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BIOENVISION INC  
Form POS AM  
October 13, 2004

As filed with the Securities  
and Exchange Commission on January 12, 2004                      Registration No. 333-115816

U.S. Securities and Exchange Commission  
Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 1 ON FORM S-3 TO FORM SB-2 ON FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BIOENVISION, INC.  
(Name of small business issuer in its charter)

|  |  |
|--|--|
| Delaware<br>-----<br>(State or other jurisdiction of<br>incorporation or organization) | 2834<br>-----<br>(Primary Standard Industrial<br>Classification Code Number) |
|--|--|

509 Madison Avenue  
Suite 404  
New York, New York 10022  
(212) 750-6660  
(Address and telephone number of principal  
executive offices and principal place of business)

David P. Luci, Esq.  
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Luke P. Iovine, III, Esq.  
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Approximate date of commencement of proposed sale to the public: As soon as practical after the effective date of this Registration Statement. 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, 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, check the following box and list the Securities Act registration statement number of the earlier effective

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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 post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier registration statement for the same offering.  \_\_\_\_\_  
 If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

CALCULATION OF REGISTRATION FEE

| Title of each class of securities to be registered<br>----- | Number of shares to be registered<br>----- | Proposed maximum offering price per share<br>----- | Proposed aggregate offering price<br>----- |
|---|--|--|--|
| Common Stock, par value \$.001 per share                    | 34,015,739 (1)                             | (1)  | (2)  |

- (1) Represents an aggregate of 34,015,739 shares of Common Stock previously registered pursuant to Registration Statement on Form SB-2 (Registration No. 333-97443) that are being carried forward in the Prospectus filed with this Registration Statement.
- (2) This amount has previously been paid by the registrant as the registration fee for the 34,015,739 shares of Common Stock carried forward from the prior Registration Statement on Form SB-2 (Registration No. 333- 97443).

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

The information in this prospectus is not complete and may be changed. The selling shareholders 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 it is not soliciting an offer to buy these securities in any state where such offer or sale is not permitted.

Subject to completion, January 12, 2004

PROSPECTUS

BIOENVISION, INC.

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34,015,739 shares of common stock

Of the shares of stock covered by this prospectus: (i) 10,880,000 shares are issuable upon the conversion of 5,440,000 preferred shares issued in connection with a private placement consummated in May 2002; (ii) 5,440,000 shares are issuable upon the exercise of warrants issued to preferred stockholders in connection with a private placement consummated in May 2002; (iii) 6,650,867 shares were issued to former stockholders of Pathagon Inc. in February 2002 in connection with the consummation of the acquisition of Pathagon Inc.; (iv) 1,008,333 shares are issuable upon the exercise of warrants issued to our financial advisor in connection with a private placement consummated in May 2002; (v) 3,751,995 shares were issued and 3,974,544 shares are issuable upon the exercise of warrants and options issued to the co-founders, early round investors and certain former consultants and advisors for services rendered to or on behalf of us; (vi) 100,000 shares were issued and 200,000 shares are issuable upon the exercise of warrants issued to a former co-development partner for services rendered to us; and (vii) 1,500,000 shares are issuable upon the exercise of warrants issued in connection with a credit facility secured by Bioenvision in November 2001.

Our common stock is traded on the American Stock Exchange under the symbol "BIV". The last reported sales price of shares of our common stock on January 6, 2004 was \$4.14 per share.

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

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

The date of this prospectus is January \_\_\_\_, 2004.

## TABLE OF CONTENTS

|  | Page |
|--|------|
| PROSPECTUS SUMMARY.....                              | 1    |
| THE OFFERING.....                                    | 2    |
| RISK FACTORS.....                                    | 3    |
| DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS..... | 11   |
| USE OF PROCEEDS.....                                 | 11   |
| DESCRIPTION OF SECURITIES.....                       | 11   |
| SELLING STOCKHOLDERS.....                            | 13   |
| PLAN OF DISTRIBUTION.....                            | 17   |

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LEGAL MATTERS.....19
EXPERTS.....19
WHERE YOU CAN GET MORE INFORMATION.....19

PROSPECTUS 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 financial statements and notes to those statements appearing elsewhere in this prospectus.

Bioenvision, Inc.

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

Clofarabine is a purine nucleoside analogue which, based on our own clinical studies and studies conducted by others on our behalf, we believe is effective in the treatment of leukemia and lymphoma. Based on Phase I/II clinical trials performed to date, we also believe Clofarabine may be effective for the treatment of solid tumors. Clofarabine is currently in Pivotal Phase II clinical trials for pediatric and adult ALL and AML. In January, 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for Clofarabine.

