

Edgar Filing: BIOENVISION INC - Form 424B3

BIOENVISION INC
Form 424B3
November 17, 2004

Filed pursuant to rule 424(b) (3)
Registration number 333-115816

PROSPECTUS

[GRAPHIC OMITTED]

BIOENVISION, INC.

30,164,746 shares of common stock

Of the shares of stock covered by this prospectus: (i) 5,121,613 shares were issued to former stockholders of Pathagon Inc. in February 2002 in connection with the consummation of the acquisition of Pathagon Inc (ii) 5,440,000 shares were issued or are issuable upon the exercise of warrants issued to preferred stockholders in connection with a private placement consummated in May 2002; (iii) 6,000,000 shares are issuable upon the conversion of 3,000,000 preferred shares issued in connection with a private placement consummated in May 2002, (iv) 1,008,333 shares are issuable upon the exercise of warrants issued to our financial advisor in connection with a private placement consummated in May 2002; (v) 3,668,559 shares were issued and 3,644,698 shares are issuable upon the exercise of warrants and options issued to the co-founders, early round investors and certain former consultants and advisors for services rendered to or on behalf of us; (vi) 44,166 shares were issued and 133,332 shares are issuable upon the exercise of warrants issued to a former co-development partner for services rendered to us; (vii) 1,500,000 shares are issuable upon the exercise of warrants issued in connection with a credit facility secured by Bioenvision in November 2001; (viii) 160,000 shares are issuable upon the exercise of warrants issued to two former financial advisors in March, 2004; (ix) 130,277 shares issued to a regulatory consultant in April of 2003 for services rendered; (x) 2,532,898 shares were issued in connection with a private placement consummated in March and May of 2004; and (xi) 780,870 shares are issuable upon the exercise of warrants issued in connection with the private placement consummated in March and May of 2004.

All of the shares of stock covered by this prospectus are beneficially owned by the selling stockholders listed in the section of this prospectus called "Selling Stockholders." We are not selling any of the shares of stock covered by this prospectus and we will not receive any proceeds from any sales of our stock covered by this prospectus effected by the selling stockholders.

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 November 9, 2004, was \$8.86 per share.

We urge you to read carefully the "Risk Factors" section beginning on page 4 where we describe specific risks associated with an investment in

Edgar Filing: BIOENVISION INC - Form 424B3

Bioenvision and these securities 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 date of this prospectus is November 17, 2004.

TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY.....	1
THE OFFERING.....	3
RISK FACTORS.....	4
DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS.....	14
USE OF PROCEEDS.....	14
SELLING STOCKHOLDERS.....	14
PLAN OF DISTRIBUTION.....	20
DESCRIPTION OF SECURITIES.....	22
LEGAL MATTERS.....	24
EXPERTS.....	24
WHERE YOU CAN FIND MORE INFORMATION.....	24
INCORPORATION BY REFERENCE.....	24
DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES.....	25

PROSPECTUS SUMMARY

Edgar Filing: BIOENVISION INC - Form 424B3

You should read the following summary together with the more detailed information regarding us and the securities being offered for sale by means of this prospectus and our financial statements and notes to those statements appearing elsewhere in this prospectus. The summary highlights information contained elsewhere in this prospectus. The terms "Bioenvision," "the company," "we," "our" and "us" refer to Bioenvision, Inc. and its consolidated subsidiaries unless the context suggests otherwise. The term "you" refers to a prospective investor.

Bioenvision, Inc.

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.

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 will continue clinical trials in other indications with the intention of aggressively seeking label extensions after clofarabine's first approval, including our Pivotal Phase II trial of clofarabine in adults with Acute Myeloid Leukemia (AML) which commenced in August 2004 and is ongoing. Following this strategy, throughout the world, approximately two-thirds of the cancer patients dosed with clofarabine to date fall outside of the pediatric acute leukemias.

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

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

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

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

In July 2004, we filed for approval of clofarabine in Europe to treat children with pediatric acute leukemia (ALL and AML). Further, we are conducting a Pivotal Phase II clinical trial of clofarabine, as first line therapy for the treatment of adults with Acute Myeloid Leukemia (AML). Also in Europe, at our

Edgar Filing: BIOENVISION INC - Form 424B3

direction, an Investigator Sponsored Trial of clofarabine as first-line therapy for adults with AML was completed ahead of schedule and an interim analysis indicates a 64% complete response rate observed in this patient population.

In the U.S., ILEX Oncology, Inc., our sub-licensor of U.S. and Canadian cancer marketing rights, filed a New Drug Application ("NDA") in March 2004 for approval of clofarabine to treat children with acute leukemias (ALL or AML). The NDA was based upon results of two Pivotal Phase II clinical trials completed by ILEX prior to the NDA filing. In connection with the NDA, the United States Food and Drug Administration (the "FDA") has set a Prescription Drug User Fee Act ("PDUFA") response date at December 30, 2004. 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 January, 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for clofarabine, upon grant of marketing authorization. The drug has also been granted orphan drug status and "fast track" treatment by the FDA. Further, in July 2004, the FDA granted six months of extended market exclusivity to clofarabine under the Best Pharmaceuticals for Children Act.

