

Edgar Filing: BIOENVISION INC - Form S-3

BIOENVISION INC
Form S-3
October 25, 2004

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Bioenvision, Inc.
(Exact name of registrant as specified in its charter)

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

509 Madison Avenue
Suite 404
New York, New York 10022
(212) 750-6700
(Address, including zip code, and telephone number,
including area code, of registrant's principal executive offices)

David P. Luci, Esq.
Chief Financial Officer and General Counsel
Bioenvision, Inc.
509 Madison Avenue
Suite 404
New York, New York 10022
(212) 750-6700
(Name, address, including zip code, and telephone number,
including area code, of agent for service)

Copy to:
Luke P. Iovine, III, Esq.
Paul, Hastings, Janofsky & Walker LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000

Approximate date of commencement of proposed sale to the public: From
time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant
to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a
delayed or continuous basis pursuant to Rule 415 under the Securities Act of
1933, other than securities offered only in connection with dividend or interest
reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant
to Rule 462(b) under the Securities Act, please check the following box and list
the Securities Act registration statement number of the earlier effective
registration statement for the same offering. _____

Edgar Filing: BIOENVISION INC - Form S-3

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. _____

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier registration statement for the same offering. _____

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

Calculation of Registration Fee

Title of each class of securities to be registered	Proposed maximum aggregate offering price	regist
Common Stock, par value \$.001 per share (2)	\$90,000,000 (3)	

- (1) The aggregate amount to be registered and the aggregate offering price per unit have been omitted pursuant to Securities Act Release No. 6964. The registration fee has been calculated on the basis of the maximum offering price of all securities listed in accordance with Rule 457(o) under the Securities Act of 1933.
- (2) An indeterminate number of shares of common stock of the registrant as may be sold from time to time by the registrant.
- (3) In no event will the aggregate offering price of all securities issued from time to time pursuant to this prospectus exceed \$90,000,000.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Prospectus Subject to completion, October 25, 2004

Edgar Filing: BIOENVISION INC - Form S-3

[BIOENVISION LOGO]

Bioenvision, Inc.

\$90,000,000

Common Stock

From time to time, we may sell our common stock, par value \$.001 per share (the "Common Stock"), in one or more offerings. The specific terms and number of shares of Common Stock so offered will be fully described in supplements to this prospectus. Please read any prospectus supplements and this prospectus carefully before you invest. This prospectus may not be used to sell shares of Common Stock unless accompanied by a prospectus supplement.

Our Common Stock is included for quotation on the Nasdaq National Market under the symbol "BIVN". The last reported sales price of shares of our common stock on October 22, 2004 was \$7.33 per share.

We urge you to read carefully the "Risk Factors" section beginning on page 3 where we describe specific risks associated with an investment in our Common Stock before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The shares of Common Stock may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. See "Plan of Distribution". If any underwriters are involved in the sale of any shares of Common Stock in respect of which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale also will be set forth in a prospectus supplement.

The date of this prospectus is October __, 2004.

TABLE OF CONTENTS

	Page

ABOUT THIS PROSPECTUS.....	1
BIOENVISION, INC.....	1
RISK FACTORS.....	3
FORWARD-LOOKING STATEMENTS.....	12
USE OF PROCEEDS.....	13
DESCRIPTION OF CAPITAL STOCK.....	13
PLAN OF DISTRIBUTION.....	14

Edgar Filing: BIOENVISION INC - Form S-3

LEGAL MATTERS..... 16

EXPERTS..... 16

WHERE YOU CAN FIND MORE INFORMATION..... 16

INCORPORATION BY REFERENCE..... 17

DISCLOSURE OF COMMISSION POSITION ON
INDEMNIFICATION FOR SECURITIES ACT LIABILITIES..... 17

ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission utilizing a "shelf" registration process. Under this shelf process, we may from time to time offer Common Stock described in this prospectus in one or more offerings up to a total dollar amount of \$90,000,000. Each time we use this prospectus to offer shares of Common Stock, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described below under the heading "Where You Can Find More Information".

In this prospectus, "Bioenvision", "we", "us, and "our" and "the Company" refer to Bioenvision, Inc.

BIOENVISION, INC.

You should read the following summary together with the more detailed information, including the consolidated financial statements and the notes thereto and other information, included, or incorporated by reference, in this prospectus.

We are an emerging biopharmaceutical company that develops and markets drugs to treat cancer. Our two lead drugs are clofarabine and Modrenal(R), although we have several other products and technologies under development. As of October 11, 2004, our internal staff consisted of nine full-time and four part-time employees based in New York, New York and Edinburgh, Scotland.

