred revenue - long term	1,124,685	
Deferred tax liability - non-current	6,317,702	7,656,000
Total liabilities	9,707,283	10,103,685
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity		
Preferred stock - $0.001 par value;		

5,920,000 shares authorized and 5,916,966 shares issued and outstanding at June 30, 2003 and June 30, 2002, respectively (liquidation preference $17,750,898)	5,917	5,917
Common stock - $0.001 par value; 50,000,000 shares authorized and 17,122,739 and 16,887,786 shares issued and outstanding at June 30, 2003 and June 30, 2002, respectively	17,123	16,887
Additional paid-in capital	47,304,449	45,491,555
Accumulated deficit	(28,651,443)	(21,027,299)
Accumulated other comprehensive income	152,346	152,346
Stockholders' equity	18,828,392	24,639,406
Total liabilities and stockholders' equity	$ 28,535,675	$ 34,743,091

The accompanying notes are an integral part of these statements.

Bioenvision, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended June 30,	
	2003	2002
Revenue	$ 504,857	$ 802,965
Costs and expenses		
Research and development	1,689,278	1,912,258
General and administrative	4,567,413	2,127,664
Depreciation and amortization	1,344,969	579,342
Total costs and expenses	7,601,660	4,619,264
Loss from operations	(7,096,803)	(3,816,299)
Interest income (expense)		
Interest and finance charges	(325,000)	(2,172,682)
Interest income	138,574	

	(186,426)	(2,172,682)
Net loss before income tax benefit	(7,283,229)	(5,988,981)
Income tax benefit	536,903	253,000
NET LOSS	(6,746,326)	(5,735,981)
Cumulative preferred stock dividend	(877,818)	(131,328)
Beneficial conversion preferred stock dividend		(9,351,339)
Net loss available to common stockholders	$(7,624,144)	$(15,218,648)
Basic and diluted net loss per share of common stock	$ (0.45)	$ (1.25)
Weighted-average shares used in computing basic and diluted net loss per share	16,920,939	12,184,152

The accompanying notes are an integral part of these statements.

Bioenvision, Inc. and Subsidiaries

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Preferred Stock		Common Stock		Additional Paid In	Acccumla
	Shares	$ -	Shares	$ -	Capital	Defici
Balance at June 30, 2001			8,248,919	8,249	3,165,540	(5,808
Net loss for the year						(5,735
Shares issued to employees for accrued salaries			1,048,352	1,048	1,269,864	

Shares issued to consultants for services			390,515	391	168,083	
Shares issued in connection with acquisition of Pathagon			7,000,000	7,000	12,484,926	
Shares issued in connection with licensing agreement - OMRF			200,000	200	619,800	
Warrants issued in connection with licensing agreement - OMRF					425,600	
Gross proceeds from issuance of preferred stock	5,916,966	5,917			17,744,081	
Direct costs incurred to issue preferred stock					(3,911,906)	
Cumulative preferred stock dividend						(131,
dividend Beneficial conversion preferred stock dividend					9,351,339	(9,351,
Warrants issued in connection with credit facility					1,872,000	
Warrants issued for services rendered					2,302,228	
Balance at June 30, 2002	5,916,966	5,917	16,887,786	16,888	45,491,554	(21,027,
Net loss for the year						(6,746,
Cumulative preferred stock dividend						(877,
Shares issued to consultants for services			234,953	235	1,258,080	
Warrants issued in connection with services					182,350	
Rrepricing of options					372,465	
Balance at June 30, 2003	5,916,966	$5,917	17,122,739	$17,123	$47,304,449	$(28,651