Modrenal(R) is an endocrine agent with a novel mode of action that has demonstrated efficacy against tamoxifen resistant advanced post-menopausal breast cancer. Modrenal(R) is an ER beta agonist and blocks the kianase mediated proliferation pathway in breast cancer., which makes it an effective agent in patients who have acquired endocrine resistance to other hormonal agents. We launched Modrenal(R) in May 2003 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. In the first half of 2004, we intend to apply for mutual recognition in the other four largest European territories in an effort to gain approval for

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Modrenal(R) in each such territory. We anticipate receiving approval in each such territory in the first half of calendar year 2005. Further, we intend to file an IND for prostate cancer clinical trials in the US and intend to commence our first US clinical trial in the first quarter of calendar year 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for Japan and South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.

Our primary business strategy is to develop and commercialize our two lead drugs, Clofarabine and Modrenal(R) for sale in the territories within which we have licensed the right to sell, market and distribute these drugs. Our portfolio of compounds also includes four other products and technologies which have potential market applicability in 12 clinical indications and we anticipate that revenues derived from Clofarabine and Modrenal(R) will permit us to further develop these four other products and technologies.

### Corporate Background

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

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### The Offering

Shares of common stock offered by the  
selling stockholders..... 34,015,739

Shares of common stock outstanding as of  
January 6, 2004..... 19,091,535

Shares to be outstanding following  
offering (assuming conversion of all  
preferred shares into common shares and  
exercise of options and warrants, and  
assuming no sales of any securities  
pursuant to this offering)..... 42,094,412

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

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

Plan of Distribution..... The shares of common stock offered for resale may be sold by the selling stockholders pursuant to this prospectus in the manner described under "Plan of Distribution" on page 17.

Amex symbol..... BIV

-2-

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. There may be additional risks that we are not currently able to identify. These may also adversely affect our business, financial condition or operating results. If any of the events we have identified or those that we cannot now identify occurs, the trading price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock.

The price of our common stock is likely to be volatile and subject to wide fluctuations.

The market price of the securities of biotechnology companies has been, and can be, especially volatile. Thus, the market price of our common stock is likely to be subject to wide fluctuations. If our revenues do not grow or grow more slowly, 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 or for other reasons.

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

As of January 6, 2004, we had 19,091,535 shares of common stock outstanding, 5,440,000 shares of Series A preferred stock outstanding which are currently convertible into 10,880,000 shares of common stock and 14,469,542 common stock equivalents including warrants and stock options, other than the options granted under the co-development agreement with ILEX. The exercise and conversion prices of the common stock equivalents range from \$0.735 to \$2.00 per

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

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

We are subject to the anti-takeover provisions of Section 203 of the Delaware corporate statute, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock. As a result, these provisions may prevent our stock price from increasing substantially in response to actual or rumored takeover attempts. These provisions may also prevent changes in our management.

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

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

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

To date, we have incurred significant net losses, including net losses of \$6,746,326 for the year ended June 30, 2003 and \$2,823,015 for the three months ended September 30, 2003. At September 30, 2003, we had a deficit accumulated of \$31,474,458. We anticipate that we may continue to incur significant operating losses for the foreseeable future. We may never generate material revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

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

Before obtaining regulatory approval for the commercial sale of a product, we must demonstrate through pre-clinical testing and clinical trials that a product candidate is safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process. We will incur substantial expense for, and devote a significant amount of time to pre-clinical testing and clinical trials.

Historically, the results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical

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trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays.

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

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

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

ILEX has primary responsibility for conducting clinical trials and administering regulatory compliance and approval matters in the United States and Canada pursuant to the terms of our co-development agreement with ILEX. While there are target dates for completion, that agreement allows ILEX time to continue working beyond those dates under certain circumstances. If ILEX does not complete clinical trials and regulatory work expeditiously, or if it fails to do so at all or otherwise fails to meet its obligations under the co-development agreement, we could lose valuable time in developing Clofarabine for commercialization. Furthermore, we intend to make use of clinical data from trials ILEX is conducting to prepare and support our regulatory applications in Europe and elsewhere. We can not provide assurance that ILEX will not fail to meet its obligations under the co-development agreement. If this were to occur, it could have a material adverse effect on our ability to develop Clofarabine, obtain necessary regulatory approvals, and generate sales and cash flow from the sale of Clofarabine. If delays in completion constitute a breach by ILEX or there are certain other breaches of the co-development agreement by ILEX, then, at our discretion, the primary responsibility for completion would revert to us, but there is no assurance that we would have the financial, managerial or technical resources to complete such tasks in timely fashion or at all.