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

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 second quarter of 2005, we intend to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such

Edgar Filing: BIOENVISION INC - Form S-3

territory. We anticipate receiving approval in each such territory during calendar 2005, but such approval is subject to the appropriate regulatory decisions.

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 in Europe for the treatment of pediatric and adult acute leukemias (ALL and AML). We anticipate launching clofarabine in Europe in mid-2005, subject to our obtaining from the European regulatory authorities the first approval for clofarabine which is expected to be for pediatric acute leukemias. We intend to continue clinical trials in other indications with the intention of aggressively seeking label extensions after clofarabine's first approval, including our Pivotal Phase II trial of clofarabine in adults with Acute Myeloid Leukemia (AML) which commenced in August 2004 and is ongoing. Following this strategy, throughout the world, approximately two-thirds of the cancer patients dosed with clofarabine to date fall outside of the pediatric acute leukemias.

In July 2004, we filed for approval of clofarabine in Europe to treat children with pediatric acute leukemia (ALL and AML). Further, we are conducting a Pivotal Phase II clinical trial of clofarabine, as first line therapy for the treatment of adults with Acute Myeloid Leukemia (AML). Also in Europe, at our direction, an Investigator Sponsored Trial of clofarabine as first-line therapy for adults with AML was completed ahead of schedule and an interim analysis indicates a 64% complete response rate observed in this patient population. In January, 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for clofarabine, upon grant of marketing authorization. The drug has also been granted orphan drug status and "fast track" treatment by the FDA. Further, in July 2004, the FDA granted six months of extended market exclusivity to clofarabine under the Best Pharmaceuticals for Children Act.

In the U.S., ILEX Oncology, Inc., our sub-licensor of U.S. and Canadian cancer marketing rights, filed a New Drug Application ("NDA") in March 2004 for approval of clofarabine to treat children with acute leukemias (ALL or AML). The NDA was based upon results of two Pivotal Phase II clinical trials completed by ILEX prior to the NDA filing. In connection with the NDA, the United States Food and Drug Administration (the "FDA") has set a Prescription Drug User Fee Act ("PDUFA") response date at December 30, 2004. A PDUFA date is the date by which the FDA is expected to review and act upon an NDA submission. Clofarabine will be reviewed by the FDA Oncologic Drug Advisory Committee ("ODAC") on December 1, 2004.

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 our 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

Edgar Filing: BIOENVISION INC - Form S-3

to sell, market and distribute clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute clofarabine for cancer indications in the U.S.

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

In the U.S., we filed an IND to conduct Modrenal(R) clinical trials for prostate cancer in February 2004 and commenced enrolling patients in this clinical trial in July 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.

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

We were incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed our name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998. Our principal executive offices are located at 509 Madison Avenue, Suite 404, New York, New York 10022. Our telephone number is (212) 750-6700 and our fax number is (212) 750-6777. Our website is www.bioenvision.com. Information contained on our website does not constitute, and shall not be deemed to constitute, part of this prospectus.

-2-

RISK FACTORS

You should carefully consider the following risks before you decide to buy our Common Stock. All known risks are presented in this prospectus. These risks may adversely affect our business, financial condition or operating results. If any of the events we have identified occur, the trading price of our Common Stock could decline, and you may lose all or part of the money you paid to buy our Common Stock.

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

Since our inception, 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

Edgar Filing: BIOENVISION INC - Form S-3

prospects can be made.

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

To date, we have incurred significant net losses, including net losses of approximately \$11,574,000 for the fiscal year ended June 30, 2004. At June 30, 2004, we had an accumulated deficit of approximately \$41,082,000. We anticipate that we may continue to incur significant operating losses for the foreseeable future. We may never generate material revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

Clinical trials for our products will be expensive and may be time consuming, and their outcome is uncertain, but we must incur substantial expenses that may not result in any viable products

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

Historically, the results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays. Clofarabine currently is at a pivotal stage of its development, but many of our other products and technologies are at various less mature stages of development including l-gossypol for which we have just commenced a Phase I clinical trial in the U.K. and gene therapy which is currently in pre-clinical and phase I clinical testing.

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

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

Edgar Filing: BIOENVISION INC - Form S-3

- o government or regulatory delays.

-3-

Our intangible assets constitute a significant portion of our assets and relate to ancillary products which may not be successfully commercialized

Our ancillary products include OLIGON and Methylene Blue which are anti-microbial agents that we acquired in February 2002. As of June 30, 2004, our intangible assets associated with these products amounted to approximately \$14.6 million and constituted approximately 33% of our total assets and approximately 53% of our stockholders' equity. We amortize approximately \$1.3 million of this amount each year for the estimated useful life of these products of approximately 13 years.

