

BIOENVISION INC

Form POS AM

October 25, 2006

As filed with the Securities and Exchange Commission on October 25, 2006

Registration No. 333-115816

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**POST-EFFECTIVE AMENDMENT NO. 5 TO FORM S-1 ON**

**FORM S-3**

**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

**BIOENVISION, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**13-4025857**

(I.R.S. Employer Identification No.)

**345 Park Avenue, 41st Floor**

**New York, New York 10154**

**(212) 750-6700**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**David P. Luci, Esq.**

**Chief Financial Officer and General Counsel**

**Bioenvision, Inc.**

**345 Park Avenue, 41st Floor**

**New York, New York 10154**

**(212) 750-6700**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

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**Paul, Hastings, Janofsky & Walker LLP**

**75 East 55th Street**

**New York, NY 10022**

**(212) 318-6000**

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

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

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

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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

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**EXPLANATORY NOTE**

We have previously registered 30,164,746 common shares pursuant to a Registration Statement on Form SB-2 filed with the Securities and Exchange Commission on May 24, 2004 (File No. 333-115816), as amended on Form SB-2 filed with the SEC on June 21, 2004 (File No. 333-115816), as further amended on Form S-3 filed with the SEC on October 13, 2004 (File No. 333-115816), as further amended on Form S-3 filed with the SEC on November 16, 2004 (File No. 333-115816), as further amended on Form S-1 filed with the SEC on August 5, 2005 (File No. 333-115816), and as further amended on Form S-1 filed with the SEC on December 16, 2005 (File No. 333-115816).

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

Subject to Completion dated October 25, 2006

## **PRELIMINARY PROSPECTUS**

# **Bioenvision, Inc.**

## **25,748,242 Shares of Common Stock**

This prospectus covers 25,748,242 shares of our common stock that the selling stockholders named herein may offer and sell from time to time.

The selling stockholders may sell the shares directly or through broker-dealers or underwriters, at various times and in various types of public or private transactions, including in the open market, in negotiated transactions or by any combination of these methods, at prevailing market prices or at privately negotiated prices. Each selling stockholder will determine the selling price of his or its shares at the time of sale, and will receive all of the net proceeds from the sales and pay all brokerage commissions and similar selling expenses, if any. We will pay the expenses incident to the registration of the shares, but we will not receive any proceeds from the sale of the shares by the selling stockholders.

The selling stockholders and any agents, broker-dealers or underwriters that are involved in selling their shares may be deemed to be underwriters within the meaning of the Securities Act of 1933 and any commissions received by them and any profit on the resale of the shares may be deemed to be underwriting commissions or discounts under that Act.

Our common stock is included for quotation on the Nasdaq National Market under the symbol **BIVN**. The last reported sales price of shares of our common stock on October 23, 2006, was \$5.60 per share.

**See Risk Factors beginning on page 9 to read about risks that you should consider before buying our common stock.**

**Neither the Securities and Exchange Commission nor any state securities commission or other regulatory body 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 October 25, 2006**

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You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with information that differs from what is contained in this prospectus. If any person does provide you with information that differs from what is contained in this prospectus, you should not rely on it. This prospectus is not an offer to sell or the solicitation of an offer to buy any securities other than the securities to which it relates, nor an offer or solicitation in any jurisdiction where offers or sales are not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, even though this prospectus may be delivered or shares may be sold under this prospectus at a later date.

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**SUMMARY**

*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 consolidated financial statements and notes to those statements incorporated by reference into 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.*

We are a product-orientated biopharmaceutical company primarily focused upon the acquisition, development, distribution and marketing of compounds and technologies for the treatment of cancer, autoimmune disease and infection. Our product pipeline includes Evoltra® (Clofarabine), Modrenal® (for which Bioenvision has obtained regulatory approval for marketing in the United Kingdom for the treatment of post-menopausal breast cancer following relapse to initial hormone therapy), and certain anti-infective technologies including the OLIGON® technology; an advanced biomaterial that has been incorporated into various FDA approved medical devices and Suvus, an antimicrobial agent

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currently in clinical development for refractory chronic hepatitis C infection.

Evoltra® is our lead product. In May 2006 the European Medicines Agency approved Evoltra® for the treatment of acute lymphoblastic leukemia (ALL) in pediatric patients who have relapsed or are refractory to at least two prior regimens. The licensed indication includes patients who were less than 21 years of age at the time of initial diagnosis of their leukemia. Evoltra® has been granted orphan drug designation, providing marketing exclusivity for 10 years in Europe, which 10-year period commenced in May 2006 upon our receipt of EMA marketing approval. We have a dedicated sales force in the U.K. and several other countries within the E.U. and will continue to expand our sales force as we continue to work through pricing and reimbursement in individual countries within the E.U.

In March 2006, we entered into a Marketing and Distribution Agreement with Mayne Pharma Limited, a public company in Australia, to sell, market and distribute Evoltra® (Clofarabine) in Australia and New Zealand in certain cancer indications. We anticipate entering into similar arrangements with other marketing and distribution partner(s) around the world (outside North America) to capitalize on the commercial potential of Evoltra® (Clofarabine), with a fully integrated sales and marketing team being a primary focus for the sales and marketing partner(s) we may select at any time or from time to time.

We also are developing Evoltra® for the treatment of adult acute myeloid leukemia (AML) as first-line therapy. The Company has completed enrollment of its Phase II clinical trial for the treatment of adult AML in elderly patients unfit for intensive chemotherapy and expects to file a Marketing Authorization Application in 2006 for this indication - the Company's first label-extension for Evoltra®.

Also, in conjunction with our North American co-development partners, Genzyme Corporation, clofarabine (Evoltra®) is in clinical development for the treatment of myelodysplastic syndrome (MDS), chronic lymphocytic leukemia (CLL), chronic myeloid leukemia (CML), non-Hodgkin's lymphoma (NHL), multiple myeloma (MM), solid tumors and as a preconditioning regimen for transplantation.

Bioenvision is also conducting late-stage preclinical development of Evoltra® for the treatment of psoriasis and is planning further worldwide development of Evoltra® in autoimmune diseases.

Bioenvision holds an exclusive worldwide license for clofarabine. Bioenvision granted an exclusive sublicense to Genzyme to co-develop clofarabine for cancer indications in the US and Canada. Genzyme is commercializing clofarabine for certain cancer indications in the US and Canada under the brand name Clolar®. Bioenvision holds an exclusive license in the US and Canada for all non-cancer indications. Bioenvision originally obtained clofarabine development and commercialization rights under patents held by Southern Research Institute.

In the U.S., in December 2004, the Food and Drug Administration, or FDA, approved clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine was the first new medicine initially approved in the U.S.,

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for children with leukemia in more than a decade. Our U.S. partner, Genzyme Corporation, received Orphan Drug designation status for clofarabine in the U.S., providing marketing exclusivity for 7 years. Genzyme is marketing clofarabine under the brand name Clolar® in the U.S.

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

With the approval of Evoltra® under the EMA's centralized process, we intend to continue to expand our sales force by adding six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden. Further, we intend to penetrate all of the other markets within the E.U. upon establishing traction in the E.U.'s major markets. Initially, outside the U.K., we maintain a fully dedicated sales force through Innovex, an affiliate of Quintiles Corporation, which we intend to convert to a direct sales force of our own by fourth quarter of calendar 2007.