We may fail to address risks we face as a developing business which could adversely affect the implementation of our business plan.

We are prone to all of the risks inherent to the establishment of any new business venture. You should consider the likelihood of our future success to be highly speculative in light of our limited operating history, as well as the limited resources, problems, expenses, risks and complications frequently encountered by similarly situated companies. To address these risks, we must,



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among other things,

- o maintain and increase our product portfolio;
- o implement and successfully execute our business and marketing strategy;
- o continue to develop new products and upgrade our existing products;
- o respond to industry and competitive developments; and
- o attract, retain, and motivate qualified personnel.

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

-4-

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

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. The development of new pharmaceutical products is highly uncertain and subject to a number of significant risks. Most products resulting from our or our collaborative partners' product development efforts are not expected to be available for sale for at least several years, if at all. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

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

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

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

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Regulation in General. Virtually all aspects of our business are regulated by federal and state statutes and governmental agencies in the United States and other countries. Failure to comply with applicable statutes and government regulations could have a material adverse effect on our ability to develop and sell products which would have a negative impact on our cash flow. The development, testing, manufacturing, processing, quality, safety, efficacy, packaging, labeling, record-keeping, distribution, storage and advertising of pharmaceutical products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies. These activities are also regulated by similar state and local agencies and equivalent foreign authorities.

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

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

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

FDA Approval Process. We have a variety of products under development, including line extensions of existing products, reformulations of existing products and new products. All "new drugs" must be the subject of an FDA-approved new drug application before they may be marketed in the United States. All generic equivalents to previously approved drugs or new dosage forms of existing drugs must be the subject of an FDA-approved abbreviated new drug application before they may be marketed in the United

States. In both cases, the FDA has the authority to determine what testing procedures are appropriate for a particular product and, in 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

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new drug application or abbreviated application for any drug product marketed under the enforcement policy if new information reveals questions about the drug's safety or effectiveness. All drugs must be manufactured in conformity with current good manufacturing practices and drugs subject to an approved new drug application or abbreviated application must be manufactured, processed, packaged, held and labeled in accordance with information contained in the new drug application or abbreviated application.

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

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

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

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

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

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

Our business strategy involves obtaining orphan drug designation for certain of the oncology products we have under development. Although Clofarabine has received orphan drug designation with the FDA and EMEA, we do not know whether any of

-6-

our other products will receive an orphan drug designation. Orphan drug designation does not prevent other manufacturers from attempting to develop the same drug for the designated indication or from obtaining the approval of a new drug application for their drug prior to the approval of our new drug application. If another sponsor's new drug application for the same drug and the same indication is approved first, that sponsor is entitled to exclusive marketing rights if that sponsor has received orphan drug designation for its drug. In that case, the FDA would refrain from approving an application by us to market our competing product for seven years, subject to limitations. Competing products may not receive orphan drug designations and FDA marketing approval before the products under development by us.

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

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

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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.

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.

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

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

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

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

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

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

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

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

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

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

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

The pharmaceutical industry places considerable importance on obtaining

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patent and trade secret protection for new technologies, products and processes. Our success will depend on our ability to obtain and enforce protection for products that we develop under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. Patents may not be issued from these applications and issued patents may not give us adequate protection. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others.

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.

-8-

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

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

We are highly dependent on the principal members of our scientific and management staff. We also rely on consultants and advisors, including our scientific advisors, to assist us in formulating our research and development strategy. Our success also depends upon retaining key management and technical personnel, as well as our ability to continue to attract and retain additional highly-qualified personnel. We face intense competition for personnel from other companies, government entities and other organizations. We may not be successful in retaining our current personnel. We may not be successful in hiring or retaining qualified personnel in the future. If we lose the services of any of our scientific and management staff or key technical personnel, or if we fail to

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continue to attract qualified personnel, our ability to acquire, develop or sell products would be adversely affected.

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 will 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 and we could lose our opportunity to gain significant market share. Any inability to manage growth effectively may harm our ability to institute our business plan.