We do not currently devote any significant time or resources to the research and development of OLIGON and Methylene Blue and only intend to do so if and to the extent we successfully commercialize our lead drugs, clofarabine and Modrenal(R), over the next two years. If at any time in the future management determines that the carrying amount of these assets is not recoverable, we would need to write down the value of these assets. Based on the estimated useful life of these assets of approximately 13 years and market considerations, no assurance can be given that there will not be an impairment of these assets in the future. Any impairment of these assets could result in a material impact on our future results of operations.

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

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

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

Edgar Filing: BIOENVISION INC - Form S-3

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

If delays in completion constitute a breach by ILEX or there are certain other breaches of the co-development agreement by ILEX, then, at our discretion, the primary responsibility for completion would revert to us, but there is no assurance that we would have the financial, managerial or technical resources to complete such tasks in timely fashion or at all.

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

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. We are developing clofarabine with ILEX Oncology, our U.S. co-development partner, but on February 26, 2004, Genzyme announced a merger pursuant to which Genzyme intends to acquire ILEX in a merger transaction. If this transaction is consummated, no assurance can be given that the operational and managerial relations with Genzyme will proceed favorably or that the timeline for development of clofarabine will not be elongated. If the U.S. regulatory timeline is elongated, this could materially and adversely affect the European regulatory timeline for the approval of clofarabine.

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

-4-

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:

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

Most of the existing and future products and technologies developed by

Edgar Filing: BIOENVISION INC - Form S-3

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:

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

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

Edgar Filing: BIOENVISION INC - Form S-3

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 be 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

-5-

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

Edgar Filing: BIOENVISION INC - Form S-3

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.

-6-

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

Edgar Filing: BIOENVISION INC - Form S-3

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

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

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

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

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

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

Because many of our competitors have substantially greater capabilities and resources, they may be able to develop products before us or develop more effective products or market them more effectively which would limit our ability

Edgar Filing: BIOENVISION INC - Form S-3

to generate revenue and cash flow

Competition in our industry is intense. Potential competitors in the United States and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Potential competitors for certain indications of our lead drugs include, with respect to clofarabine, Schering AG, which markets fludarabine, and certain generic drug companies in Europe which could market fludarabine upon expiry of the patent protections held by Schering. Potential competitors with respect to Modrenal(R) include Astra-zeneca and Novartis, which market tamoxifen and other aromatase inhibitors, which could be used by clinicians as first and second line therapies in patients with hormone sensitive, advanced, post-menopausal breast cancer prior to a Modrenal(R) regimen

-7-

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

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

If we fail to keep up with rapid technological change and evolving therapies, our technologies and products could become less competitive or obsolete

The pharmaceutical industry is characterized by rapid and significant technological change. We expect that pharmaceutical technology will continue to develop rapidly, and our future success will depend on our ability to develop and maintain a competitive position. Technological development by others may result in products developed by us, branded or generic, becoming obsolete before they are marketed or before we recover a significant portion of the development and commercialization expenses incurred with respect to these products. Alternative therapies or new medical treatments could alter existing treatment regimes, and thereby reduce the need for one or more of the products developed by us, which would adversely affect our revenue and cash flow. See also "--Generic products which third parties may develop may render our products noncompetitive or obsolete" above.

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

We do not currently have any internal product testing capabilities. Our inability to retain third parties for the clinical testing of products on acceptable terms would adversely affect our ability to develop products. Any

Edgar Filing: BIOENVISION INC - Form S-3

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

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

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

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

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

If we lose key management our business will suffer

-8-

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

Edgar Filing: BIOENVISION INC - Form S-3

ancillary technologies. He also maintains a position on the clofarabine management team that is responsible for all drug development activities relating to that lead drug, and has been instrumental in the development and maintenance of our key relationships within the scientific research and medical communities, and those with our vendors, inventors, co-development partners and licensors. If Dr. Wood was no longer employed by the company, the development of our drugs would be significantly delayed and otherwise would be adversely impacted, and we may be unable to maintain and develop these important relationships.