In addition to Evoltra® and Modrenal®, we are currently in clinical development of Suvus® for chronic hepatitis C. This product is also in pre-clinical development for the treatment of West Nile Virus and influenza.

## Products and pipeline

Candidate	Indication	Status	U.S. and Canada rights	Ex-U.S. and Canada rights
Evoltra®	Relapsed or Refractory Acute Lymphoblastic Leukemia (ALL)	Marketed in U.S. (pediatric); Filed in E.U. (pediatric)	Genzyme	Bioenvision
Clofarabine (Clolar®)	Acute Myelogenous Leukemia (AML)	Phase II in E.U. (adult)	Genzyme	Bioenvision
	Refractory Chronic Lymphocytic Leukemia (CLL)	Phase II in U.S. (adult)	Genzyme	Bioenvision
	Solid Tumors	Phase I (Intravenous)	Genzyme	Bioenvision
	Solid Tumors	Phase I (Oral)	Genzyme	Bioenvision
	Non-Cancer	Developmental	Bioenvision	Bioenvision
Modrenal®	Breast Cancer	Marketed in U.K. and Germany; Phase IV in U.K.;	Bioenvision	Bioenvision
		Phase II in U.K.		
	Prostate Cancer	Phase II in U.S.	Bioenvision	Bioenvision
Suvus®	Hepatitis C	Investigator Sponsored Phase II in Europe and Middle East	Bioenvision	Bioenvision

## Our Products

### Evoltra® (Clofarabine)

Evoltra® is our lead product. In May 2006 the European Medicines Agency approved Evoltra® for the treatment of acute lymphoblastic leukemia (ALL) in pediatric patients who have relapsed or are refractory to at least two prior regimens. The licensed indication includes patients who were less than 21 years of age at the time of initial diagnosis of their leukemia. Evoltra® has been granted orphan drug designation, providing marketing

exclusivity for 10 years in Europe which 10-year period commenced in May 2006 upon our receipt of EMA marketing approval. We have a dedicated sales force in the U.K. and several other countries within the EU and will continue to expand our sales force and medical science liaison team as we continue to work through pricing and reimbursements locally within the EU.

We also are developing Evoltra® for the treatment of adult acute myeloid leukemia (AML) as first-line therapy. The Company has completed enrollment of its Phase II clinical trial for the treatment of adult AML in elderly patients unfit for intensive chemotherapy and expects to file a Marketing Authorization Application in 2006 for the Company's first label-extension for Evoltra®.

In addition, clofarabine (Evoltra®) is in clinical development for the treatment of myelodysplastic syndrome (MDS), chronic lymphocytic leukemia (CLL), chronic myeloid leukemia (CML), non-Hodgkin's lymphoma (NHL), multiple myeloma (MM), solid tumors and as a preconditioning regimen for transplantation.

Bioenvision is also conducting late-stage preclinical development of Evoltra® for the treatment of psoriasis and is planning further worldwide development of Evoltra® in autoimmune diseases.

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Bioenvision holds an exclusive worldwide license for clofarabine. Bioenvision granted an exclusive sublicense to Genzyme to co-develop clofarabine for cancer indications in the US and Canada. Genzyme is commercializing clofarabine for certain cancer indications in the US and Canada under the brand name Clolar®. Bioenvision holds an exclusive license in the US and Canada for all non-cancer indications. Bioenvision originally obtained clofarabine development and commercialization rights under patents held by Southern Research Institute.

In the U.S., in December 2004, the Food and Drug Administration, or FDA, approved clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL, in patients who are relapsed or refractory to at least two prior regimens of treatment. We believe clofarabine was the first new medicine initially approved in the U.S., for children with leukemia in more than a decade. Our U.S. partner, Genzyme Corporation, received Orphan Drug designation status for clofarabine in the U.S., providing marketing exclusivity for 7 years. Further, in July 2004, the FDA granted a six-month extension of the marketing exclusivity for clofarabine in pediatric ALL under the federal Best Pharmaceuticals for Children Act.

Pediatric leukemia is the most prevalent form of cancer among children up to age 19 in the U.S. It is estimated that approximately 3,400 children were diagnosed with leukemia in the U.S. in 2004, with ALL accounting for over 75% of the incidence rate. Although survival rates for childhood leukemia have improved significantly since the early 1970s, approximately 20% of pediatric patients with ALL and 60% of pediatric patients with AML do not achieve long-term survival and we believe there is a medical need for new agents to treat this population of patients. Clofarabine is approved for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two prior regimens. The adult leukemia market represents a potentially significantly larger commercial opportunity with over 11,500 patients with AML and over 8,000 patients with CLL, diagnosed each year within the U.S. Based on population and incidence rates data, we believe that the E.U. patient population with pediatric leukemias and adult AML and CLL approximates that of the U.S.

Clofarabine is a purine nucleoside analog, which is a small molecule, that we are developing with Genzyme, our co-development partner, for the treatment of acute and chronic leukemias, lymphomas and solid tumors. Clofarabine attacks cancer cells by damaging DNA in cancer cells, preventing DNA repair by damaged cancer cells, damaging the cancer cell's important control structures, and initiating the process of programmed cell death, or apoptosis, in cancer cells. Clofarabine appears to combine many of the favorable properties of the two most commonly used purine nucleoside analog drugs, fludarabine and cladribine, but appears to have greater potency at damaging the DNA of leukemia cells and a broader range of clinical activity.

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

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In Europe, we facilitated an investigator sponsored trial, or an IST, of clofarabine as first line therapy for older adult patients with AML who were unsuitable for intensive chemotherapy. The IST was closed to recruitment in August 2004 because a 67% overall response rate was achieved. This response rate was more than three times greater than the expected response rate under the current standard of care for this patient population and the investigator determined that these positive results warranted accelerated initiation of the Phase II regulatory study of clofarabine as a first-line treatment for older adult patients newly diagnosed with AML. We completed enrollment of this Bioenvision-sponsored Phase II regulatory trial in February 2006 and locked the database in anticipation of our submitting a Marketing Authorization Application with EMA later in calendar 2006 based in large part upon this clinical data.

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

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Clofarabine is currently being evaluated in an IST Phase II clinical trial for refractory CLL in the U.S. In addition, commencing in fourth quarter of calendar 2006, we intend to investigate clofarabine in European Phase II clinical trials for MDS and solid tumor cancer indications. In pre-clinical studies, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the lung, colon, kidney, breast, pancreas and prostate, as well as its action against leukemia cells. Bioenvision believes the initial data from the Phase I clinical trials indicate sufficient possible activity for clofarabine in certain solid tumor types to warrant further clinical development. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon, pancreatic, lung, breast and prostate cancer.

Pursuant to the terms of our co-development agreement with Genzyme, the successor-in-interest to ILEX Oncology, Inc. following the merger consummated between Genzyme and Ilex in December 2004, both parties are required to share promptly all information, including clinical data, generated under the co-development program and Genzyme is obligated to pay all of the U.S. and Canadian research and development costs and 50% of all approved ex-U.S. and Canada research and development costs (except for Japan and Southeast Asia and except for non-cancer indications). If additional resources are required above the agreed upon costs, we may elect to pay these additional costs and certain of these payments will be credited against future royalty payments to Genzyme at the rate of \$1.50 for every \$1.00 of additional expenditures. Under the co-development agreement with Genzyme, we receive royalties on Genzyme's annual net sales on a sliding scale based on the level of annual net sales. Similarly, we pay a royalty to Genzyme and Southern Research Institute, or SRI, the inventor of clofarabine, on our European annual net sales. Although we have not received payment from Genzyme for our development costs incurred since the Genzyme's acquisition of Ilex, we are actively discussing these reimbursements with Genzyme in an ongoing dialogue and are actively working on developing a consensus with Genzyme management for a development plan and budget going forward.