The accompanying notes are an integral part of this statement.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ende June 30,
	2003
Cash flows from operating activities	
Net loss	
Adjustments to reconcile net loss to net	$ (6,746,326)
cash used in operating activities	
Depreciation and amortization	1,344,969
Financing charges - noncash	
Amortization of deferred tax liability	(536,903)
Compensation costs - shares and warrants issued to nonemployees	1,440,429
Compensation costs - re-pricing of options	372,465
Changes in assets and liabilities	
Deferred costs	(63,573)
Deferred revenue	870,139
Accounts payable	(22,924)
Other current assets	(105,976)
Other long term assets	(126,869)
Accounts receivable	25,000
Security deposits	(79,111)
Officer's salary for equity conversion	
Other accrued expenses and liabilities	(782,901)
Net cash used in operating activities	(4,411,581)
Cash flows from investing activities	
Purchase of intangible assets	(191,848)
Capital expenditures	(59,406)
Restricted cash	(290,000)
Net cash used in investing activities	(541,254)
Cash flows from financing activities	
Bank overdraft	
Proceeds from loan financing	
Repayment of loan financing	
Proceeds from issuance of preferred stock	
Costs incurred in connection with offering	
Net cash provided by financing activities	
Net (decrease) increase in cash and cash equivalents	(4,952,835)
Cash and cash equivalents, beginning of year	12,882,521

Cash and cash equivalents, end of year	$ 7,929,686
	==========
Supplemental disclosure of cash flow information:	
Cash paid during the year for	
Interest	$ -
Supplemental disclosure of noncash investing and financing activities:	
Noncash conversion of officer's salary into common stock	$ -
Noncash conversion of trade payables into common stock	$ -
Noncash issuance of warrants related to SCO financing agreement	$ -
Noncash issuance of warrants in connection with preferred stock	$ -
Noncash issuance of stock related to Pathagon acquisition	$ -
Noncash issuance of warrants and shares related to OMRFA	$ -

The accompanying notes are an integral part of these statements.

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2003 AND 2002

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. 101, 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. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is 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. 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, which approximates the life of the patent.

Research and development

Research and development costs are charged to expense as incurred.

Stock based compensation

At June 30, 2003, the Company has stock based compensation plans which are described more fully in Note 9. 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. Under APB 25, no stock based employee compensation cost is reflected in reported net loss, as all options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant. For year ended June 30, 2003, the Company recognized stock based employee compensation cost of $372,465 as a result of the March 31, 2003 re-pricing of 380,000 options granted to an employee pursuant to the terms of his Employment Agreement (see Note 7).

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.

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,	
	2003	2002
Net loss available to common stockholders, as reported	$(7,624,144)	$(15,218,6
Add: Stock based employee compensation expense included in reported net loss	372,465	--
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards	(1,214,723)	--
Pro forma net loss available to common stockholders	$(8,466,402)	$(15,218,6
Loss per share		
Basic and diluted - as reported	$(0.45)	$(1.25)
Basic and diluted - pro forma	$(0.50)	$(1.25)

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

	2003
Expected life (years)	4.00
Risk free interest rate	3.00%
Expected volatility	80%
Expected dividend yield	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 15,749,543 and 13,604,543 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2003 and 2002, respectively, as their effect would have been anti-dilutive.

Foreign currency translation

Through June 30, 2001, the functional currency of the Company was the Pound Sterling and its reporting currency was the United States dollar. Translation adjustments arising from differences in exchange rates from these transactions were reported

as accumulated other comprehensive income in stockholders' equity (deficit). Effective July 1, 2001, the functional and reporting currency is the United States dollar.

Note 1 - Organization and significant accounting policies - continued

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.

Advertising costs

Costs related to advertising and other promotional expenditures are expensed as incurred. Advertising costs totaled $144,300 and $4,850, respectively, for the years ended June 30, 2003 and 2002, respectively.

Deferred costs

Deferred costs represents royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology advance royalties. These costs have been presented together with research and development costs on the statement of operations for the years ended June 30, 2003 and 2002.

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 an estimated three-year useful life.

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.

Impact of recently issued accounting pronouncements

In July 2002, the FASB Issued Statement 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS

146"). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Cost to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The principal difference between this Statement and Issue 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. Effective January 1, 2003, the Company adopted the provisions of SFAS 146 which did not have an impact on the results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45, "Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). FIN 45 requires that certain guarantees be initially recorded at fair value, which is different from the general current practice of recording a liability only when a loss is probable and reasonably estimable. FIN 45 also requires a guarantor to make significant new disclosures for virtually all guarantees. Effective January 1, 2003, the Company adopted the disclosure requirements under FIN 45 which did not have a material impact on the results of operations or financial position of the Company.