Need for additional personnel

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

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

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

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

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend on our ability to obtain and enforce protection for products that we develop under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. Several of the original patents to Modrenal(R) have expired in the United States and foreign countries. Thus, we and our licensors are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal(R). We cannot guarantee that

Edgar Filing: BIOENVISION INC - Form S-3

such applications will result in issued patents or that such patents if issued will provide adequate protection against competitors. Patents may not be issued from these applications and issued patents may not give us adequate protection or a competitive advantage. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from Southern Research Institute. The current projected expiration date of the license is March 2021. These patents cover pharmaceutical compositions and methods of using clofarabine. We cannot guarantee that these patents would survive an attack on their validity or that they will provide a competitive advantage over our competitors. Moreover, we cannot guarantee that Southern Research Institute was the first to invent the subject matter of these patents. In addition, we are aware of a third party patent which is directed to the treatment of chronic myeloid leukemia ("CML") using specific doses of clofarabine. We do not believe that we will infringe this patent. If this patent is asserted against us, even though we may be successful in defending against such an assertion, our defense would require substantial financial and human resources. And, we may

-9-

need a license to this patent to use the claimed dose in the treatment of CML. However, we do not know if such a license is available at commercially reasonable terms, if at all.

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

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

We require our employees, consultants, members of the scientific advisory board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements may not provide meaningful protection of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information.

Because we have international operations, we will be subject to risks of conducting business in foreign countries

Edgar Filing: BIOENVISION INC - Form S-3

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

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

- o difficulty in establishing or managing distribution relationships;
- o different standards for the development, use, packaging, pricing and marketing of our products and technologies;
- o our inability to locate qualified local employees, partners, distributors and suppliers;
- o the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and
- o 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

As of June 30, 2004, we had stockholders' equity of approximately \$27,383,000 and net working capital of approximately \$18,828,000. However, we may need additional financing to continue to fund the research and development and marketing programs for our products and to generally expand and grow our business. For example, we will need to employ a European sales force within the next twelve months to capitalize on the commercial potential for clofarabine and Modrenal(R) if and to the extent our lead drugs are at market in Europe by mid-2005. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders would result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or accounting methods, even though these actions would otherwise benefit our business. As of June 30, 2004, we had stockholders' equity of approximately \$27,383,000 and net working capital of approximately \$18,828,000.

Edgar Filing: BIOENVISION INC - Form S-3

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

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

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

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

Our products may be subject to recall

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

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

We face exposure to product liability claims if the use of our technologies or products or those we license from third parties is alleged to have resulted in adverse effects to users of such products. Product liability claims may be brought by clinical trial participants, although to date, no such claims have been brought against us. If any such claims were brought against us, the cost of defending such claims may adversely affect our business. Regulatory approval for commercial sale of our products does not mitigate product liability risks. Any precautions we take may not be sufficient to avoid significant product liability exposure. Although we have obtained product liability and clinical trial insurance on our technologies and products at levels with which management deems reasonable, no assurance can be given that this insurance will cover any particular claim or that we have obtained an appropriate level of liability insurance coverage for our development activities. We currently

Edgar Filing: BIOENVISION INC - Form S-3

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.

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 October 22, 2004, our closing stock price has ranged from a high of \$11.75 to a low of \$3.00. If our revenues do not grow or grow more slowly than we anticipate, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our Common Stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in investor confidence or otherwise fails, the market price of our Common Stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, companies that have experienced volatility in the market price of their stock have been the subject of securities class action litigation.

-11-

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 holders of our Common Stock

As of October 22, 2004, we had 28,797,170 shares of Common Stock outstanding, 3,275,000 shares of Series A Convertible Preferred Stock outstanding which are currently convertible into 6,550,000 shares of Common Stock and common stock equivalents, and warrants and stock options, convertible or exercisable into 12,916,868 shares of our Common Stock. The exercise and conversion prices of the common stock equivalents range from \$0.74 to \$8.25 per share. We have also reserved for issuance an aggregate of 3,000,000 shares of Common Stock for a stock option plan for our employees. Historically, from time to time, we have awarded our Common Stock to officers of the Company, in lieu of cash compensation, although we do not expect to do so in the future. As of October 22, 2004, (i) we have 37,750,699 shares of common stock registered under the Securities Act and (ii) the sale of shares of Common Stock underlying 4,500,000 options are registered under the Securities Act on Form S-8. The future resale of these shares and shares underlying stock options and warrants

Edgar Filing: BIOENVISION INC - Form S-3

will result in a dilution to your percentage ownership of our Common Stock and could adversely affect the market price of our Common Stock.