Pursuant to the terms of our co-development agreement with SRI, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications except for certain U.S. and Canadian cancer indications. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the development and marketing of clofarabine, which we expect to expire in 2021.

To date, the majority of our development activities and resulting R&D expenditures have related to the development of clofarabine. Our primary business strategy has included taking clofarabine to market in the E.U. and using the proceeds from our resulting marketing efforts, in part, to progress the other products and technologies in our pipeline.

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### Modrenal®

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

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

Modrenal® has been extensively studied in clinical trials in the U.S., Europe and Australia, and an analysis, known as a meta-analysis, of a series of these clinical studies, that together included 714 patients with post-menopausal advanced breast cancer who received Modrenal® has been conducted. Overall, a clinical benefit rate of 35% was achieved in patients with both hormone-sensitive and hormone-insensitive breast cancers. Generally, a clinical benefit is achieved when a patient's disease disappears, is decreased by greater than fifty percent or is stabilized for at least six months. In a sub-set analysis of these clinical trial data, a clinical benefit rate of 46% was achieved for 351 patients with hormone-sensitive breast cancer who had responded to one or more prior hormonal therapies and were given Modrenal® upon relapse of the cancer. In one of the studies which was conducted in Australia, a clinical benefit rate of 55% was achieved for 64 patients who received Modrenal® having previously responded to tamoxifen and subsequently relapsed. We believe these data compare favorably to currently marketed aromatase inhibitors and other agents given as second line or subsequent therapies. Furthermore, Modrenal® has an acceptable side-effect profile. On the basis of these data, Modrenal® was granted a product license in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy.



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We began marketing Modrenal® in May 2004 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. Our strategy may include seeking regulatory approval for Modrenal® in the U.S. as a therapy for hormone-sensitive breast cancers and hormone independent prostate cancers, but this strategy is dependent upon the results of the ongoing clinical trials and the resource capability of the Company. Our ongoing clinical trials in breast cancer target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as tamoxifen or any of the aromatase inhibitors. We will continue to develop our commercial and regulatory strategies for Modrenal® as we continue to analyze the results of these clinical data.

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

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

### Other Products and Technologies

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

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### Suvus®

Suvus®, especially when photo-sensitized by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Investigator sponsored Phase II clinical trials have been completed in the Middle East to study Suvus® use in treating hepatitis C virus infection. We announced interim results at the UBS Global Life Sciences Conference in New York in September 2005 and continue to monitor these data. Suvus® was given to 25 patients with genotype 4 hepatitis C who had failed a prior treatment, including interferon in many of the patients. Sixteen (64%) of the patients had cirrhosis. Suvus® was given orally for 100 days and measurement of the viral load was made at 50 days. At 50 days, 22 (88%) patients had shown a reduction in viral load of greater than 70%. Of these responders, 14 (64%) had a clearance of greater than 90%, with four responders having complete viral clearance.

Seven of the 25 patients have had viral load measured at 100 days. Six of these patients show continued reduction in viral load and the seventh patient, who had been one of the three non-responders at 50 days, had a greater than 90% reduction in viral load. No major adverse events were noted.

Methylene blue, the parent compound in Suvus®, is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. Prior to the fourth quarter of 2005, we tested for impairment our methylene blue intangibles acquired in connection with the Pathagon acquisition and determined that, based on our assumptions, the sum of the expected future cash flows, undiscounted and pertaining solely and exclusively to approved indications, exceeded the carrying value of its long-lived assets and therefore we did not recognize an impairment. Due to the loss of an intellectual property patent suit relating to the international use of methylene blue in fresh frozen plasma we re-evaluated the intangible asset relating to methylene blue at June 30, 2005. At that date, we estimated that our undiscounted future cash flows, again relating solely and exclusively to approved uses of methylene blue, were less than the carrying value. As a result, we recognized a non-cash impairment loss of \$5,276,000, equal to the difference between the estimated future cash flows for approved uses of methylene blue, discounted at an appropriate rate, and the carrying amount of the asset. Making the impairment determination and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows. Changes in events or circumstances that may affect long-lived assets makes judgments and assumptions with respect to the future cash flows highly subjective. At June 30, 2006, we received an independent third-party valuation of this intangible asset which confirmed that such estimated future cash flows continued to be

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worth more than the carrying value of methylene blue and, therefore, no further impairment was deemed to be required.

### Velostan

Velostan is a cytostatic drug currently under investigation as an anticancer agent and as an antimicrobial. Velostan is the first compound in a group of chemically related compounds that are believed to work by blocking cell division and reversing the malignant process in the cancer cell. We believe the optical isomer we have developed is more active and less toxic than its parent compound.

### OLIGON® Technology

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

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

### Gene Therapy Technology

Our product portfolio also includes a variety of gene therapy products that, we believe, may offer advancements in the field of cancer treatment and may have additional applications in certain non-cancer diseases such as diabetes, cystic fibrosis and other auto-immune disorders. Pursuant to a co-development agreement with the Royal Free and University College Medical School and a Canadian biotechnology company, we are developing gene vector technologies which, based on pre-clinical research and early Phase I clinical trials, we believe have potential in a wide array of clinical conditions. To date, the technology has undergone small-scale clinical testing with the albumin and thrombopoietin genes. The results showed the technology is capable of producing a prolonged elevation in serum albumin levels in cancer and cirrhosis patients with hypo-albuminemia, a serious physiological disorder. The gene therapy technology has been allocated limited resources for development because of the emphasis on the commercial development of clofarabine. However, it is our intention to add resource to the development of this platform technology when sufficient revenue resources allow.

### Animal Health Products

We also have one animal health product, Veteryl® (trilostane), at market in the United Kingdom for the treatment of Cushing's disease in dogs. In November 2001, we granted to Arnolds Ltd., a major distributor of animal products in the U.K., the right to market the drug for a six-month trial period, after which time, if the results were satisfactory to Arnolds, we would enter into a licensing arrangement whereby Arnolds would pay royalties to us on sales from April 2002 onward. During the trial period, Arnolds posted more than \$400,000 of sales of the drug. Arnolds has licensed the drug from us for sale in the U.K. market in consideration of a payment of a 5% royalty on sales. Separately, in May 2003, we granted to Dechra Pharmaceuticals, PLC, an affiliate of Arnolds Ltd., the exclusive right to market the drug in the U.S. for \$5.5 million of total consideration (including milestone payments) and a royalty of 2% - 4% of annual net sales.

### Corporate Information

We were incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed our name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in January 1999. Our principal executive offices are located at 345 Park Avenue, 41st Floor, New York, New York 10154. Our telephone number is (212) 750-6700 and our fax number is (212) 750-6777. Our website is [www.bioenvision.com](http://www.bioenvision.com). Information included or referred to on our website is not incorporated by reference in or otherwise a part of this

prospectus. Our website address is included in this prospectus as an inactive textual reference only.