In August 2003, we obtained the exclusive, irrevocable option to sell, market and distribute clofarabine in Japan and Southeast Asia from the inventor of clofarabine. These rights were not previously granted by Southern Research Institute and fall outside the scope of the Company's then current licensing and development contracts with respect to clofarabine. We originally

obtained an exclusive license from Southern Research Institute to sell, market and distribute clofarabine throughout the world, except for Japan and Southeast Asia, for all human applications, pursuant to a co-development agreement, dated August 31, 1998, between the Company and Southern Research Institute. On March 12, 2001, we granted an exclusive option to sell, market and distribute clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute clofarabine for cancer indications in the U.S.

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

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

We originally obtained an exclusive license from Stegram Pharmaceuticals

Edgar Filing: BIOENVISION INC - Form 424B3

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.

Corporate Background

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 345 Park Avenue, 41st Floor, New York, New York 10154. Our telephone number is (212) 750-6700 and our fax number is (212) 750-6777. Our website is www.bioenvision.com. Information contained on our website does not constitute, and shall not be deemed to constitute, part of this prospectus.

-2-

The Offering

Shares of common stock offered by the
selling stockholders..... 30,164,746

Shares of common stock outstanding as of
November 9, 2004..... 28,882,319

Shares to be outstanding following
offering (assuming conversion of all
preferred shares into common shares and
the exercise of options and warrants,
and assuming no sales of any securities
pursuant to this
offering)..... 48,264,038

Use of proceeds..... We will not receive any proceeds from the issuance or sale of the shares included in this offering. We may receive consideration upon the exercise of options and we will receive consideration upon the conversion of warrants which we intend to use for general corporate purposes.

Risk Factors..... An investment in our common stock is subject to significant risks. You should carefully consider the information set forth in the "Risk Factors" section of this prospectus as well as other information set forth in this prospectus, including our financial statements and related notes.

Plan of Distribution..... The shares of common stock offered

Edgar Filing: BIOENVISION INC - Form 424B3

for resale may be sold by the selling stockholders pursuant to this prospectus in the manner described under "Plan of Distribution" on page 20.

Nasdaq symbol..... BIVN

-3-

RISK FACTORS

You should carefully consider the following risks before you decide to buy our Common Stock. Our business, financial condition or operating results may suffer if any of the events described in the following risk factors actually occur. All known risks are presented in this 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.

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 November 10, 2004, our closing stock price has ranged from a high of \$11.75 to a low of \$3.00. If our revenues do not grow or grow more slowly than we anticipate, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our Common Stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in investor confidence or otherwise fails, the market price of our Common Stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, companies that have experienced volatility in the market price of their stock have been the subject of securities class action litigation. If we were to become the subject of securities class action litigation, it could result in substantial costs and a diversion of management's attention and resources.

Certain events could result in a dilution of holders of our Common Stock

As of November 9, 2004, we had 28,882,319 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

Edgar Filing: BIOENVISION INC - Form 424B3

Stock and common stock equivalents, including warrants and stock options, convertible or exercisable into 12,886,865 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 November 9, 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 will result in a dilution to your percentage ownership of our Common Stock and could adversely affect the market price of our Common Stock.

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

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

Section 203 of the Delaware corporate statute

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

Issuance of Preferred Stock Without Common Stockholder Approval.

Our charter authorizes our board of director to increase the number of shares of preferred stock we may issue without approval of common stockholders. Preferred stock may be issued in one or more series, the terms of which may be determined without further

action by common stockholders. These terms may include preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends, qualifications or terms or conditions of redemption. The issuance of any

Edgar Filing: BIOENVISION INC - Form 424B3

preferred stock could materially adversely affect the rights of holders of our common stock, and therefore could reduce its value. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell assets to, a third party. The power of the board of directors to issue preferred stock could make it more difficult, delay, discourage, prevent or make it more costly to acquire or effect a change in control, thereby preserving the current stockholders' control.

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

Since our inception, August of 1996, we have been primarily engaged in organizational activities, including developing a strategic operating plan, entering into various collaborative agreements for the development of products and technologies, hiring personnel and developing and testing our products. We have not generated any material revenues to date. Accordingly, we have no relevant operating history upon which an evaluation of our performance and prospects can be made.

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

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

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

Edgar Filing: BIOENVISION INC - Form 424B3

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
- o government or regulatory delays.

-5-

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

Edgar Filing: BIOENVISION INC - Form 424B3

trials if the trials are ongoing at December 31, 2002 and progressing to completion within a reasonable time thereafter. Further, ILEX was required under the co-development agreement to have filed a New Drug Application by August 31, 2003, subject to extension if ILEX continues to use its reasonable efforts to promptly complete the filing after August 31, 2003. ILEX continued to use its reasonable efforts to complete the filing after August 31, 2003 and in October 2003, Ilex filed the first part of a "rolling NDA" with the FDA.

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

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

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

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

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

Edgar Filing: BIOENVISION INC - Form 424B3

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 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;

Edgar Filing: BIOENVISION INC - Form 424B3

- 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.

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

-7-

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 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

Edgar Filing: BIOENVISION INC - Form 424B3

to continual review and periodic inspections. Subsequent discovery of previously unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

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

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

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

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

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

Edgar Filing: BIOENVISION INC - Form 424B3

the level of marketing exclusivity that is currently afforded by orphan drug status and marketing approval may not remain in effect in the future.

-8-

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

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

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

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

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

Edgar Filing: BIOENVISION INC - Form 424B3

tumor cancer patients, but the required dose is high, private healthcare/science foundations could recommend various other regimens of treatment which may from time to time show activity at lower doses.