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

FORWARD LOOKING STATEMENTS

Our disclosure and analysis in this prospectus, the applicable prospectus supplement and the documents incorporated by reference into this prospectus and the applicable prospectus supplement contain forward-looking statements, which provide information regarding our current expectations, plans, objectives and forecasts of future events. Words such as "may," "will," "believe," "estimate," "anticipate," "plan," "expect," "may affect," and "intend", or statements concerning "potential" or "opportunity" and similar expressions or the negative thereof, are intended to identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements include, without limitation:

- o statements about our drug development and commercialization goals and expectations;
- o potential regulatory approvals;
- o our plans for and anticipated results of our clinical development activities;
- o the potential advantage of our drug candidates;
- o statements about our future capital requirements, the sufficiency of our capital resources to meet those requirements and the expected composition of our capital resources; and
- o other statements that are not historical facts.

Forward looking statements are based on the judgment of management at the time the statements are made. Inaccurate assumptions and known and unknown risks and uncertainties can affect the accuracy of forward-looking statements. Our actual results could differ materially from those stated in or implied by forward-looking statements for a number of reasons, including the risks described in the sections of this prospectus and the applicable prospectus entitled "Risk Factors," in our other public filings, press releases and statements by our management. Other factors besides those described in this prospectus, the applicable prospectus supplement and in our other public filings, press releases and statements by our management could also affect actual results.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus or the applicable prospectus supplement. We undertake no obligation to publicly update any forward-looking statement to reflect new information, events or circumstances, whether anticipated or unanticipated, or to conform the statement to actual results or

Edgar Filing: BIOENVISION INC - Form S-3

changes in our expectations. You should, however, review the factors, risks and other information we provide in the reports we file from time to time with the SEC.

-12-

USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we intend to use any net proceeds from the sale of Common Stock offered by this prospectus for additional working capital and other general corporate purposes, including, but not limited to, further development of our lead products and increased sales and marketing expenses related to the commercial launch of our products. Until we have used the net proceeds, we may invest them in short-term marketable securities.

DESCRIPTION OF CAPITAL STOCK

Description of Common Stock

Number of Authorized and Outstanding Shares. Our Certificate of Incorporation authorizes the issuance of 70,000,000 shares of common stock, \$.001 par value per share, of which 28,797,170 shares were outstanding on October 22, 2004. All of the outstanding shares of common stock are fully paid and non-assessable.

Voting Rights. Holders of shares of common stock are entitled to one vote for each share on all matters to be voted on by the stockholders. Holders of common stock have no cumulative voting rights. Accordingly, the holders of a simple majority of the outstanding common stock and Series A convertible preferred stock, voting together as a class at a stockholders meeting at which a quorum is present, can elect all of the directors nominated for election at the meeting.

Other. Holders of common stock have no preemptive rights to purchase our common stock. There are no conversion rights or redemption or sinking fund provisions with respect to the common stock.

Transfer Agent. Shares of common stock are registered at the transfer agent and are transferable at such office by the registered holder (or duly authorized attorney) upon surrender of the common stock certificate, properly endorsed. No transfer shall be registered unless we are satisfied that such transfer will not result in a violation of any applicable federal or state securities laws. The transfer agent for our common stock is Liberty Transfer Company, 274B New York Avenue, Huntington, New York 11743.

Description of Preferred Stock

Number of Authorized Shares. Our certificate of incorporation authorizes the issuance of up to 20,000,000 shares of preferred stock, par value \$.001 per share, in one or more series with such limitations and restrictions as may be determined in the sole discretion of our board of directors, with no further authorization by stockholders required for the creation and issuance thereof.

We have designated 5,920,000 shares of our preferred stock as Series A convertible preferred stock, of which 3,275,000 shares were issued and outstanding as of October 22, 2004. The holders of the Series A convertible preferred stock vote as a single class with the common stock, on an as-converted

Edgar Filing: BIOENVISION INC - Form S-3

basis, on all matters upon which the holders of the common stock are entitled to vote. Each outstanding share of Series A convertible preferred stock may currently be converted into two shares of common stock, at the conversion price of \$1.50 per share. The shares of Series A convertible preferred stock shall be automatically convertible into shares of common stock if the market price of the common stock after one year from the date of issuance is \$10.00 or more for 30 consecutive trading days and the trading volume is at least 150,000 shares per trading day during such 30-day period. Holders of Series A convertible preferred stock have a liquidation preference over holders of common stock of \$3.00 per share. Holders of the Series A convertible preferred stock are entitled to an annual 5% dividend which may be paid in cash or additional shares of common stock in our sole discretion.

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

-13-

Delaware Law and Certain By-Law Provisions

Certain provisions of our by-laws are intended to strengthen our board of directors' position in the event of a hostile takeover attempt. These by-law provisions have the following effects:

- o they provide that only business brought before the annual meeting by our board of directors or by a stockholder who complies with the procedures set forth in the by-laws may be transacted at an annual meeting of stockholders; and
- o they establish a procedure for our board of directors to fix the record date whenever stockholder action by written consent is undertaken.