## THE OFFERING

Common stock offered by selling stockholders	25,748,242 shares.
Common stock outstanding as of October 25, 2006	41,458,615 shares.
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering. We may receive consideration upon the exercise of options and will receive consideration upon the conversion of warrants which we intend to use for general corporate purposes.
Trading	Our common stock currently trades on the Nasdaq National Market under the symbol BIVN.
Risk Factors	You should carefully consider all of the information in this prospectus. In particular, you should evaluate the information under Risk Factors beginning on page 9 of this prospectus before deciding whether to invest in our common stock.
Plan of Distribution	The shares of common stock offered for resale may be sold by the selling stockholders pursuant to this prospectus in the manner described under Plan of Distribution on page 30.

## 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.

## Risks Related to Our Business

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

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

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

To date, we have incurred significant net losses, including net loss applicable to common stockholders of approximately \$24,236,000 for the fiscal year ended June 30, 2006. At June 30, 2006, we had an accumulated deficit of approximately \$86,567,000. We anticipate that we will continue to incur operating losses for the foreseeable future. We may never generate substantial revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

### *Clinical trials for our products are expensive and time consuming, and may not result in any viable products.*

Before obtaining regulatory approval for the commercial sale of a product, we must demonstrate through pre-clinical testing and clinical trials that a product candidate is safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process. We will incur substantial expense for, and devote a significant amount of time to pre-clinical testing and clinical trials. Even with our lead drugs, Evoltra® and Modrenal®, each of which has received at least one regulatory approval, additional pre-clinical and clinical studies are required in our effort to seek further approved indications for these drugs.

Modrenal® is approved and we market Modrenal® in the U.K. for the treatment of advanced, post-menopausal breast cancer. Currently, we are conducting a Phase II clinical trial in the U.K. for its treatment of pre-menopausal breast cancer which is a new potential indication for this approved drug.

Evoltra® is being studied in pediatric ALL, adult AML, MDS, solid tumor cancers and certain non-cancer indications in studies ranging from pre-clinical to Phase II/III.

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

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

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

government or regulatory delays.

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

Our ancillary products include OLIGON<sup>®</sup>, an anti-microbial compound, and Suvus<sup>®</sup>, an anti-viral agent, respectively, which we acquired in February 2002 in the Pathagon acquisition. At June 30, 2005, due to the loss of an intellectual property patent suit relating to the international use of Suvus<sup>®</sup> in fresh frozen plasma, we re-evaluated the fair value of the intangible assets relating to Suvus<sup>®</sup>. At that date, we estimated that our undiscounted future cash flows pertaining solely and exclusively to approved uses of Suvus<sup>®</sup> were less than the carrying value of our long-lived asset. As a result, we recognized a non-cash impairment loss of \$5,276,000, equal to the difference between the estimated future cash flows related solely to approved uses of Suvus<sup>®</sup>, discounted at an appropriate rate, and the carrying amount of the asset. Making the determinations of impairment and the amount of impairment requires significant judgment by management and assumptions with respect to the future cash flows of the assets. At June 30, 2006, subsequent to the recognition of the impairment, the net intangible assets associated with these products amounted to approximately \$6,886,000 and constituted approximately 11% of our total assets and approximately 15% of our stockholders' equity.

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

***We depend on our co-development agreement with Genzyme and if it does not proceed as planned, we may incur delay in the commercial value realized from Evoltra<sup>®</sup> (clofarabine), which may delay our ability to generate significant revenues and cash flow from the sale of Evoltra<sup>®</sup>.***

We have a co-development agreement with Genzyme, and pursuant to that agreement, Genzyme and any third party to which Genzyme grants a sublicense or transfer its obligations, has primary responsibility for conducting clinical trials and administering regulatory compliance and approval matters in certain cancer indications in the U.S. and Canada.

If Genzyme fails to meet its obligations under the co-development agreement including its obligation to cooperate and share data with us, we could lose valuable time in further developing clofarabine and further commercializing the drug both in the U.S. and in Europe. We can not provide assurance that Genzyme will cooperate with us or that Genzyme will not fail to meet its obligations under the co-development agreement. Development of compounds to the stage of approval includes inherent risk at each stage of development that the FDA, in its discretion, will mandate a requirement not foreseeable by us or by Genzyme. There would also be

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testing delays if, for example, our sources of drug supply could not produce enough Evoltra<sup>®</sup> 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 and/or market Evoltra<sup>®</sup>, obtain necessary regulatory approvals, and generate sales and cash flow from the sale of Evoltra<sup>®</sup>.

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

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

## Edgar Filing: BIOENVISION INC - Form POS AM

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. We are developing clofarabine with Genzyme, our U.S. co-development partner since its acquisition of ILEX Oncology, which occurred on December 21, 2004. No assurance can be given that the operational and managerial relations with Genzyme will proceed favorably or that the timeline for development of clofarabine will not be elongated now that Genzyme has replaced ILEX as our U.S. cancer-indication marketing partner. No assurance can be given that we or Genzyme have the oncology experience required to work successfully with the applicable regulatory authorities to build upon the licensed indications for clofarabine.

With respect to Modrenal<sup>®</sup>, our long-term drug development objectives for Modrenal<sup>®</sup> may include attempting to test the drug and get approval in the U.S. for treatment of advanced post-menopausal breast cancer patients. These trials would take significant time and resources and no assurance can be given that developing the drug in this indication will result in a U.S. approval for Modrenal<sup>®</sup> in advanced post-menopausal breast cancer patients.

Certain of our unapproved compounds or potential new indications for our approved drugs are not expected to be available for sale for at least several years, if at all. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

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

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

***We rely on compounds and technology licensed from third parties and termination of any of those licenses would result in the loss of significant rights.***

We hold an exclusive worldwide license for clofarabine. We granted an exclusive sublicense to Genzyme to develop and commercialize clofarabine for cancer indications in the U.S. and Canada. We hold an exclusive

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license in the U.S. and Canada for all non-cancer indications. We originally obtained clofarabine development and commercialization rights under patents held by Southern Research Institute, or SRI.

Our licenses generally may be terminated by SRI under the co-development agreement under certain circumstances. If any of our licenses are terminated, we may lose certain rights to manufacture, sell, market and distribute clofarabine or other product candidates which would significantly reduce our actual and potential revenues and have a material and negative impact on our operations.

***If we are unsuccessful in developing and commercializing our products, our business, financial condition and results of operations could be materially adversely affected which could have a negative impact on the value of our securities.***

Many of our products and processes are in the early or mid-stages of research, development and/or commercialization and, therefore, will require the commitment of substantial financial resources, extensive research, development, sales and marketing activities prior to being ready for sale or marketed in significant quantities. All of our commercially available products will require further development, clinical testing and regulatory approvals as we seek approvals in new indications and geographic markets. If it becomes too expensive to sustain our present

commitment of resources on a long-term basis, we will be unable to continue certain necessary research and development activities. Furthermore, we cannot be certain that our clinical testing will render satisfactory results, or that we will receive required regulatory approvals for our new products or new indications. If any of our products, even if developed and approved, cannot be successfully commercialized, our business, financial condition, results of operations and liquidity could be materially adversely affected which could have a negative impact on the value of our common stock or debt securities obligations.