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

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

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

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

-9-

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

Edgar Filing: BIOENVISION INC - Form 424B3

competition from manufacturers of generic drugs which may claim to offer equivalent therapeutic benefits at a lower price. The aggressive pricing activities of our generic competitors could have a material adverse effect on our operations, revenue and cash flow.

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

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

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

We do not currently have any internal product testing capabilities. Our inability to retain third parties for the clinical testing of products on acceptable terms would adversely affect our ability to develop products. Any failures by third parties to adequately perform their responsibilities may delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position. Our dependence on third parties for the development of products may adversely affect our potential profit margins and our ability to develop and deliver products on a timely basis.

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

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

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

The creation of infrastructure to commercialize oncology products is a difficult, expensive and time-consuming process. We may not be able to establish direct or indirect sales and distribution capabilities or be successful in gaining market acceptance for proprietary products or for other products. We

Edgar Filing: BIOENVISION INC - Form 424B3

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.

-10-

If we lose key management our business will suffer

We are highly dependent on our Chief Executive Officer to develop our lead drug. Dr. Wood has an employment agreement with the Company, dated December 31, 2002, for an initial term of one year which automatically extends for an additional one year periods until either party gives the other written notice of termination at least 90 days prior to the end of the current term. Dr. Wood is not near retirement age and he does not, to our knowledge, plan on leaving the Company in the near future. Dr. Wood is one of the founders of the company and he is intimately familiar with the science that underlies our lead drugs and ancillary technologies. He also maintains a position on the clofarabine management team that is responsible for all drug development activities relating to that lead drug, and has been instrumental in the development and maintenance of our key relationships within the scientific research and medical communities, and those with our vendors, inventors, co-development partners and licensors. If Dr. Wood was no longer employed by the company, the development of our drugs would be significantly delayed and otherwise would be adversely impacted, and we may be unable to maintain and develop these important relationships.

Need for additional personnel

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

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

Our success will depend in significant part on the expansion of our operations and the effective management of growth. This growth has and will continue to place a significant strain on our management and information systems and resources and operational and financial systems and resources. To manage

Edgar Filing: BIOENVISION INC - Form 424B3

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

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

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend on our ability to obtain and enforce protection for products that we develop under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. Several of the original patents to Modrenal(R) have expired in the United States and foreign countries. Thus, we and our licensors are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal(R). We cannot guarantee that such applications will result in issued patents or that such patents if issued will provide adequate protection against competitors. Patents may not be issued from these applications and issued patents may not give us adequate protection or a competitive advantage. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from Southern Research Institute. The current projected expiration date of the license is March 2021. These patents cover pharmaceutical compositions and methods of using clofarabine. We cannot guarantee that these patents would survive an attack on their validity or that they will provide a competitive advantage over our competitors. Moreover, we cannot guarantee that Southern Research Institute was the first to invent the subject matter of these patents. In addition, we are aware of a third party patent which is directed to the treatment of chronic myeloid leukemia ("CML") using specific doses of clofarabine. We do not believe that we will infringe this patent. If this patent is asserted against us, even though we may be successful in defending against such an assertion, our defense would require substantial financial and human resources. And, we may

-11-

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

reasonable terms, if at all.

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

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

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

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

We have the right to manufacture, market and distribute our lead drugs, clofarabine and Modrenal(R), in territories outside of the 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,

Edgar Filing: BIOENVISION INC - Form 424B3

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.

-12-

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

Edgar Filing: BIOENVISION INC - Form 424B3

decline in sales of Modrenal(R). This lack of reimbursement would diminish the market for products developed by us and would have a material adverse effect on us.

Our products may be subject to recall

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

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

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

-13-

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

We have made statements under the captions "Risk Factors," and in other sections of this prospectus that are forward-looking statements. In some cases,

Edgar Filing: BIOENVISION INC - Form 424B3

you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," the negative of these terms and other comparable terminology. These forward-looking statements which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, or anticipated growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed under the section entitled "Risk Factors." You should specifically consider the numerous risks outlined under "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness or any of these forward-looking statements.

USE OF PROCEEDS

The selling stockholders will receive the proceeds from the resale of the shares of common stock. We will not receive any proceeds from the resale of the shares of common stock by the selling stockholders. We may receive consideration upon the exercise of options and we will receive consideration upon the conversion of warrants which we will use for general corporate purposes.

Expenses we are expected to incur in connection with this registration are estimated at approximately \$100,000. The selling stockholders will pay all of their underwriting commissions and discounts and counsel fees and expenses in connection with the resale of the shares covered by this prospectus.

SELLING STOCKHOLDERS

As discussed elsewhere in this prospectus, the selling stockholders are individuals or entities who or which either hold shares of our common stock or may acquire the same upon the conversion of preferred shares or upon the exercise of certain options or warrants and, as discussed under the caption "Plan of Distribution" below, may include certain of their pledgees, donees, transferees or other successors-in-interest who receive shares as a gift, pledge, partnership distribution or other non-sale related transfer. The following table sets forth, as of the date of this prospectus:

- o the name of each selling stockholder;
- o the number of shares of common stock beneficially owned by each selling stockholder;
- o the number of shares of common stock that may be sold in this offering; and
- o the number and percentage of shares of common stock that will be beneficially owned by each selling stockholder following the offering to which this prospectus relates.

The information with respect to ownership after the offering assumes the sale of all of the shares offered and no purchases of additional shares. The selling stockholders may offer all or part of the shares covered by this prospectus at any time or from time to time.