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

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

- o difficulty in establishing or managing distribution relationships;
- o different standards for the development, use, packaging and marketing of our products and technologies;
- o our inability to locate qualified local employees, partners, distributors and suppliers;
- o the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and
- o general geopolitical risks, such as political and economic instability, changes in diplomatic and trade relations, and foreign currency risks.

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

In May 2002, we completed a \$17,750,000 offering through the sale of shares of Series A preferred stock and common stock purchase warrants. The common stock purchase warrants are exercisable within five years of the issuance date. However, we may need additional financing to continue to fund the research and development of our products and to generally expand and grow our business. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders may result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur additional debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or accounting methods, even though these actions would otherwise benefit our business. As of June 30, 2003, we had stockholders' equity of \$18,828,392 and net working capital of \$6,108,493.

If adequate financing is not available, we may be required to delay,



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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.

-9-

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

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

In the United States, for instance, we expect that there will continue to be a number of federal and state proposals to implement government control of pricing and profitability of prescription pharmaceuticals. Government imposed controls could decrease the price we receive for products by preventing the recovery of development costs and an appropriate profit margin. Any of these cost controls could have a material adverse effect on our ability to make a profit. Furthermore, federal and state regulations govern or influence the reimbursement to health care providers in connection with medical treatment of certain patients. If any actions are taken by federal and/or state governments, they could adversely affect the prospects for sales of our products. Actions taken by federal and/or state governments with regard to health care reform could have a material adverse effect on our business and our prospects.

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. This could cause the acceptance and/or use of our products to decline. This lack of reimbursement would diminish the market for products developed by us and could have a material adverse effect on us.

Our products may be subject to recall.

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

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

We face exposure to product liability claims if the use of our

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technologies or products or those we license from third parties is alleged to have resulted in adverse effects to users thereof. Regulatory approval for commercial sale of our products does not mitigate product liability risks. Any precautions we take may not be sufficient to avoid significant product liability exposure. Although we have obtained product liability insurance on our technologies and products at levels with which management deems reasonable, no assurance can be given that this insurance will cover any particular claim or that we have obtained an appropriate level of liability insurance coverage for our development and marketing activities. 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.

-10-

### DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

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

### USE OF PROCEEDS

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

Expenses we are expected to incur in connection with this registration are estimated at approximately \$150,000. The selling stockholders will pay all

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of their underwriting commissions and discounts and counsel fees and expenses in connection with the resale of the shares covered by this prospectus.

### DESCRIPTION OF SECURITIES

#### Description of Common Stock

Number of Authorized and Outstanding Shares. Our Certificate of Incorporation authorizes the issuance of 50,000,000 shares of common stock, \$.001 par value per share, of which 19,091,535 shares were outstanding on January 6, 2003. 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 shareholders meeting at which a quorum is present, can elect all of the directors nominated for election at the meeting.

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

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

#### Description of Preferred Stock

Number of Authorized Shares. Our certificate of incorporation authorizes the issuance of up to 10,000,000 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 5,440,000 shares were issued and outstanding as of January 6, 2004. The holders of the Series A convertible preferred stock vote as a single class with the common stock, on an as-converted basis, on all matters upon which the holders of the common stock are entitled to vote. Each outstanding share of Series A convertible preferred stock may currently be converted into two shares of common stock, at the conversion price of \$1.50 per share. The shares of Series A convertible preferred stock shall be automatically convertible into

-11-

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

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period. Holders of Series A convertible preferred stock have a liquidation preference over holders of common stock of \$3.00 per share. Holders of the Series A convertible preferred stock are entitled to an annual 8% dividend which may be paid in cash or additional shares of common stock in our sole discretion.

### Warrants

As of January 6, 2004, there were outstanding warrants to purchase an aggregate of 8,899,999 shares of our common stock, exercisable at prices ranging from \$1.25 to \$2.33 per share.

### Stock Options

As of January 6, 2004, there were outstanding options to purchase an aggregate of 5,269,544 shares of our common stock, exercisable at prices ranging from \$0.735 to \$3.53 per share, of which, options to purchase 4,396,210 shares were exercisable.

-12-

### SELLING STOCKHOLDERS

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

- o the name of each selling shareholder;
- o the number of shares of common stock beneficially owned by each selling shareholder;
- o the number of shares of common stock that may be sold in this offering; and
- o the number and percentage of shares of common stock that will be beneficially owned by each selling shareholder 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 shareholders 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 19,091,535 shares of our common stock outstanding as of January 6, 2004.