*During the next several years, we will be very dependent on the commercial success of Evoltra®.*

At our present and anticipated level of operations, we may not be able to achieve and maintain profitability without continued growth in our revenues. The growth of our business during the next several years will be largely dependent on the commercial success of Evoltra® and our other products. We do not have long-term data on the use of the product and cannot predict whether Evoltra® will gain widespread acceptance, which will mostly depend on the acceptance of regulators, physicians, patients and other key opinion leaders as a relatively safe and effective drug that has certain advantages as compared to existing or future therapies.

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

*Regulation in General.* Virtually all aspects of our business are regulated by federal, state and local statutes and governmental agencies in the U.S. and other countries. Failure to comply with applicable statutes and government regulations could have a material adverse effect on our ability to develop and sell products which would have a negative impact on our cash flow. The development, testing, manufacturing, processing, quality, safety, efficacy, packaging, labeling, record-keeping, distribution, storage and advertising of pharmaceutical products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies. These activities are also regulated by similar state and local agencies and equivalent foreign authorities. In our material contracts with vendors providing any portion of these types of services, we seek assurances that our vendors comply and will continue to maintain compliance with all applicable rules and regulations. This is the case, for example, with respect to our contracts with Ferro Pfanstiehl and Penn Pharmaceuticals. No assurance can be given that our most significant vendors will continue to comply with these rules and regulations.

*FDA Regulation.* All pharmaceutical manufacturers in the U.S. are subject to regulation by the FDA under the authority of the Federal Food, Drug, and Cosmetic Act. Under the Act, the federal government has extensive administrative and judicial enforcement powers over the activities of pharmaceutical manufacturers to ensure compliance with FDA regulations. Those powers include, but are not limited to the authority to:

initiate court action to seize unapproved or non-complying products;

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enjoin non-complying activities;

halt manufacturing operations that are not in compliance with current good manufacturing practices prescribed by the FDA;

recall products which present a health risk; and

seek civil monetary and criminal penalties.

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

*FDA Approval Process.* We have a variety of products under development, including line extensions of existing products, reformulations of existing products and new products. All new drugs must be the subject of an FDA-approved new drug application before they may be marketed in the U.S. All generic equivalents to previously approved drugs or new dosage forms of existing drugs must be the subject of an FDA-approved abbreviated new drug application before they may be marketed in the U.S. In both cases, the FDA has the authority to determine what testing

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

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

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

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

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

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

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



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

Our business strategy involves obtaining orphan drug designation for certain of the oncology products we have under development. Although clofarabine has received orphan drug designation with the FDA and EMA, 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 EMA 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

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Orphan Drug Act. The precise scope of protection that may be afforded by orphan drug designation and marketing approval may be subject to change in the future.

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

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

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

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

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

Competition in our industry is intense. Potential competitors in the U.S. and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Potential competitors for certain indications of our lead drugs include, with respect to Evoltra®, Schering AG, which markets fludarabine, and certain generic drug companies in Europe which could market fludarabine upon expiry of the patent protections held by Schering AG. Potential competitors with respect to Modrenal® 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® regimen of treatment. No assurance can be given that the ongoing business activities of our competitors will not have a material adverse effect on our business prospects and projections going forward.

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

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

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

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

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

***We have no commercial manufacturing facilities and if the third-party manufacturers upon whom we rely fail to produce consistently and on a timely basis the raw materials or finished products in the volumes that we require or fail to meet quality standards and maintain necessary licensure from regulatory authorities, we may be unable to meet demand for our products, potentially resulting in lost revenues.***

We have never manufactured any of our products and our third party manufacturers will need to consistently manufacture appropriate commercial quantities of drug supply for our products in order to fully exploit the commercial potential for our commercial products. No assurance can be given our products will be consistently manufactured in a cost effective manner. Manufacturers of products developed by us will be subject to current good manufacturing practices prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities. We may not be able to enter into or maintain relationships either domestically or abroad with manufacturers whose facilities and

procedures comply or will continue to comply with current good manufacturing practices or applicable foreign requirements. Failure by a manufacturer of our products to comply with current good manufacturing practices or applicable foreign requirements could result in significant time delays or our inability to commercialize or continue to market a product and could have a material adverse effect on our sales of products and, therefore, our cash flow. In the U.S., failure to comply with current good manufacturing practices or other applicable legal requirements can lead to federal seizure of violative products, injunctive actions brought by the federal government, and potential criminal and civil liability on the part of a company and its officers and employees.

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

The creation of infrastructure to commercialize oncology products is a difficult, expensive and time-consuming process. We may not be able to establish direct or indirect sales and distribution capabilities outside of the UK or be successful in gaining market acceptance for proprietary products or for other products. We currently have very limited sales and marketing capabilities outside of the UK. We currently employ six full-time sales employees and two full-time marketing employees. Recently, we have entered into arrangements with Innovex, an affiliate of Quintiles Corporation, for the sales and marketing of Evoltra® (clofarabine) in certain E.U. countries from the date of marketing approval in May 2006 through November 2007, subject to certain circumstances. 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

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marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

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

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

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

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

Our success will depend in significant part on the expansion of our operations and the effective management of growth. This growth has and will continue to place a significant strain on our management and information systems and resources and operational and financial systems and resources. To manage future growth, our management must continue to improve our operational and financial systems and expand, train, retain and manage our employee base. Our management may not be able to manage our growth effectively. If our systems, procedures, controls, and resources are inadequate to support our operations, our expansion would be halted or delayed and we could lose our opportunity to gain

significant market share or the timing with which we would otherwise gain significant market share. Any inability to manage growth effectively may harm our ability to institute our business plan. The strain on our systems, procedures, controls and resources is further heightened by the fact that our executive office and operational development facilities are located in separate time zones (New York, New York and Edinburgh, Scotland, respectively).

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

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

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

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

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

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

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

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We have the right to manufacture, market and distribute our lead drugs, Evoltra® and Modrenal®, in territories outside of the U.S. Specifically, we currently market Modrenal® in the United Kingdom and Evoltra® throughout Europe. Further, more than half of our employees are employed by Bioenvision Limited, our wholly-owned subsidiary with offices in Edinburgh, Scotland.

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

- difficulty in establishing or managing distribution relationships;
- different standards for the development, use, packaging, pricing and marketing of our products and technologies;

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- our inability to locate qualified local employees, partners, distributors and suppliers;
  - the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment;
  - general geopolitical risks, such as political and economic instability, changes in diplomatic and trade relations, and foreign currency risks; and
  - risks related to the fluctuation in currency exchange rates.

We do not engage in forward currency transactions which means we are susceptible to fluctuations in the U.S. dollar against foreign currencies such as the pound sterling. Accordingly, as the value of the dollar becomes weaker against the pound sterling, ongoing services provided by our UK employees, clinical research organizations and other service providers become more expensive to us. No assurance can be given that the U.S. dollar will not continue to weaken which could have a material adverse effect on the costs associated with our drug development activities.

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

As of June 30, 2006, we had stockholders' equity of approximately \$46,588,000 and working capital of approximately \$40,065,000. 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. Because we will be required to fund additional operating losses in the foreseeable future, our financial position will continue to deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders would result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or accounting methods, even though these actions would otherwise benefit our business.