For purposes of the table below, the number of shares "beneficially

Edgar Filing: BIOENVISION INC - Form 424B3

owned" are those beneficially owned as determined under the rules of the SEC. Such information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power and any shares for which the person has the right to acquire such power within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. Percentages in the table below are based on 28,882,319 shares of our common stock outstanding as of November 9, 2004.

-14-

Name -----	Shares Owned Prior to the Offering		Number of Shares which may be Sold in this Offering -----
	Number -----	Percent -----	
Perseus-Soros BioPharmaceutical Fund, LP (1)	9,450,053	24.90%	9,450,053
Caduceus Private Investments, LP (2)	1,040,410	3.52%	770,482
OrbiMed Associates LLC (2)	21,632	*	16,038
UBS Juniper Crossover Fund, L.L.C. (2)	995,698	3.41%	363,516
Special Situations Private Equity Fund, L.P. (3)	250,000	*	250,000
SDS Merchant Fund, LP (4)	144,999	*	48,333
SDS Merchant Fund, LP (5)	354,999	1.21%	118,333
SDS Merchant Fund, LP (6)	380,001	1.31%	166,667
Orion Biomedical Offshore Fund, LP (7)	133,875	*	44,625
Orion Biomedical Fund, LP (8)	616,125	2.13%	205,375
Beaver Ltd. (9)	75,000	*	25,000
CKH Invest Aps. (10)	50,001	*	16,667
Merlin Nexus I LP (11)	673,617	2.31%	406,949
Alexandra Global Master Fund, ltd. (12)	310,666	1.07%	310,666
DWS Investment GmbH (13)	1,360,600	4.71%	493,934
Michael Sistenich (14)	125,001	*	41,667
Global Biotechnology Fund (15)	209,369	*	76,037
Oklahoma Medical Research Foundation (16)	44,166	*	44,166
Robert A. Floyd (16)	66,666	*	66,666
Raymond A. Schinazi (16)	66,666	*	66,666
Christopher B. Wood (17)	3,986,571	13.80%	2,319,905
Julie Wood (17)	318,750	*	318,750

Edgar Filing: BIOENVISION INC - Form 424B3

Stuart Smith (18)	700,000	2.38%	700,000
Thomas Nelson (19)	370,959	1.28%	287,523
Kevin Leech (20)	1,813,912	6.19%	413,912
Bioaccelerate, Inc. (21)	1,162,100	3.96%	434,828
Sterling Securities Ltd. (21)	74,045	*	74,045
Carpe DM, Inc. (21)	59,058	*	59,058
Michelle Tidball (21)	254,114	*	254,114
Weil Consulting Corporation (21)	75,000	*	75,000
Kingsley Securities Ltd. (21)	102,679	*	102,679
Fontenelle LLC (21)	50,000	*	50,000
George Margetts (22)	100,000	*	100,000
Nagy Habib (23)	46,732	*	46,732
NAB Holdings Ltd. (21) (24)	451,913	1.56%	451,913
SCO Capital Partners LLC (25), (27)	7,009,946	24.19%	7,009,946
SCO Financial Group LLC (25), (27)	100,000	*	100,000
SCO Securities LLC (25), (27)	260,290	*	260,290
Daniel DiPietro (29)	50,000	*	50,000
Jeremy Kaplan	10,000	*	10,000
Joshua Golumb	10,000	*	10,000
The Sophie C. Rouhandeh Trust (25)	150,000	*	150,000
The Chloe H. Rouhandeh Trust (25)	150,000	*	150,000
Jeffrey B. Davis (26), (27), (29)	749,243	2.57%	250,000
Edward W. Kelly (27), (28)	356,013	1.22%	200,000
RRD International, Inc. (30)	130,277	*	130,277
RLB Capital, Inc. (31)	100,000	*	100,000
Stamford Capital (32)	60,000	*	60,000
Palladin Opportunity Fund LLC	13,632	*	13,632
SDS Capital Group SPC, Ltd. (33)	159,802	*	159,802
Baystar Capital II, L.P. (34)	60,000	*	60,000
North Sound Legacy Fund, LLC (35)	1,440	*	1,440
North Sound Legacy Institutional Fund, LLC (36)	15,840	*	15,840
North Sound Legacy International Fund, LLC (37)	30,720	*	30,720
Vertical Ventures, LLC (38)	115,200	*	115,200
Iroquois Capital LP (39)	76,800	*	76,800
Alpha Capital AG (40)	96,000	*	96,000
Millenium Partners LP (41)	120,000	*	120,000
Jennison Health Sciences Fund (42)	288,000	1.00%	288,000
BioPharmaceutical Portfolio (43)	30,240	*	30,240
MP BioPharmaceutical Partners, L.P. (44)	16,680	*	16,680
MP BioPharmaceutical Fund Ltd. (45)	68,880	*	68,880
MP BioPharm Market-Neutral, L.P. (46)	4,200	*	4,200
Silveroak Investments, Inc. (47)	48,000	*	48,000
SF Capital Partners Ltd. (48)	288,000	*	288,000
Perceptive Lifesciences Master Fund, Ltd. (49)	216,000	*	216,000
Cranshire Capital, L.P. (50)	48,000	*	48,000

-15-

Quogue Capital LLC (51)	14,000	*	14,000
Meditor Master Curra Fund Limited (52)	192,000	*	192,000
Atlas Equity I, Ltd. (53)	120,000	*	120,000
Steve Oliviera (54)	24,000	*	24,000
SRG Capital LLC (55)	24,000	*	24,000
StoneStreet LP (56)	60,000	*	60,000
DKR Soundshore Oasis Holding Company, Ltd. (57)	48,000	*	48,000

Edgar Filing: BIOENVISION INC - Form 424B3

Total

38,085,080

30,164,746

* Represents less than 1% of our outstanding shares of common stock.