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| Name  | Shares<br>Owned Prior to<br>the Offering |         | Number of Shares<br>Which May be<br>Sold in<br>This Offering |
|---|--|---------|--|
|   | Number                                   | Percent |  |
| Perseus-Soros<br>BioPharmaceutical Fund, LP (1)<br>Caduceus Private Investments,<br>LP(2) | 9,000,000                                | 32.60   | 9,000,000  |
| OrbiMed Associates LLC (2)  | 2,009,892                                | 9.75    | 2,009,892  |
| PW Juniper Crossover Fund,<br>L.L.C.(2)   | 41,835                                   | *       | 41,835   |
| Special Situations Private<br>Equity Fund, L.P. (3)                                       | 948,273                                  | 4.85    | 948,273  |
| Xmark Fund, L.P. (4)  | 250,000                                  | 1.33    | 250,000  |
| Xmark Fund, Ltd. (5)  | 144,999                                  | *       | 144,999  |
| SDS Merchant Fund, LP (6)   | 354,999                                  | 1.87    | 354,999  |
| Orion Biomedical Offshore<br>Fund, LP (7)   | 380,001                                  | 2.61    | 380,001  |
| Orion Biomedical Fund, LP (8)   | 133,875                                  | *       | 133,875  |
| Beaver Ltd. (9)   | 616,125                                  | 3.20    | 616,125  |
| CKH Invest Aps. (10)  | 75,000                                   | *       | 75,000   |
| Merlin Biomed Private Equity<br>Fund LP (11)  | 50,001                                   | *       | 50,001   |
| Palladin Opportunity Fund LLC(12)   | 1,000,002                                | 5.10    | 1,000,002  |
| DWS Investment GmbH (13)  | 166,666                                  | *       | 166,666  |
| Michael Sistenich (14)  | 1,299,999                                | 6.53    | 1,299,999  |
| Global Biotechnology Fund (15)  | 125,001                                  | *       | 125,001  |
| Oklahoma Medical Research<br>Foundation (16)  | 199,998                                  | 1.06    | 199,998  |
| Christopher B. Wood (17)  | 300,000                                  | 1.39    | 300,000  |
| Julie Wood (17)   | 3,805,258                                | 18.10   | 3,638,592  |
| Stuart Smith (18)   | 318,750                                  | 1.71    | 318,750  |
| Thomas Nelson (19)  | 700,000                                  | 3.66    | 700,000  |
| Kevin Leech (20)  | 287,523                                  | 1.06    | 287,523  |
| Bioaccelerate, Inc. (21)  | 1,900,000                                | 9.94    | 500,000  |
| Sterling Securities Ltd. (21)   | 1,227,272                                | 6.42    | 500,000  |
| Carpe DM, Inc. (21)   | 74,045                                   | *       | 74,045   |
| Michelle Tidball (21)   | 59,058                                   | *       | 59,058   |
| Weil Consulting Corporation (21)  | 254,114                                  | 1.37    | 254,114  |
| Kingsley Securities Ltd. (21)   | 75,000                                   | *       | 75,000   |
| Fontenelle LLC (21)   | 124,544                                  | *       | 124,544  |
|   | 50,000                                   | *       | 50,000   |

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| Name                                      | Shares<br>Owned Prior to<br>the Offering |         | Number of Shares<br>Which May be<br>Sold in |
|---|--|---------|---|
|   | Number                                   | Percent | This Offering                               |
| Jano Holdings, Ltd. (22)                  | 250,000                                  | 1.33    | 250,000                                     |
| George Margetts (23)                      | 100,000                                  | *       | 100,000                                     |
| Nagy Habib (24)                           | 50,000                                   | *       | 50,000                                      |
| NAB Holdings Ltd. (21) (25)               | 478,247                                  | 2.55    | 478,247                                     |
| SCO Capital Partners LLC (26), (28)       | 7,009,946                                | 37.67   | 7,009,946                                   |
| SCO Financial Group LLC (26), (28)        | 100,000                                  | *       | 100,000                                     |
| Daniel DiPietro (30)                      | 50,000                                   | *       | 50,000                                      |
| Jeremy Kaplan                             | 10,000                                   | *       | 10,000                                      |
| Joshua Golumb                             | 10,000                                   | *       | 10,000                                      |
| The Sophie C. Rouhandeh Trust (26)        | 150,000                                  | *       | 150,000                                     |
| The Chloe H. Rouhandeh Trust (26)         | 150,000                                  | *       | 150,000                                     |
| Jeffrey B. Davis (27), (28), (30)         | 749,243                                  | 3.97    | 749,243                                     |
| David Berstein (28)                       | 269,200                                  | 1.45    | 269,200                                     |
| Eugene Zurlo (28)                         | 282,900                                  | 1.52    | 282,900                                     |
| Robert J. Donohoe (28)                    | 282,400                                  | 1.52    | 282,400                                     |
| Al-Midani Investment Company Limited (28) | 14,629                                   | *       | 14,629                                      |
| Community Investment Partners (28)        | 2,560                                    | *       | 2,560                                       |
| Oakwood Investors I, LLC (28)             | 10,240                                   | *       | 10,240                                      |
| Gutrafin, Ltd. (28)                       | 14,629                                   | *       | 14,629                                      |
| Edward W. Kelly (28), (29)                | 356,013                                  | 1.89    | 356,013                                     |
| <b>Total</b>                              | <b>36,309,677</b>                        |         | <b>34,015,739</b>                           |