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

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

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

Third-party payors may attempt to control costs further by selecting exclusive providers of their pharmaceutical products. If third-party payors were to make this type of arrangement with one or more of our competitors, they would not reimburse patients for purchasing our competing products. For example, if a third-party payor in the U.K. were to pay patients for regimens of aromatase inhibitor treatment but not treatments of

Modrenal®, this would cause a decline in sales of Modrenal®. 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 EMA, 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 claims made product liability insurance coverage in an amount which we believe is commercially reasonable. Existing coverage may not be adequate as we further develop our products. In the future, adequate insurance coverage or indemnification by collaborative partners may not be available in sufficient amounts, or at acceptable costs, if at all. To the extent that product liability insurance, if available, does not cover potential claims, we will be required to self-insure the risks associated with those claims. The successful assertion of any uninsured product liability or other claim against us could limit our ability to sell our products or could cause monetary damages. In addition, future product labeling may include disclosure of additional adverse effects, precautions and contra indications, which may adversely impact product sales. The pharmaceutical industry has experienced increasing difficulty in maintaining product liability insurance coverage at reasonable levels, and substantial increases in insurance premium costs, in many cases, have rendered coverage economically impractical.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq market rules, are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity. As a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We are committed to maintaining high standards of corporate governance, internal control and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, our reputation may be harmed and our operations and revenues may be adversely affected.

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

We have evaluated and continue to evaluate our internal controls systems in order to allow management to report on the effectiveness of our internal control over financial reporting and our registered independent public accounting firm to attest to this report, as required by Section 404 of the Sarbanes-Oxley Act. We are performing the system and process evaluation and testing, and implementing any necessary remediation,

required in an effort to comply with the management report and public accounting firm attestation requirements and continue to incur

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additional expenses and devote significant management time towards completing actions required for management's evaluation. The evaluation and attestation processes required by Section 404 are new and neither public companies nor public accounting firms have significant experience in testing or complying with these requirements. While we have developed and are implementing plans to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since, like other public companies, we and our registered independent public accounting firm are undergoing the process for the first time in a regulatory environment where the standards to assess adequacy of compliance are under development. We cannot assure you that there may not be significant deficiencies or material weaknesses that would be required to be reported as a result of the process.

#### **Risks Related to the Offering and Ownership of 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 June 30, 2006, our stock price has ranged from a high of \$9.18 to a low of \$4.76. If our revenues do not grow or grow more slowly than we anticipate, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our common stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in investor confidence or otherwise fails, the market price of our common stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, companies that have experienced volatility in the market price of their stock have been the subject of securities class action litigation. If we were to become the subject of securities class action litigation, it could result in substantial costs and a diversion of management's attention and resources.

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

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

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

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

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

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

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

Our certificate of incorporation also authorizes us to issue up to 20,000,000 shares of preferred stock in one or more different series with terms fixed by the board of directors. Stockholder approval is not necessary to issue preferred stock in this manner. Thus, our board of directors can authorize and issue shares of preferred stock with voting or conversion rights that could adversely affect the voting or other rights of holders of our common stock and thereby reduce its value. These rights could have the effect of making it more difficult for a person or group to acquire control of us, as well as prevent or frustrate any attempt by stockholders to change our direction or management. While our board of directors has no current intention to issue any preferred stock, the issuance of these shares may deter potential acquirors.

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

Our existing principal stockholders, executive officers and directors beneficially own, in the aggregate, approximately 52% of our outstanding common stock as of October 25, 2006. As a result, these stockholders will, if they so choose, be able to substantially control all matters requiring stockholder approval. These matters include the election of directors and approval of significant corporate transactions, such as a merger, consolidation, takeover or other business combination involving us. Our existing principal stockholders, executive officers and directors may have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership could also adversely affect the market price of our common stock or reduce any premium over market price that an acquirer might otherwise pay.

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

As of June 30, 2006, we had 41,456,616 shares of common stock outstanding, 2,250,000 shares of Series A Convertible Participating Preferred Stock outstanding which are currently convertible into 4,500,000 shares of common stock and common stock equivalents, and warrants and stock options, convertible or exercisable into 11,563,313 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from \$1.25 to \$8.80 per share. We have also reserved for issuance an aggregate of 4,500,000 shares of common stock for a stock option plan for our employees. Historically, from time to time, we have awarded our common stock to our officers, in lieu of cash compensation, although we do not expect to do so in the future. As of June 30, 2006, we have the sale of shares of common stock underlying 4,500,000 options are registered under the Securities Act on Form S-8. The future resale of these shares underlying stock options will result in a dilution to your percentage ownership of our common stock and could adversely affect the market price of our common stock.

The terms of our cumulative Series A Convertible Participating 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 the holder's percentage ownership of our common stock. The resale of many of the shares of common stock which underlie these options and warrants are registered under this prospectus and the sale of such shares may adversely affect the market price of our common stock.



## FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements are based on current expectations, estimates, forecasts and projections about the industry in which we operate, management's beliefs and assumptions made by management. Such statements include, in particular, statements about our plans, strategies and prospects under the headings Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business. You can generally identify forward-looking statements by the use of words such as believes, expects, may, should, could, seeks, approximately, plans, objectives, goals, projects, estimates, anticipates, continues to, designed to, foreseeable future, scheduled and similar words. These statements reflect our current views concerning future events and are based on current assumptions, they involve risks, uncertainties and other factors which may lead to actual results or effects that are materially different from those anticipated or contemplated in the forward-looking statements. Some, but not all, of the factors that may cause these differences include, but are not limited to:

statements about our drug development and commercialization goals and expectations;

potential regulatory approvals;

our plans for and anticipated results of our clinical development activities;

the potential advantage of our drug candidates;

statements about our future capital requirements, the sufficiency of our capital resources to meet those requirements and the expected composition of our capital resources;

other statements that are not historical facts; and

those items discussed in the Risk Factors section of this prospectus.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We caution you not to place undue reliance on these forward-looking statements. All written and oral forward-looking statements attributable to us or persons acting on our behalf are qualified in their entirety by these cautionary statements. We undertake no obligation to publicly update any forward-looking statement to reflect new information, events or circumstances, whether anticipated or unanticipated, or to conform the statement to actual results or changes in our expectations. You should, however, review the factors, risks and other information we provide in the reports we file from time to time with the SEC.

## 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.

The selling stockholders will not pay any of the expenses that are incurred in connection with the registration of the shares of common stock, but they will pay all commissions, discounts and any other compensation to any securities broker-dealers through whom they sell any of the shares of common stock.

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## 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 December 16, 2005, except for with respect to Perseus-Soros BioPharmaceutical Fund, LP, SCO Capital Partners LLC, SCO Financial Group LLC and SCO Securities LLC, RLB Capital, Inc. which information is as of the date of this prospectus:

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the name of each selling stockholder;

the number and percentage of shares of common stock beneficially owned by each selling stockholder;

the number of shares of common stock that may be sold in this offering; and

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 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 41,458,615 shares of our common stock outstanding as of October 25, 2006.