- (1) Includes 3,000,000 shares of Series A Preferred Stock currently convertible into 6,000,000 shares of common stock and a warrant to purchase 3,000,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Also includes 375,044 common shares and a warrant to purchase 75,009 shares of common stock exercisable at \$7.50 for five years from May 13, 2004. Based upon information contained in its report on Schedule 13D filed with the Commission on May 20, 2002 and amended on January 8, 2003, Perseus-Soros BioPharmaceutical Fund, L.P. reported that Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners may be deemed to have sole power to direct the voting and disposition of the 9,000,000 shares of common stock. By virtue of the relationships between and among Perseus-Soros BioPharmaceutical Fund, L.P., Perseus-Soros Partners, LLC, Perseus BioTech Fund Partners, LLC, SFM Participation, L.P., SFM AH, LLC, Frank H. Pearl, George Soros, Soros Fund Management LLC, Perseus EC, LLC, Perseuspur, LLC, each of such Perseus entities, other than Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners, may be deemed to share the power to direct the voting and disposition of the 9,000,000 shares of common stock. After the company's May 2002 financing, Perseus-Soros named two individuals to the company's board of directors.
- (2) Includes 353,693 shares of common stock, a warrant to purchase 669,964 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, and a warrant to purchase 16,753 shares of common stock exercisable at \$7.50 for five years from May 13, 2004 all of which are held by Caduceus Private Investments, LP; 7,338 shares of common stock, a warrant to purchase 13,945 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, and a warrant to purchase 349 shares of common stock exercisable at \$7.50 for five years from May 13, 2004, all of which are held by OrbiMed Associates LLC; and 671,703 shares of common stock, a warrant to purchase 316,091 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, and a warrant to purchase 7,904 shares of common stock exercisable at \$7.50 for five years from May 13, 2004, all of which are held by UBS Juniper Crossover Fund, L.L.C. Based upon information contained in its report on Schedule 13G filed with the Commission on June 21, 2002, OrbiMed Advisors Inc., OrbiMed Advisors LLC, OrbiMed Capital LLC and Samuel D. Isaly reported that they share the power to direct the voting and disposition of the shares of common stock.
- (3) Includes a Warrant to purchase 250,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (4) Includes 48,333 shares of Series A Preferred Stock currently convertible into 96,666 shares of common stock and a warrant to purchase 48,333 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002, which were sold to SDS Merchant Fund, LP by XMark Fund, LP. All securities held registered to SDS Merchant Fund, LP are beneficially owned by SDS

Edgar Filing: BIOENVISION INC - Form 424B3

Capital Group SPC, Ltd.

- (5) Includes 118,333 shares of Series A Preferred Stock currently convertible into 236,666 shares of common stock and a warrant to purchase 118,333 shares of common stock exercisable at \$3.00 per share for five years from May 8, 2002, which were sold to SDS Merchant Fund, LP by XMark Fund, Ltd. All securities held registered to SDS Merchant Fund, LP are beneficially owned by SDS Capital Group SPC, Ltd.
- (6) Includes 213,334 shares of common stock and a warrant to purchase 166,667 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. All securities held registered to SDS Merchant Fund, LP are beneficially owned by SDS Capital Group SPC, Ltd.
- (7) Includes 133,875 shares of common stock resulting from converting their Series A Preferred Stock and exercising a warrant on May 25, 2004.
- (8) Includes 616,125 shares of common stock resulting from converting their Series A Preferred Stock and exercising a warrant on May 25, 2004.
- (9) Includes 75,000 shares of common stock resulting from converting their Series A Preferred Stock and exercising a warrant on May 7, 2004.

-16-

- (10) Includes 33,334 shares of common stock and a warrant to purchase 16,667 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002.
- (11) Includes 108,334 shares of Series A Preferred Stock currently convertible into 216,668 shares of common stock; 444,680 shares of common stock and a warrant to purchase 12,269 shares of common stock at \$7.50 per share for five years from March 22, 2004. Based upon information contained in its report on Schedule 13G filed with the Commission on June 28, 2002, Merlin Nexus I (formerly known as, Merlin BioMed Private Equity Fund, L.P.) reported that it shares the power to direct the voting and disposition of its shares of common stock with Merlin BioMed Private Equity, LLC, its general partner and Dominique Semon, who is the sole managing member of the general partner.
- (12) Includes 120,000 common shares; a warrant to purchase 166,666 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002; and a warrant to purchase 24,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (13) Includes 1,350,500 shares of common stock resulting from converting their Series A Preferred Stock, the purchase of an additional 50,501 shares of common stock in the March 2004 financing and exercising a warrant on March 17, 2004. Also a warrant to purchase 10,100 shares of common stock exercisable at \$7.50 for five years from May 13, 2004.
- (14) Includes 83,334 shares of common stock and a warrant to purchase 41,667

Edgar Filing: BIOENVISION INC - Form 424B3

shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002.