Impact of recently issued accounting pronouncements - continued

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 January 2003, the FASB issued interpretation No. 46, "Consolidation of Variable Interest Entities--An Interpretation of ARB No. 51" ("FIN 46"), which addresses consolidation of variable interest entities. FIN 46 expands the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disburse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and variable interest entities in which an enterprise obtains and interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material impact on the results of operation or financial position of the Company.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (SFAS 150"). The objective of SFAS No. 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. The adoption of SFAS 150 is not expected to have a material impact on the results of operations or financial position of the Company.

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.

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 vivos

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, 2003	June 30, 2002
Patents and licensing rights	$17,644,521	$17,487,548
Less: accumulated amortization	1,865,122	565,756
	$15,779,399	$16,921,792

Amortization of patents and licensing rights amounted to $1,334,241 and $561,832 for the years ended June 30, 2003 and June 30, 2002, respectively. Amortization for each of the next five fiscal years will amount to approximately $1,342,000 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. The Company also granted Ilex an option to purchase $1 million of Common Stock after completion of the pivotal Phase II clinical trial, and ILEX has an additional option to purchase $2 million of Common Stock after the filing of a new drug application in the United States for the use of Clofarabine in the treatment of lymphocytic leukemia. The exercise price per share for each option is determined by a formula based around the date of exercise. Under the co-development agreement, ILEX also pays royalties to Southern Research Institute based on certain milestones. The Company is obligated to milestones and royalties to Southern Research Institute in respect to Clofarabine.

The Company received a nonrefundable, upfront payment of $1.35 million when they entered into the agreement with ILEX and is entitled to receive milestone payments of $2.5 million upon completion of management designed pivotal Phase II clinical trials of Clofarabine and $5.0 million after submission of a new drug application with the FDA. The upfront payment was deferred and recognized as revenues ratably, on a straight-line basis concurrent with certain development activities described in the contract, through December 2002. The Company recognized revenues of approximately $490,000 and $800,000_in connection with the up-front payment of ILEX agreement for the years ended June 30, 2003 and 2002, respectively.

Deferred costs represents royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology. The Company also 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 Ilex agreement. Research and Development includes approximately $207,000 and $368,000 for the years ended June 30, 2003 and 2002, respectively, related to such charges.

Note 4 - License and Co-Development Agreements - continued

Modrenal(R)

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

Anti-Estrogen Prostate. We have received Institutional Review Board approval from the Massachusetts General Hospital for a Phase II study of trilostane for the treatment of androgen independent prostate cancer. The study will be conducted by The Dana Faber Cancer Institute and currently is intended to commence in October 2003.

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 Bioenvisions 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. Through June 30, 2003, the Company paid and capitalized $50,000 related to development costs.

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

In May 2003, we entered into a master services agreement with Penn-Pharmaceutical Services Limited ("Penn"), pursuant to which Penn has agreed to label, package and distribute clofarabine on behalf of and at our request. The services to be performed by Penn also include regulatory support and the manufacture , quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of

termination upon no less than three month prior written notice

NOTE 4 - License and Co-Development Agreements - continued

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 in the form of a soft gel capsule. CLL intends to use its proprietary MIDDS.-patented technology to perform this service on behalf of the Company. This new formulation, once in hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell modrenal throughout Europe. Through June 30, 2003, the Company paid and capitalized $175,000 related to development costs over an eighteen month period.

Note 5 - Income taxes

The components of the income tax benefit are as follows:

	June 30,	
	2003	2002
Current:		
Federal	$ --	$ --
State	--	--
Deferred:		
Federal	(404,000)	(160,000)
State	(133,000)	(93,000)
	(537,000)	(253,000)
Total benefit	$(537,000)	$(253,000)

Note 5 - Income taxes - continued

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

	June 30,	
	2003	2002
Deferred tax liability		
Acquired intangibles	$(6,318,000)	$(7,656,000)
Deferred tax assets		
Net operating loss	5,512,000	3,256,000
Depreciation	11,000	13,000
Net deferred revenue	401,000	--
Other	66,000	1,000
Total deferred tax assets	5,990,000	3,270,000
Valuation allowance for deferred tax assets	(5,990,000)	(3,270,000)
Net deferred tax asset	--	--
Net deferred tax liability	(6,318,000)	(7,656,000)

At June 30, 2003, the Company had approximately $13,609,000 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 $5,512,000. 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 the valuation allowance established against the net operating loss deferred tax assets.