Furthermore, our Company is subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law. In general, the statute prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a "business combination" includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation's voting stock.

PLAN OF DISTRIBUTION

Edgar Filing: BIOENVISION INC - Form S-3

We may sell our securities from time to time by any method permitted by the Securities Act of 1933, including in the following ways:

- o through one or more underwriters on a firm commitment or best efforts basis;
- o directly to one or more purchasers;
- o through agents;
- o through broker-dealers, who may act as agents or principals, including a block trade in which a broker or dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o in privately negotiated transactions; and
- o in any combination of these methods of sale.

The applicable prospectus supplement will set forth:

- o the specific terms of the offering of our securities, including the name or names of any underwriters, dealers or agents;
- o the purchase price of the securities and the proceeds to us from the sale;
- o any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation;
- o the initial offering price to the public and any discounts or concessions allowed or reallocated or paid to dealers; and
- o the name of any securities exchange on which the securities may be listed.

Any public offering price, discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

We expect that any common stock sold pursuant to a prospectus supplement will be listed on the Nasdaq National Market.

-14-

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices (which may be changed), at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices.

Offers to purchase our securities may be solicited by agents designated by us from time to time. Broker-dealers or agents may receive compensation in

Edgar Filing: BIOENVISION INC - Form S-3

the form of commissions, discounts or concessions from us. Broker-dealers or agents may also receive compensation from the purchasers of the securities for whom they sell as principals. Each particular broker-dealer will receive compensation in amounts negotiated in connection with the sale, which might be in excess of customary commissions. Broker-dealers or agents and any other participating broker-dealers participating in the distribution of our securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions.

If required under applicable state securities laws, we will sell the securities only through registered or licensed brokers or dealers. In addition, in some states, we may not sell securities unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

If the securities are sold by means of an underwritten offering, we will execute an underwriting agreement with an underwriter or underwriters, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and dealers, if any, will be set forth in the applicable prospectus supplement, which will be used by the underwriters to make resales of the securities. Under agreements into which we may enter, underwriters, dealers and agents who participate in the distribution of the securities may be entitled to indemnification by us against some liabilities, including liabilities under the Securities Act.

If we use underwriters for an offering of securities, the underwriters may acquire the securities for their own accounts. The underwriters may resell the securities from time to time in one or more transactions at a fixed price or prices, which may be changed, at varying prices determined by the underwriters at the time of sale, or at negotiated prices. We also may, from time to time, authorize underwriters acting as our agents to offer and sell the securities upon the terms and conditions as will be set forth in the applicable prospectus supplement. In connection with the sale of the securities, underwriters may be deemed to have received compensation from us in the form of underwriting discounts or commissions and also may receive commissions from purchasers of the securities. Underwriters may sell the securities to or through dealers, who may receive compensation in the form of discounts, concessions from the underwriters and/or commissions from the purchasers of the securities.

Any underwriting compensation paid by us to underwriters or agents in connection with any offering of the securities and any discounts, concessions or commissions allowed by underwriters to participating dealers will be set forth in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of our securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions.

If so indicated in the applicable prospectus supplement, we may authorize underwriters, dealers or agents to solicit offers from certain types of institutions to purchase securities from us at the public offering price set forth in the applicable prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a future date. Institutions with which delayed delivery contracts may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and

Edgar Filing: BIOENVISION INC - Form S-3

charitable institutions, and other institutions. The applicable prospectus supplement will set forth the commission payable for solicitation of such offers.

Our securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. If any underwriters are utilized in the sale of the securities, the underwriting agreement will provide that the obligations of the underwriters are subject to specified conditions precedent. If we sell our securities to one or more underwriters on a firm commitment basis, then the underwriters will be obligated to purchase all of the securities offered if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions, as may be set forth in the applicable prospectus supplement. If we grant any over-allotment option, the terms of the over-allotment option will be set forth in the applicable prospectus supplement.

In connection with any offering, persons participating in the offering, such as any underwriters, may purchase and sell the securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to cover syndicate short positions created in connection with the offering. Stabilizing transactions consist of bids or purchases for the purpose of preventing or retarding a decline in the market price of the securities and syndicate short positions involve the sale by underwriters of a greater number of securities than they are required to purchase from us in the offering. Underwriters also may impose a penalty bid, whereby selling concessions allowed to syndicate members or other broker-dealers in respect of the securities sold in the offering

-15-

for their account may be reclaimed by the syndicate if the securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the securities, which may be higher than the price that might prevail in the open market, and these activities, if commenced, may be discontinued at any time.