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

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

(2) Includes 669,964 shares of Series A Preferred Stock currently convertible into 1,339,928 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 669,964 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, both of which are held by Caduceus Private Investments, LP; 13,945 shares of

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

- (3) Warrant to purchase 250,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.

-14-

- (4) Includes 48,333 shares of Series A Preferred Stock currently convertible into 96,666 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 48,333 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (5) Includes 118,333 shares of Series A Preferred Stock currently convertible into 236,666 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 118,333 shares of common stock exercisable at \$3.00 per share for five years from May 8, 2002.
- (6) Includes 106,667 shares of Series A Preferred Stock currently convertible into 213,334 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 166,667 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (7) Includes 44,625 shares of Series A Preferred Stock currently convertible into 89,250 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 44,625 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (8) Includes 205,375 shares of Series A Preferred Stock currently convertible into 410,750 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 205,375 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (9) Includes 25,000 shares of Series A Preferred Stock currently convertible into 50,000 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 25,000 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002.
- (10) Includes 16,667 shares of Series A Preferred Stock currently convertible into 33,334 shares of common stock at a conversion price of \$1.50 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 333,334 shares of Series A Preferred Stock currently convertible into 666,668 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 333,334 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Based

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upon information contained in its report on Schedule 13G filed with the Commission on June 28, 2002, Merlin BioMed Private Equity Fund, L.P. reported that it shares the power to direct the voting and disposition of the 1,000,002 shares of common stock with Merlin BioMed Private Equity, LLC, its general partner and Dominique Semon, who is the sole managing member of the general partner.

- (12) Includes a warrant to purchase 166,666 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
  - (13) Includes 433,333 shares of Series A Preferred Stock currently convertible into 866,666 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 433,333 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002.
  - (14) Includes 41,667 shares of Series A Preferred Stock currently convertible into 83,334 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 41,667 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002.
  - (15) Includes 66,666 shares of Series A Preferred Stock currently convertible into 133,332 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 66,666 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002.
  - (16) Under the terms of an amendment to a license agreement with Oklahoma Medical Research Foundation, we issued 200,000 shares of common stock, 100,000 of which were sold in October 2003, 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.
  - (17) Dr. Wood is Chairman and Chief Executive Officer of the Company. Includes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest, 1,500,000 options which are exercisable at \$1.25 for five years from April 30, 2001 and 166,666 options which are exercisable at \$1.45 per share from December 31, 2003. Excludes 333,334 options which vest in equal installments on December 31, 2004 and December 31, 2005.
- 15-
- (18) Includes options to acquire 500,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
  - (19) Includes options to acquire 200,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
  - (20) These shares are owned of record by Phoenix Ventures Limited, a Channel Islands (Jersey) corporation, which, to our knowledge, is wholly-owned by Kevin Leech. These shares include 500,000 options which are exercisable at \$1.25 per share for the benefit of Phoenix.
  - (21) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors and includes options to acquire 500,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001. 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;
- (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
- (vi) Fontenelle LLC received options to purchase 50,000 shares of common stock, which it exercised in November 2003 for 50,000 shares of common stock.

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

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

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

- (22) Includes an option to purchase 250,000 shares of common stock exercisable at \$1.25 per share for five years from August 8, 2001.
- (23) Includes an option to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (24) Includes an option to purchase 50,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (25) 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.
- (26) Includes a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share issued to SCO Financial Group LLC for five years from November 16, 2001. Excludes a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 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 serves as financial advisor to the company. SCO Capital Partners LLC extended a \$1 million secured credit line to the company in November

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2001. SCO Securities LLC, a related entity, served as placement agent in the company's May 2002

-16-

private placement of Series A Preferred Stock. After the Pathagon acquisition, SCO Capital named one individual to the company's board of directors. After the May 2002 financing, SCO named a second individual to the company's board of directors.