Name	Shares Owned Prior to the Offering Number	Percent	Number of Shares which may be Sold in this Offering	Shares Owned After the Offering Number	Percent
Perseus-Soros BioPharmaceutical					
Fund, LP (1)	7,950,053	19.18%	7,950,053	--	--
SDS Merchant Fund, LP (4)	144,999	*	48,333	96,666	*
SDS Merchant Fund, LP (5)	354,999	*	118,333	236,666	*
SDS Merchant Fund, LP (6)	380,001	*	166,667	213,334	*
Orion Biomedical Offshore Fund, LP (7)	133,875	*	44,625	89,250	*
Orion Biomedical Fund, LP (8)	616,125	1.49%	205,375	410,750	1.00%
Beaver Ltd. (9)	75,000	*	25,000	50,000	*
CKH Invest Aps. (10)	50,001	*	16,667	33,334	*
Merlin Nexus I LP (11)	673,617	1.63%	406,949	266,668	*
Alexandra Global Master Fund, Ltd.(12)	666	*	666	--	--
DWS Investment GmbH (13)	1,360,600	3.28%	493,934	866,666	2.09%
Michael Sistenich (14)	125,001	*	41,667	83,334	*
Global Biotechnology Fund (15)	209,369	*	76,037	133,332	*
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)	4,121,987	9.94%	2,239,905	1,882,082	4.54%
Julie Wood (17)	318,750	*	318,750	--	--
Stuart Smith (18)	700,000	1.69%	700,000	--	--
Thomas Nelson (19)	261,787	*	178,351	83,436	*
Kevin Leech (20)	1,813,912	4.38%	413,912	1,400,000	3.38%
Bioaccelerate, Inc. (21)	1,162,100	2.80%	434,828	727,272	1.75%

Name	Shares Owned Prior to the Offering Number	Percent	Number of Shares which may be Sold in this Offering	Shares Owned After the Offering Number	Percent
Sterling Securities Ltd. (21)	74,045	*	74,045	--	--

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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	--	--
Nagy Habib (23)	41,881	*	41,881	--	--
NAB Holdings Ltd. (21) (24)	451,913	1.09%	451,913	--	--
SCO Capital Partners LLC (25), (27)	7,009,946	16.91%	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	1.81%	250,000	499,243	1.20%
Edward W. Kelly (27), (28)	356,013	*	250,000	156,013	*
RRD International, Inc. (30)	130,277	*	130,277	--	--
RLB Capital, Inc. (31)	44,000	*	44,000	--	--
Stamford Capital (32)	54,722	*	54,722	--	--
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	*	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	--	--
Quogue Capital LLC (51)	14,000	*	14,000	--	--
Meditor Master Curra Fund Limited (52)	192,000	*	192,000	--	--
Atlas Equity I, Ltd. (53)	103,333	*	103,333	--	--
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	--	--
Total	32,976,288		25,748,242	7,228,046	

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

- (1) Includes 2,250,000 shares of Series A Preferred Stock currently convertible into 4,500,000 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. Perseus-Soros Partners, LLC is the general partner of the Perseus-Soros BioPharmaceutical Fund, LP. Perseus BioTech Fund Partners, LLC and SFM Participation, L.P. are the managing members of Perseus-Soros Partners, LLC. Perseuspur, LLC is the managing member of Perseus BioTech Fund Partners, LLC. Frank Pearl is the sole member of Perseuspur, LLC and in such capacity may be deemed a beneficial owner of securities held for the account of the Perseus-Soros BioPharmaceutical Fund, LP. SFM AH, LLC is the general partner of SFM Participation, L.P. The sole managing member of SFM AH, LLC is Soros Fund Management LLC. George Soros is the Chairman of Soros Fund Management LLC and in such capacity may be deemed a beneficial owner of securities held for the account of the Perseus-

Soros BioPharmaceutical Fund, LP. The address of Perseus-Soros BioPharmaceutical Fund, LP is 888 Seventh Avenue, 30th Floor, New York, New York 10106.

- (2) Intentionally omitted.
- (3) Intentionally omitted.
- (4) Includes 96,666 shares of common stock resulting from converting their Series A Preferred 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 Capital Group SPC, Ltd.
- (5) Includes 236,666 shares of common stock resulting from converting their Series A Preferred Stock and a warrant to purchase 118,333 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, 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.
- (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 216,668 shares of common stock resulting from converting their Series A Preferred 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) Pursuant to a SC 13G/A filed by Alexandria on December 31, 2004, as of December 31, 2004 they beneficially owned 666 common shares.
- (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 125,001 shares of common stock.
- (15) Includes 209,369 shares of common stock.
- (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 225,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (19) Includes 261,787 shares of common stock.
- (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:

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- (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;
- (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) Intentionally omitted.
- (23) Includes 41,881 common shares.
- (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 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.

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- (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)

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- Includes a warrant to purchase 60,000 shares of common stock exercisable at \$1.25 per share for three years from March 8, 2004 and 40,000 common shares issued pursuant to an exercise of 40,000 warrants.
- (32) Includes a warrant to purchase 40,000 shares of common stock exercisable at \$1.80 per share at anytime from March 4, 2004 through February 23, 2007 and 14,722 common shares issued pursuant to a cashless exercise of 20,000 warrants.
  - (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 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 216,000 shares of common stock.
  - (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 103,333 shares of common stock.
  - (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.

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- (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:

- on Nasdaq or on any other market on which our common stock may from time to time be trading;
- 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;
- purchases by a broker or dealer as principal and resale by the broker or dealer for its account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- in public or privately-negotiated transactions;
- 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;
- an exchange distribution in accordance with the rules of an exchange;
- through agents; or
- through market sales, both long or short, to the extent permitted under the federal securities laws; or in any combination of these methods.

The sale price to the public may be:

- the market price prevailing at the time of sale;
- a price related to the prevailing market price;
- at negotiated prices; or
- 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;

sell the shares short and redeliver the shares to close out such short positions;

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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  
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:

- the names of the selling stockholder(s) and of the participating broker-dealer(s), identifying them as underwriters, as required;
- the number of shares involved;
- the price at which such shares were sold;
- the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable; and
- 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 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

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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:

- the number of shares being offered;



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

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## DESCRIPTION OF OUR CAPITAL STOCK

The following summarizes the material provisions of our certificate of incorporation and by-laws that relate to our capital stock. Copies of those documents are incorporated by reference as exhibits to the registration statement that includes this prospectus. See [Where You Can Find More Information](#).

### 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 41,458,615 shares were outstanding on October 25, 2006. 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 American Stock Transfer & Trust Company, 59 Maiden Lane, New York, New York 10038, Attn: Susan Silber.

### **Description of Preferred Stock**

*Number of Authorized and Outstanding 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 2,250,000 shares were issued and outstanding as of October 25, 2006.

*Voting Rights.* 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.

*Conversion.* 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.

*Liquidation Preference and Dividends.* Holders of Series A convertible preferred stock have a liquidation preference over holders of common stock of \$3.00 per share. Holders of the Series A convertible preferred stock are entitled to an annual 5% dividend which may be paid in cash or additional shares of common stock in our sole discretion.

Our charter also authorizes our board of directors to increase the number of shares of preferred stock we may issue without approval of common stockholders. Preferred stock may be issued in one or more series, the terms of which may be determined without further action by common stockholders. These terms may include preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends, qualifications or terms or

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

### **Stockholder Rights Plan**

Under our stockholder rights plan, if a person or group acquires 15% or more of our common stock, all rightsholders, except the acquiror, will be entitled to acquire at the then exercise price of a right that number of shares of our common stock which at the time will have a market value of two times the exercise price of the right. In addition, under certain circumstances, all rightsholders, other than the acquiror, will be entitled to receive at the then exercise price of a right that number of shares of common stock of the acquiring company which at the time will have a market value of two times the exercise price of the right. The initial exercise price of a right is \$70. Such rights provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock and may have the effect of delaying or preventing a change in control. The issuance of preferred stock also could decrease the amount of earnings and assets available for distribution to the holders of common stock or could adversely affect the rights and powers, including voting rights, of the holders of our common stock.