Any underwriters, dealers or agents involved in any distribution or sale of our securities may be customers of, engage in transactions with or perform services for us from time to time.

We will bear all costs, expenses and fees in connection with the registration of the securities as well as the expense of all commissions and discounts, if any, attributable to the sales of the securities by us.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the shares of common stock offered by this prospectus and other legal matters relating to this offering will be passed on by Paul, Hastings, Janofsky & Walker LLP, New York, New York.

Edgar Filing: BIOENVISION INC - Form S-3

EXPERTS

Our auditors are Grant Thornton LLP. Our consolidated financial statements as at and for the years ended June 30, 2004 and June 30, 2003 included in our annual report on Form 10-KSB for the year ended June 30, 2004 and incorporated by reference herein, have been incorporated by reference herein in reliance upon the report of Grant Thornton LLP, independent registered public accountants, given on the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any materials we have filed with the SEC at the SEC's public reference rooms. The SEC also maintains a web site (<http://www.sec.gov>) that contains reports, proxy statements and other information concerning us. Please call the SEC at 1-800-SEC-0330 for information concerning the operations of the public reference rooms or visit the SEC at the following locations:

Public Reference Room	Midwest Regional Office
450 Fifth Street, N.W.	Citicorp Center
Room 1024	500 West Madison Street
Washington, D.C. 20549	Suite 1400
	Chicago, Illinois 60661-2511

We have filed with the SEC a registration statement on Form S-3 under the Securities Act to register the securities to be sold in this offering. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules to the registration statement. For further information regarding Bioenvision and our securities, please refer to the registration statement and the documents filed as exhibits to the registration statement.

INCORPORATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those filed documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information.

The following documents, which have been filed with the SEC, are hereby incorporated by reference:

- o Our definitive proxy statement dated October __, 2004, relating to our December 2004 annual meeting of stockholders, and
- o Our annual report on Form 10-KSB for the year ended June 30, 2004 filed on September 24, 2004 (File No. 001-31787);

All other reports and documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act after the date of this prospectus and prior to the termination of the offering are deemed incorporated by reference into this prospectus and a part hereof from the date of filing of those documents. Any statement contained in any document incorporated by reference shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a

-16-

statement contained in a later document modifies or supersedes such statement. Any statements so modified or superseded shall not be deemed to constitute a part of this prospectus, except as modified or superseded.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request of such person, a copy of any or all of the documents referred to above which have been or may be incorporated by reference into this prospectus (other than the exhibits to such documents). Requests for such documents should be directed to Bioenvision Inc., 509 Madison Avenue, Suite 404, New York, New York 10022, Attention: David P. Luci (telephone: (212) 750-6700).

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You should not rely on any unauthorized information. This prospectus does not offer to sell or solicit an offer to buy any shares in any jurisdiction in which it is unlawful. The information in this prospectus is current as of the date on the cover.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR
SECURITIES ACT LIABILITIES

Our bylaws provide that directors and officers shall be indemnified by us to the fullest extent authorized by the Delaware General Corporation Law, against all expenses and liabilities reasonably incurred in connection with services for us or on our behalf.

Insofar as indemnification for liabilities arising under the Securities Act might be permitted to directors, officers or persons controlling our company under the provisions described above, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

-17-

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The following sets forth the estimated expenses payable in connection with the preparation and filing of this Registration:

*Printing and Engraving Expenses.....	15,000
*Accounting Fees and Expenses.....	15,000
*Legal Fees and Expenses.....	50,000
*Blue Sky Fees and Expenses.....	2,000
*Transfer Agent's and Registrar's Fees and Expenses.....	1,000
*Miscellaneous.....	17,000

Edgar Filing: BIOENVISION INC - Form S-3

*Total..... \$100,000
=====

* Estimated.

Item 15. Indemnification of Directors and Officers.

The indemnification of officers and directors of the Registrant is governed by Section 145 of the General Corporation Law of the State of Delaware (the "DGCL") and the Certificate of Incorporation, as amended, and By-Laws of the Registrant. Subsection (a) of DGCL Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in the manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

Subsection (b) of DGCL Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in a connection with the defense or settlement of such action or suit if the person acted in good faith and in the manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Delaware Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

DGCL Section 145 further provides that to the extent that to a present or former director or officer is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. In all cases in which indemnification is permitted under subsection (a) and (b) of Section 145 (unless ordered by a court), it shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the applicable standard of conduct has been met by the party to be indemnified. Such determination must be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are no parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a

Edgar Filing: BIOENVISION INC - Form S-3

quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders. The statute authorizes the corporation to pay expenses incurred by an officer or director in advance of the final disposition of a proceeding upon receipt of an undertaking by or on behalf of the person to whom the advance will be made, to repay the advances if it shall ultimately be determined that he was not entitled to indemnification. DGCL Section 145 also provides that indemnification and advancement of expenses permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain

II-1

liability insurance on behalf of its directors, officers, employees and agents regardless of whether the corporation would have the statutory power to indemnify such persons against the liabilities insured.