- (27) 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.
- (28) Indicates the selling stockholder was a former stockholder of Pathagon.
- (29) 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.
- (30) Indicates the selling stockholder is a current employee of SCO Financial Group LLC.

### PLAN OF DISTRIBUTION

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

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

- o on the Amex or on any other market on which our common stock may from time to time be trading;
- o one or more block trades in which the broker or dealer so engaged will attempt to sell the shares of common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker or dealer as principal and resale by the broker or dealer for its account pursuant to this prospectus;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;

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- o in public or privately-negotiated transactions;
  - o through the writing of options on the shares;
- through underwriters, brokers or dealers (who may act as agents or principals) or directly to one or more purchasers;
- o an exchange distribution in accordance with the rules of an exchange;
  - o through agents;
  - o through market sales, both long or short, to the extent permitted under the federal securities laws; or
  - o in any combination of these methods.

The sale price to the public may be:

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

-17-

- o any other prices as the selling stockholder may determine from time to time.

In connection with distributions of the shares or otherwise, the selling stockholders may

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

In addition to the foregoing methods, the selling stockholders may offer their share 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

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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.

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 of the shares offered by this prospectus, may be deemed "underwriters" as that term is defined under the securities act or the exchange act, or the rules and regulations under those acts. In that event, any commissions received by the broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the securities act.

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

- o the number of shares being offered;
- o the terms of the offering, including the name of any selling stockholder, underwriter, broker, dealer or agent;
- o the purchase price paid by any underwriter;
- o any discount, commission and other underwriter compensation;
- o any discount, commission or concession allowed or reallocated or paid to any dealer;

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- o the proposed selling price to the public; and
- o other facts material to the transaction.

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

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

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

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

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

### LEGAL MATTERS

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

### EXPERTS

Our auditors are Grant Thornton LLP. Our consolidated financial statements as at and for the year ended June 30, 2003 and June 30, 2002 included in our annual report on Form 10-KSB for the year ended June 30, 2003 and incorporated by reference herein, have been incorporated by reference herein in reliance upon the report of Grant Thornton LLP, independent accountants, given on the authority of said firm as experts in accounting and auditing.

### WHERE YOU CAN GET MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and

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

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

Midwest Regional Office  
Citicorp Center  
500 West Madison Street  
Suite 1400  
Chicago, Illinois 60661-2511

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

-19-

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

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

- o Our definitive proxy statement on Schedule 14A filed on December 15, 2003 (File No. 001-31787);
- o Our quarterly report on Form 10-QSB for the fiscal quarter ended September 30, 2003 filed on November 14, 2003 (File No. 001-31787);
- o Our annual report on Form 10-KSB for the year ended June 30, 2003 filed on September 29, 2003 (File No. 001-31787);

All other reports and documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act after the date of this prospectus and prior to the termination of the offering are deemed incorporated by reference into this prospectus and a part hereof from the date of filing of those documents. Any statement contained in any document incorporated by reference shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained in a later document modifies or supersedes such statement. Any statements so modified or superseded shall not be deemed to constitute a part of this prospectus, except as modified or superseded.

We will provide without charge to each person to whom this prospectus is delivered, upon written or oral request of such person, a copy of any or all of the documents referred to above which have been or may be incorporated by reference into this prospectus (other than the exhibits to such documents). Requests for such documents should be directed to Bioenvision Inc., 509 Madison

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Avenue, Suite 404, New York, New York 10022, Attention: David P. Luci  
(telephone: (212) 750-6660).

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.

-20-

### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution. The following sets forth the estimated expenses payable in connection with the preparation and filing of this Registration:

|  |           |
|--|-----------|
| *Printing and Engraving Expenses.....                    | 15,000    |
| *Accounting Fees and Expenses.....                       | 18,000    |
| *Legal Fees and Expenses.....                            | 100,000   |
| *Blue Sky Fees and Expenses.....                         | 2,000     |
| *Transfer Agent's and Registrar's Fees and Expenses..... | 1,000     |
| *Miscellaneous.....                                      | 14,000    |
|  | -----     |
| *Total.....  | \$150,000 |
| =====  | =====     |

\* Estimated.