- (15) Includes 66,666 shares of Series A Preferred Stock currently convertible into 133,332 shares of common stock and a warrant to purchase 66,666 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002. Also includes 7,809 common shares and a warrant to purchase 1,562 shares of common stock exercisable at \$7.50 for five years from May 13, 2004.
- (16) Under the terms of an amendment to a license agreement with Oklahoma Medical Research Foundation, we issued 200,000 shares of common stock, (all of which have been sold) and a five-year warrant to purchase an additional 200,000 shares of common stock. Such warrant to purchase 200,000 shares of common stock is exercisable at \$2.33 per share for five years from May 14, 2002. On February 17, 2004, Oklahoma Medical Research Foundation did a non-sale transfer of its warrant to purchase 66,666 shares of common stock to Dr. Robert A. Floyd and its warrant to purchase 66,666 shares of common stock to Dr. Raymond A. Schinazi. On April 12, 2004, Oklahoma Medical Research Foundation converted its warrant into common shares and has 44,166 of such shares remaining.
- (17) Dr. Wood is Chairman and Chief Executive Officer of the Company. Excludes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest.
- (18) Includes options to acquire 450,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (19) Includes options to acquire 200,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (20) These shares are owned of record by Phoenix Ventures Limited, a Channel Islands (Jersey) corporation, which, to our knowledge, is wholly-owned by Kevin Leech.
- (21) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors. On October 8, 2003, certain options originally issued to Bioaccelerate, Inc. were transferred as follows:
 - (i) NAB Holdings Ltd. received options to purchase 500,000 shares of common stock, 350,000 of which were transferred to Michelle Tidball on December 9, 2003; on February 20, 2004, they did a cashless exercise of their remaining option to purchase 150,000 shares of common stock and received 123,666 shares of common stock ;
 - (ii) Sterling Securities Ltd. received options to purchase 100,000 shares of common stock;
 - (iii) Carpe DM, Inc. received options to purchase 80,000 shares of common stock;
 - (iv) Michelle Tidball received options to purchase 100,000 shares of common stock;

Edgar Filing: BIOENVISION INC - Form 424B3

- (v) Kingsley Securities Ltd. received options to purchase 124,544 shares of common stock and on February 20, 2004, they did a cashless exercise of this option and received 102,679 shares of common stock; and
- (vi) Fontenelle LLC received options to purchase 50,000 shares of common stock, which it exercised in November 2003 for 50,000 shares of common stock.

Further, on November 25, 2003, the following recipients of such options executed a cashless exercise of such options and received the following shares of the Company's common stock:

- (i) Sterling Securities Ltd. received 74,045 shares of common stock; (ii) Carpe DM, Inc. received 59,058 shares of common stock; and
- (iii) Michelle Tidball received 73,811 shares of common stock. On December 16, 2003, Ms. Tidball executed a cashless exercise of 350,000 options transferred to her by NAB Holdings Inc. and received 255,303 shares of the Company's common stock, which includes 75,000 shares issued to Weil Consulting Corporation.

Barbara Platts, in her capacity as Managing Director of Bioaccelerate, Inc., has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.

- (22) Includes an option to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (23) Includes an option to purchase 30,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (24) Includes an option to purchase 450,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001. On December 16, 2003, NAB Holdings Ltd. exercised these options and received 328,247 shares of common stock pursuant to a cashless exercise.
- (25) Includes a warrant to purchase 1,200,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 issued to SCO Capital, LLC; a warrant to purchase 688,333 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 issued to SCO Capital, LLC; a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 issued to SCO Securities, LLC; a warrant to purchase 150,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 held by the Sophie C. Rouhandeh Trust; and a warrant to purchase 150,000 shares of common stock at \$1.25 per share for five years from November 16, 2001 held by the Chloe H. Rouhandeh Trust. Steven H. Rouhandeh, in his capacity as President of SCO Capital Partners, LLC and trustee of the trusts, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof. Excludes a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 which were originally held by SCO Financial Group, LLC, but transferred to (i) Daniel DiPietro (50,000), (ii) Jeremy Kaplan (10,000), and (iii) Joshua Golumb (10,000). SCO Financial Group, LLC served as a financial advisor to the Company through May 2004 and SCO Capital Partners, LLC extended a \$1 million secured credit facility to the Company in November 2001. SCO Securities, LLC, a related entity, served as placement agent to the Company in connection with the Company's May 2002 and March and May 2004 financings. As placement agent in connection with the March and May 2004 financing, SCO Securities, LLC received a warrant to purchase 204,452 shares of common stock exercisable at \$6.25 per share for

Edgar Filing: BIOENVISION INC - Form 424B3

five years from March 22, 2004 and a warrant to purchase 55,838 shares of common stock exercisable at \$6.25 per share for five years from May 13, 2004.

- (26) Includes a warrant to purchase 250,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002. Mr. Davis is the President of SCO Financial Group LLC, an affiliate of SCO Capital Partners LLC. Mr. Davis disclaims beneficial ownership of all shares of common stock deemed beneficially owned by SCO Capital Partners LLC.
- (27) Indicates the selling stockholder was a former stockholder of Pathagon.
- (28) Mr. Kelly has executed a consulting agreement with us pursuant to which we issued to him 200,000 shares of common stock which vested over an eighteen month period.
- (29) Indicates the selling stockholder is a current employee of SCO Financial Group LLC.