Article Seventh of the Certificate of Incorporation of the Registrant, as amended (the "Certificate"), provides that no director of the Registrant shall be personally liable to the Registrant or its stockholders for monetary damages for breach of fiduciary duty as a director except for liability (i) for any breach of the director's duty of loyalty to the Registrant or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (involving certain unlawful dividends or stock purchases or redemptions), or (iv) for any transaction from which the director derived an improper personal benefit.

Pursuant to Section 145(g) of the DGCL, the Registrant's By-Laws, as amended, authorize the Registrant to obtain insurance to protect officers and directors from certain liabilities, including liabilities against which the Registrant cannot indemnify its officers and directors.

In derivative actions, Bioenvision may only protect from liability its officers, directors, employees and agents against expenses actually and reasonably incurred in connection with the defense or settlement of a suit, and only if they acted in good faith and in a manner they reasonably believed to be in, or not opposed to, the best interests of the corporation. Indemnification is not permitted in the event that the director, officer, employee or agent is actually adjudged liable to Bioenvision unless, and only to the extent that, the court in which the action was brought so determines.

Bioenvision's Certificate of Incorporation permits it to protect from liability its directors except in the event of: (1) any breach of the director's duty of loyalty to Bioenvision or its stockholders; (2) any act or failure to act that is not in good faith or involves intentional misconduct or a knowing violation of the law; (3) liability arising under Section 174 of the Delaware General Corporation Law, relating to unlawful stock purchases, redemptions, or payment of dividends; or (4) any transaction in which the director received an improper personal benefit.

Item 16. Exhibits

Exhibit Number -----	Description -----
5.1*	Opinion of Paul, Hastings, Janofsky & Walker, LLP

Edgar Filing: BIOENVISION INC - Form S-3

- 23.1 Consent of Grant Thornton LLP
- 23.2* Consent of Paul, Hastings, Janofsky & Walker LLP (included in Exhibit 5.1)
- 24.1 Power of Attorney (appears on signature page)

* To be filed by amendment.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933.

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b), if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

II-2

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is on Form S-3, Form S-8, or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

Edgar Filing: BIOENVISION INC - Form S-3

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against such public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

II-3

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on the 25th day of October, 2004.

BIOENVISION, INC.

By /s/ Christopher B. Wood

Edgar Filing: BIOENVISION INC - Form S-3

 Christopher B. Wood, Chairman of the
 Board and Chief Executive Officer

KNOW ALL MEN BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Christopher B. Wood as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution for him/ and in his name, place and stead, in any and all capacities, to sign any and all amendments and post-effective amendments to this registration statement, and make such changes and additions to this registration statement for the same offering that may be filed under Rule 462(b), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto the attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done and about the premises, as fully to all intents and purposes as he/she might or could do in person, thereby ratifying and confirming all that the attorney-in-fact and agent, or his/her substitutes, may lawfully do or cause to be done by virtue thereof and the registrant hereby confers like authority on its behalf.

In accordance with the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature -----	Title -----	
/s/ Christopher B. Wood, M.D. ----- Christopher B. Wood	Chairman and Chief Executive Officer and Director (Principal Executive Officer)	Octo
/s/ David P. Luci ----- David P. Luci	Chief Financial Officer, General Counsel (Principal Financial and Accounting Officer)	Octo
/s/ Thomas S. Nelson, C.A. ----- Thomas S. Nelson, C.A.	Director	Octo
/s/ Michael Kauffman ----- Michael Kauffman	Director	Octo
/s/ Andrew N. Schiff ----- Andrew N. Schiff	Director	Octo
/s/ Steven A. Elms ----- Steven A. Elms	Director	Octo

Edgar Filing: BIOENVISION INC - Form S-3

EXHIBIT INDEX

Exhibit Number -----	Description -----
5.1*	Opinion of Paul, Hastings, Janofsky & Walker, LLP
23.1	Consent of Grant Thornton LLP
23.2*	Consent of Paul, Hastings, Janofsky & Walker LLP (included in Exhibit 5.1)
24.1	Power of Attorney (appears on signature page)

* To be filed by amendment.

II-5