## Warrants

As of October 25, 2006, there were outstanding warrants to purchase an aggregate of 6,508,147 shares of our common stock, exercisable at prices ranging from \$1.25 to \$8.25 per share. The weighted average exercise price of the warrants is \$2.34.

## Stock Options

As of October 25, 2006, there were outstanding options to purchase an aggregate of 4,693,333 shares of our common stock, exercisable at prices ranging from \$1.25 to \$8.87 per share, of which, options to purchase 3,294,835 shares were exercisable. The weighted average exercise price of the outstanding options is \$4.26.

## Delaware Law and Certain By-Law Provisions

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

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

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

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## LEGAL MATTERS

Certain legal matters have been passed upon for us by Paul, Hastings, Janofsky & Walker LLP, New York, New York.

## EXPERTS

Effective April 18, 2006, we appointed J.H. Cohn LLP as our independent registered public accounting firm after our former independent registered public accounting firm, Deloitte & Touche LLP resigned effective February 15, 2006. Information regarding the appointment of J.H. Cohn LLP and the resignation of Deloitte Touche LLP was reported on our Current Reports on Forms 8-K and Form 8-K/A filed with the SEC on April 19, 2006, February 21, 2006 and January 20, 2006. We changed independent registered public accounting firms in April 2005, from Grant Thornton LLP to Deloitte & Touche LLP. Information regarding the change in independent accountants was reported in our Current Report on Form 8-K filed with the SEC on April 7, 2005. There were no disagreements or reportable events requiring disclosure under Item 304(b) of Regulation S-K.

Our consolidated financial statements for the year ended June 30, 2004, incorporated by reference herein, have been audited by Grant Thornton LLP, an independent registered public accounting firm, as set forth in their report thereon included therein and incorporated herein by reference in reliance upon the report of such firm given on the authority of said firm as experts in accounting and auditing.

Our consolidated financial statements as of and for the year ended June 30, 2005, incorporated by reference from our annual report on Form 10-K for the year ended June 30, 2006 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

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Our consolidated financial statements as of and for the year ended June 30, 2006, incorporated by reference herein have been audited by J.H. Cohn LLP, an independent registered public accounting firm, as stated in their report thereon included therein and incorporated by reference herein. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any documents we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our filings with the SEC are also available to the public through the SEC's website at <http://www.sec.gov>.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act for the registration of the common stock offered by this prospectus. This prospectus, which is a part of the registration statement, does not contain all of the information included in the registration statement. Any statement made in this prospectus concerning the contents of any contract, agreement or other document is not necessarily complete. For further information regarding our company and the common stock offered by this prospectus, please refer to the registration statement, including the exhibits and schedules thereto. If we have filed any contract, agreement or other document as an exhibit to the registration statement, you should read the exhibit for a more complete understanding of the documents of matter involved.

### INCORPORATION BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those filed documents. The information incorporated by

reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information.

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

Our annual report on Form 10-K for the year ended June 30, 2006 filed on September 11, 2006;

Our definitive proxy statement dated October 20, 2006, relating to our December 2006 annual meeting of stockholders, filed on October 20, 2006; and

Our current reports on Form 8-K filed on September 18, 2006 and October 11, 2006.

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, including to any beneficial owner, to whom this prospectus is delivered, upon written or oral request of such person, a copy of any or all of the documents referred to above which have been or may be incorporated by reference into this prospectus but not delivered with the prospectus. 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.

**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.

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**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated fees and expenses in connection with the issuance and distribution of the securities being registered hereunder, which fees and expenses will be borne solely by the registrant.

<u>Description</u>	<u>Amount</u>
Legal fees and expenses*	\$ 25,000
Accounting fees and expenses*	15,000
Printing fees and expenses*	15,000
Blue sky fees and expenses*	2,000
Transfer agent fees and expenses*	1,000
Miscellaneous expenses*	17,000
Total	\$ 75,000

\* Estimated pursuant to Rule 511 of Regulation S-K.

**Item 14. Indemnification of Directors and Officers.**

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

Subsection (b) of DGCL Section 145 empowers a corporation to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a

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

DGCL Section 145 further provides that to the extent that a present or former director or officer is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. In all cases in which indemnification is permitted under subsection (a) and (b) of Section 145 (unless

ordered by a court), it shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the applicable standard of conduct has been met by the party to be indemnified. Such determination must be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders. The statute authorizes the corporation to pay expenses incurred by an officer or director in advance of the final disposition of a proceeding upon receipt of an undertaking by or on behalf of the person to whom the advance will be made, to repay the advances if it shall ultimately be determined that he was not entitled to indemnification. DGCL Section 145 also provides that indemnification and advancement of expenses permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain liability insurance on behalf of its directors, officers, employees and agents regardless of whether the corporation would have the statutory power to indemnify such persons against the liabilities insured.

Article Seven of our Certificate of Incorporation, as amended, which we refer to as the Certificate, provides that none of our directors shall be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director except for liability (i) for any breach of the director's duty of loyalty to us or our stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL (involving certain unlawful dividends or stock purchases or redemptions), or (iv) for any transaction from which the director derived an improper personal benefit.

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

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

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

#### **Item 15. Recent Sales of Unregistered Securities.**

We did not sell any equity securities during our 2006 fiscal year that were not registered under the Securities Act and have not previously been described in a Quarterly Report on Form 10-Q or a Current Report on Form 8-K.

**Item 16. Exhibits and Financial Statement Schedules.**

<b>Exhibit Number</b>	<b>Description</b>
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1)
2.2	Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (2)

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<b>Exhibit Number</b>	<b>Description</b>
4.1	Certificate of Designation (3)
4.2	Form of Warrant (3)
4.3	Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (4)
4.4	Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (4)
4.5	Rights Agreement, dated as of November 17, 2004, between Bioenvision, Inc. and American Stock Transfer & Trust Company (5)
+5.1	Opinion of Paul, Hastings, Janofsky & Walker LLP
*23.1	Consent of J.H. Cohn LLP
*23.2	Consent of Deloitte & Touche LLP
*23.3	Consent of Grant Thornton LLP
+24.1	Power of Attorney

\* Filed herewith.

+ Previously filed.

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

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

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

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

(5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on November 18, 2004.

**Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

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

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

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent not more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

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

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

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

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

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.



## Edgar Filing: BIOENVISION INC - Form POS AM

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on October 25, 2006.

BIOENVISION, INC.

By /s/ Christopher B. Wood

Christopher B. Wood, Chairman of the

Board and Chief Executive Officer

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

Signatures	Title	Date
<u>/s/ Christopher B. Wood, M.D.</u> Christopher B. Wood _____*_____ David P. Luci _____*_____ Thomas S. Nelson, C.A. _____*_____ Michael Kauffman _____*_____ Andrew N. Schiff	Chairman and Chief Executive Officer and Director (Principal Executive Officer)  Chief Financial Officer, General Counsel (Principal Financial and Accounting Officer)  Director  Director  Director	October 25, 2006  October 25, 2006  October 25, 2006  October 25, 2006

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

Christopher B. Wood

Attorney-in-fact

**POWER OF ATTORNEY**

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Joseph P. Cooper</u>	Director	October 25, 2006
Joseph P. Cooper		

**Exhibit Index**

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