NOTE 6 - Stockholders' transactions

Common Stock and Securities Convertible into Common Stock

In April 2001, in accordance with the terms of the Company's stock option plan, the Company issued the following options at an exercise price of $1.25 per share, which immediately vested:

- a total of 2,200,000 options to employees (Christopher Wood - 1,500,000 options; Stuart Smith - 500,000 options; and Thomas Scott Nelson - 200,000 options);
- a total of 2,654,544 options to certain consultants to the Company; and
- a total of 500,000 options to Phoenix Ventures, which were issued in connection with a credit facility made available to the Company by Glen Investments Limited, a Jersey (Cnannel Islands) corporation wholly owned by Kevin R. Leech, a U.K. citizen and one of the Company's stockholders, which facility was terminated in August 2001.

Originally, the terms of the options were that each option could be exercised after April 30, 2001 for a period of three years, whereby the options would no longer be able to be exercised after April 30, 2004 unless otherwise agreed to with the Company. In July 2002, the Company changed the three-year term to a five-year term. The extension of the foregoing options to a five-year term required the Company to record additional compensation, interest and finance charges and consulting fees and expenses of $422,500 in the quarter ended September 30, 2002.

In August 2001, the Board of Directors approved the issuance of 208,333 shares of common stock to its officers and directors in exchange for accrued compensation at a rate of $1.25 per share. In October 2001, the Board of Directors approved the issuance of 134,055 shares of commons stock to its officers and directors in exchange for accrued compensation of approximately $206,000.

In connection with securing the Facility with SCO Capital in November 2001, the Company issued warrants to purchase 1,500,000 shares of the Company's 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 Company measured the fair market value of the warrants and recorded financing costs of $1,872,000, which were amortized over the term of the Facility. 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.

In December 2001, the Company granted 200,000 shares of common stock to a consultant to the Company, these shares vesting over an eighteen month period. Compensation expense of $212,108 and $80,456 were recorded as consulting fees for the years ended June 30, 2003 and 2002, respectively.

On February 1, 2002, in connection with the Company's acquisition of Pathagon, the Company issued 7,000,000 shares of its common stock. In connection with the closing of the acquisition of Pathagon, the Company also entered into Registration Rights Agreements, with the persons or entities who were shareholders of Pathagon, pursuant to which the Company is required to register the offer and resale of the shares of common stock issued in the acquisition. Affiliates of SCO Capital owned 82% of Pathagon prior to the acquisition.

On May 12, 2002, a majority of the Company's shareholders delivered a written consent to authorize amendment of 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 25,000,000 to 50,000,000 and to authorize the issuance of 10,000,000 shares of the Company's Series A Convertible

Preferred Stock. The shareholder action became effective, and the amendment was filed and became effective, on April 30, 2002.

Note 6 - Stockholders' transactions - continued

In March 2002, the Company issued 705,984 shares of common stock to its officers and directors as payment for salaries accrued through June 30, 2001 of $910,000

In June 2002, the Company granted options to David Luci 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 Mr Luci, 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 $372,465 for the year ended June 30, 2003.

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

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

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

On December 31, 2002 the Company issues options to purchase 200,000 shares of common stock at an exercise price of $2.00 per share to a consultant to the Company who performs European regulatory services for the Company. Of these options, options to purchase 66,666 shares of common stock vest on each of the first, second and third anniversary of the grant date. Compensation expense of $24,333 was recorded as consulting fees for the year ended June 30, 2003.

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 (TM) 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 $182,350 was recorded as consulting fees for the year ended June 30, 2003.

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 Participating 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 fo $17.7 million (see Note 8). 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 Participating Preferred Stock. 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 Capital, 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.