-18-

- (30) Includes 130,277 shares of common stock resulting from the cashless exercise of a warrant to purchase 175,000 shares of common stock on July 21, 2004.
- (31) Includes a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share for three years from March 8, 2004.
- (32) Includes a warrant to purchase 60,000 shares of common stock exercisable at \$1.80 per share at anytime from March 4, 2004 through February 23, 2007.
- (33) Includes 133,168 shares of common stock and warrant to purchase 26,634 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (34) Includes 50,000 shares of common stock and warrant to purchase 10,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (35) Includes 1,200 shares of common stock and warrant to purchase 240 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (36) Includes 13,200 shares of common stock and warrant to purchase 2,640 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (37) Includes 25,600 shares of common stock and warrant to purchase 5,120 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (38) Includes 96,000 shares of common stock and warrant to purchase 19,200 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (39) Includes 64,000 shares of common stock and warrant to purchase 12,800 shares of common stock exercisable at \$7.50 per share for five years from

Edgar Filing: BIOENVISION INC - Form 424B3

March 22, 2004.

- (40) Includes 80,000 shares of common stock and warrant to purchase 16,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (41) Includes 100,000 shares of common stock and warrant to purchase 20,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (42) Includes 240,000 shares of common stock and warrant to purchase 48,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (43) Includes 25,200 shares of common stock and warrant to purchase 5,040 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (44) Includes 13,900 shares of common stock and warrant to purchase 2,780 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (45) Includes 57,400 shares of common stock and warrant to purchase 11,480 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (46) Includes 3,500 shares of common stock and warrant to purchase 700 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (47) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (48) Includes 240,000 shares of common stock and warrant to purchase 48,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (49) Includes 180,000 shares of common stock and warrant to purchase 36,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.

-19-

- (50) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (51) Includes a warrant to purchase 14,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (52) Includes 160,000 shares of common stock and warrant to purchase 32,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (53) Includes 100,000 shares of common stock and warrant to purchase 20,000 shares of common stock exercisable at \$7.50 per share for five years from

Edgar Filing: BIOENVISION INC - Form 424B3

March 22, 2004.

- (54) Includes 20,000 shares of common stock and warrant to purchase 4,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (55) Includes 20,000 shares of common stock and warrant to purchase 4,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (56) Includes 50,000 shares of common stock and warrant to purchase 10,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (57) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.

PLAN OF DISTRIBUTION

The shares covered by this prospectus may be offered and sold from time to time by the selling stockholders. The term "selling stockholders" includes pledgees, donees, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholders as a pledge, gift, partnership distribution or other non-sale related transfer. The number of shares beneficially owned by each selling stockholder will decrease as and when it effects any such transfers. The plan of distribution for the selling stockholders' shares sold hereunder will otherwise remain unchanged, except that the transferees, pledgees, donees or other successors will be selling stockholders hereunder. To the extent required, we may amend and/or supplement this prospectus from time to time to describe a specific plan of distribution.

The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. The selling stockholders may offer their shares from time to time pursuant to one or more of the following methods:

- o on Nasdaq or on any other market on which our common stock may from time to time be trading;
- o one or more block trades in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker or dealer as principal and resale by the broker or dealer for its account pursuant to this prospectus;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o in public or privately-negotiated transactions;
- o through the writing of options on the shares; through underwriters, brokers or dealers (who may act as agents or principals) or directly to one or more purchasers;
- o an exchange distribution in accordance with the rules of an exchange; through agents;
- o through market sales, both long or short, to the extent permitted

Edgar Filing: BIOENVISION INC - Form 424B3

under the federal securities laws; or in any combination of these methods.

The sale price to the public may be:

- o the market price prevailing at the time of sale;

-20-

- o a price related to the prevailing market price;
- o at negotiated prices; or
- o any other prices as the selling stockholder may determine from time to time.

In connection with distributions of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares in the course of hedging the positions they assume;

- o sell the shares short and redeliver the shares to close out such short positions;
- o enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to them of shares offered by this prospectus, which they may in turn resell; and
- o pledge shares to a broker-dealer or other financial institution, which, upon a default, they may in turn resell.

In addition to the foregoing methods, the selling stockholders may offer their shares from time to time in transactions involving principals or brokers not otherwise contemplated above, in a combination of such methods as described above or any other lawful methods.

Sales through brokers may be made by any method of trading authorized by any stock exchange or market on which the shares may be listed or quoted, including block trading in negotiated transactions. Without limiting the foregoing, such brokers may act as dealers by purchasing any or all of the shares covered by this prospectus, either as agents for others or as principals for their own accounts, and reselling such shares pursuant to this prospectus. A selling stockholder may effect such transactions directly, or indirectly through underwriters, broker-dealers or agents acting on their behalf. In effecting sales, brokers and dealers engaged by the selling stockholders may arrange for other brokers or dealers to participate.

Upon our being notified by the selling stockholders that any material arrangement has been entered into with a broker-dealer for the sale of shares offered hereby through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, disclosing:

- o the names of the selling stockholder(s) and of the participating

Edgar Filing: BIOENVISION INC - Form 424B3

- broker-dealer(s), identifying them as underwriters, as required;
- o the number of shares involved;
- o the price at which such shares were sold;
- o the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable; and
- o other facts material to the transaction.

The shares may also be sold pursuant to Rule 144 under the securities act, which permits limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the availability of certain current public information concerning the issuer, the resale occurring following the required holding period under 144 and the number of shares during any three-month period not exceeding certain limitations. The selling stockholders have the sole and absolute discretion not to accept any purchase offer or make any sale of their shares if they deem the purchase price to be unsatisfactory at any particular time.

The selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom these broker-dealers may act as agents or to whom they sell as principal or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares will do so for their own account and at their own risk. It is possible that the selling stockholders will attempt to sell shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the

-21-

then market price. The selling stockholders cannot assure that all or any of the shares offered by this prospectus will be issued to, or sold by, the selling stockholders if they do not exercise or convert the common stock equivalents that they own. The selling stockholders and any brokers, dealers or agents, upon effecting the sale of any of the shares offered by this prospectus, may be deemed "underwriters" as that term is defined under the securities act or the exchange act, or the rules and regulations under those acts. In that event, any commissions received by the broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the securities act.

The selling stockholders, alternatively, may sell all or any part of the shares offered by this prospectus through an underwriter. To our knowledge, none of the selling stockholders have entered into any agreement with a prospective underwriter and there can be no assurance that any such agreement will be entered into. If the selling stockholders enter into such an agreement or agreements, then we will set forth in a post-effective amendment to this prospectus the following information:

- o the number of shares being offered;

Edgar Filing: BIOENVISION INC - Form 424B3

- o the terms of the offering, including the name of any selling stockholder, underwriter, broker, dealer or agent;
- o the purchase price paid by any underwriter;
- o any discount, commission and other underwriter compensation;
- o any discount, commission or concession allowed or reallocated or paid to any dealer;
- o the proposed selling price to the public; and
- o other facts material to the transaction.

We will also file such agreement or agreements. In addition, if we are notified by the selling stockholders that a donee, pledgee, transferee or other successor-in-interest intends to sell more than 500 shares, a supplement to this prospectus will be filed.

The selling stockholders and any other persons participating in the sale or distribution of the shares will be subject to applicable provisions of the exchange act and the rules and regulations under the exchange act, including, without limitation, Regulation M. These provisions may restrict certain activities of, and limit the timing of purchases and sales of any of the shares by, the selling stockholders or any other such person. Furthermore, under Regulation M, persons engaged in a distribution of securities are prohibited from simultaneously engaging in market making and certain other activities with respect to the same securities for a specified period of time prior to the commencement of the distribution, subject to specified exceptions or exemptions. All of these limitations may affect the marketability of the shares.

We have agreed to pay all costs and expenses incurred in connection with the registration of the shares offered by this prospectus, except that the selling stockholder will be responsible for all selling commissions, transfer taxes and related charges in connection with the offer and sale of the shares and the fees of the selling stockholder's counsel.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus forms a part continuously effective until the earlier of the date that the shares covered by this prospectus may be sold pursuant to Rule 144(k) of the securities act and the date that all of the shares registered for sale under this prospectus have been sold.

We have agreed to indemnify the selling stockholders, or their respective transferees or assignees, against certain liabilities, including liabilities under the securities act, or to contribute to payments that the selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may be required to make in respect of those liabilities.

DESCRIPTION OF SECURITIES

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 28,882,319 shares were outstanding on November 9, 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, Attention: Ms. Lisa Conger.

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 November 9, 2004. The holders of the Series A convertible preferred stock vote as a single class with the common stock, on an as-converted 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. 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.

Warrants

As of November 9, 2004, there were outstanding warrants to purchase an aggregate of 8,475,868 shares of our common stock, exercisable at prices ranging from \$1.25 to \$7.50 per share. The weighted average exercise price of the warrants is \$2.36.

Stock Options

As of November 9, 2004, there were outstanding options to purchase an aggregate of 4,441,000 shares of our common stock, exercisable at prices ranging from \$0.735 to \$8.25 per share, of which, options to purchase 3,133,334 shares

Edgar Filing: BIOENVISION INC - Form 424B3

were exercisable. The weighted average exercise price of the options is \$1.84.

-23-

LEGAL MATTERS

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.

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
450 Fifth Street
Room 1024
Washington, D.C. 20549

Midwest Regional Office
Citicorp Center
500 West Madison Street
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

Edgar Filing: BIOENVISION INC - Form 424B3

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 document, which has been filed with the SEC, is hereby incorporated by reference:

- o Our annual report on Form 10-KSB for the year ended June 30, 2004 filed on September 24, 2004 (File No. 001-31787); and
- o Our quarterly report on Form 10-QSB for the quarter ended September 30, 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 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 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., 345 Park Avenue, 41st Floor, New York, New York 10154, 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.

-24-

DISCLOSURE OF COMMISSION POSITION OF 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.

-25-

=====

You should rely only on the information incorporated or contained in this prospectus or any supplement. We have not authorized anyone else to provide you with different or additional information. This prospectus is not an offer to sell to - nor is it seeking an offer to buy these securities from - any person in any jurisdiction in which it is illegal or impermissible to make an offer or solicitation. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date on the front of those documents.

TABLE OF CONTENTS

Page

Prospectus Summary.....	1
The Offering.....	3
Risk Factors.....	4
Disclosure Regarding Forward Looking Statements.....	14
Use of Proceeds.....	14
Selling Stockholders.....	14
Plan of Distribution.....	20
Description of Securities.....	22
Legal Matters.....	24
Experts.....	24
Where You Can Find More Information.....	24
Incorporation by Reference.....	24
Disclosure of Commission Position on Indemnification For Securities Act Liabilities	25

=====

30,164,746 Shares of Common Stock

BIOENVISION, INC.

PROSPECTUS

November 17, 2004

=====