NOTE 8 - Stock options

The Company adopted its 2001 Stock Option Plan (the "Plan") on April 30, 2001. The purchase price of stock options under the Plan is determined by the Compensation Committee of the Board of Directors of the Company (the "Committee"). The term is fixed by the Committee, but no incentive stock option is exercisable after 5 years from the date of grant.

In June 2002, the Company granted options to David Luci 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 Mr Luci, 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 record a charge for compensation expense to the extent the vested portions are in the money. Compensation expense recognized as a result of this re-pricing amounted to $372,467 for the year ended June 30, 2003.

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

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

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

On December 31, 2002 the Company issues options to purchase 200,000 shares of common stock at an exercise price of $2.00 per share to a consultant to the Company who performs European regulatory services for the Company. Of these options, options to purchase 66,666 shares of common stock vest on each of the first, second and third anniversary of the grant date. Compensation expense of $24,333 was recorded as consulting fees for the year ended June 30, 2003.

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.

NOTE 8 - Stock options - continued

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

	No. of Shares	Weighted Avg. Exercise Price
Balance - July 1, 2001	2,200,000	$ 1.25
Granted during 2002	-	-
Exercised during 2002	-	-
Forfeiture during 2002	-	-
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

	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	9.13	170,000
$1.25 - $1.45	$ 1.29	3,070,000	8.89	2,210,000
		3,570,000		2,380,000

BIOENVISION, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2003 AND 2002

NOTE 9 - Commitments and Contingencies

Leases

The Company leases 3,229 square feet of office space for its New York headquarters under a non-cancellable operating lease expiring on September 30, 2005. Rent expense in 2003, excluding real estate taxes, insurance and repair costs, was approximately $110,000. At June 30, 2003, total minimum rentals under operating leases with initial or remaining non-cancellable lease terms of more than one year were:

Year ended June 30,	
2004	$193,317
2005	197,873
2006	63,439
2007	10,185
2008	
	$464,814

========

The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision Ltd. in Edinburgh, Scotland.

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 January 1, 2000, we entered into an employment agreement with Stuart Smith under which he serves as our Senior Vice President. The initial term of Mr. Smith's employment agreement is two years, with automatic one-year extensions thereafter unless either party gives written notice to the contrary. Mr. Smith's agreement provides for an initial base salary of $150,000, a bonus as determined by the board of directors, life insurance benefits equal to his annual salary, health insurance and other benefits currently or in the future provided to our key employees. On September 30, 2002, Mr. Smith resigned from his position as Senior Vice President of the Company; his employment agreement was terminated and the Company agreed to issue shares of its common stock to Mr. Smith at the then current fair market value in satisfaction of all outstanding obligations of the Company to Mr. Smith pursuant to the employment agreement.

Note 9 - 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 alleges a breach of contract by the Company and demands 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. The Company believes that the grounds for the complaint are meritless and intends to defend this matter vigorously. If the Company is not able to successfully defend this complaint, management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations.

NOTE 10 - Subsequent Events

In August 2003, we entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, we succeeded to the U.K. marketing rights to modrenal.

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.

In September 2003, we entered into a letter agreement with ILEX Oncology, Inc. pursuant to which we are working with ILEX to co-develop an oral formulation for clofarabine; the rights and related costs to which we agreed to split equally with ILEX.

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 April 1, 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
Director of Finance, General Counsel and
Corporate Secretary

(Principal Financial and
Accounting Officer)

In accordance with the requirements of the Exchange Act, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christopher B. Wood, M.D. Christopher B. Wood, M.D.	Chairman and Chief Executive and Officer and Director (Principal Executive Officer)	April 1, 2004
* David P. Luci	Director of Finance, General Counsel and Corporate Secretary (Principal Financial and Accounting Officer)	April 1, 2004
* Thomas S. Nelson, C.A.	Director	April 1, 2004
/s/ Michael Kauffman Michael Kauffman	Director	April 1, 2004
* Jeffrey B. Davis	Director	April 1, 2004
* Andrew N. Schiff	Director	April 1, 2004
* Steven A. Elms	Director	April 1, 2004