Item 15. Indemnification of Directors and Officers.

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

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

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

DGCL Section 145 further provides that to the extent that to a present or former director or officer is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. In all cases in which indemnification is permitted under subsection (a) and (b) of Section 145 (unless ordered by a court), it shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the applicable standard of conduct has been met by the party to be indemnified. Such determination must be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are no parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders. The statute authorizes the corporation to pay expenses incurred by an officer or director in advance of the final disposition of a proceeding upon receipt of an undertaking by or on behalf of the person to whom the advance will be made, to repay the advances if it shall ultimately be determined that he was not entitled to indemnification. DGCL Section 145 also provides that indemnification and advancement of expenses permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain

II-1

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

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



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

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

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

### Item 16. Exhibits

| Exhibit<br>Number<br>----- | Description<br>-----   |
|----------------------------|--|
| 2.1                        | Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1) |
| 2.2                        | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)                                    |
| 3.1                        | Certificate of Incorporation of Registrant. (2)  |
| 3.1(a)                     | Amendment to Certificate of Incorporation filed January 29, 1999. (3)  |
| 3.1(b)                     | Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)  |
| 3.1(c)                     | Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)   |
| 3.2                        | Amended and Restated By-Laws of the Registrant. (13)   |
| 3.2(a)                     | Amendment to Bylaws, effective April 30, 2002 (6)  |
| 4.1                        | Certificate of Designation (6)   |
| 4.2                        | Form of Warrant (6)  |
| 4.3                        | Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International,  |

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LLC (14)

4.4 Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)

### II-2

- 5.1\* Opinion of Paul, Hastings, Janofsky & Walker, LLP
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc. (15)
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision, Inc. (15)
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. And Bioenvision, Inc. dated July 15, 1998. (3)
- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc (15)
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
- 10.8 Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003. (14)
- 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC.

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(7)

- 10.14 Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 10.15 Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 10.16 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.17 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.18 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)

II-3

- 10.19 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.20 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.21 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.22 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.23 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.24 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.25 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
- 10.26 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)

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- 10.27 Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC(14)
- 16.1 Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
- 16.2 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
- 16.3 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
- 21.1 Subsidiaries of the registrant (4)
- 23.1 Consent of Grant Thornton LLP
- 23.2\* Consent of Paul, Hastings, Janofsky & Walker LLP (included in Exhibit 5.1)
- 24.1 Power of Attorney (appears on signature page)

\* To be filed by amendment.

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- (1) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 12, 1999.
  - (2) Incorporated by reference and filed as an Exhibit to Registrant's Registration Statement on Form 10-12g filed with the SEC on September 3, 1998.
  - (3) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.
  - (4) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.
  - (5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2002.
  - (6) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2002.

II-4

- (7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.
- (8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.
- (9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.
- (10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.
- (11) Incorporated by reference and filed as an Exhibit to Registrant's Current

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Report on Form 8-K, filed with the SEC on December 6, 2001.

- (12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.
- (13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.
- (14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.
- (15) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on September 29, 2003.

### 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 registration statement is on Form S-3, Form S-8, or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration

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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.

II-5

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

II-6

### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the

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requirements for filing on Form S-3 and authorized this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on the 12th day of January, 2004.

BIOENVISION, INC.

By /s/ Christopher B. Wood  
-----

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

KNOW ALL MEN BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Christopher B. Wood as his/her 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.

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

| Signature<br>-----  | Title<br>-----  | Date<br>-----  |
|---|---|----------------|
| /s/ Christopher B. Wood, M.D.<br>-----<br>Christopher B. Wood, M.D. | Chairman and Chief Executive Officer and<br>Director<br>(Principal Executive Officer)             | January 12, 20 |
| /s/ David P. Luci<br>-----<br>David P. Luci                         | Director of Finance, General Counsel and<br>Corporate Secretary<br>(Principal Accounting Officer) | January 12, 20 |
| /s/ Thomas S. Nelson, C.A.<br>-----<br>Thomas S. Nelson, C.A.       | Director  | January 12, 20 |
| /s/ Jeffrey B. Davis<br>-----<br>Jeffrey B. Davis                   | Director  | January 12, 20 |
| /s/ Andrew N. Schiff<br>-----<br>Andrew N. Schiff                   | Director  | January 12, 20 |
| /s/ Steven A. Elms  | Director  | January 12, 20 |

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-----  
Steven A. Elms

II-7

EXHIBIT INDEX

| Exhibit<br>Number<br>----- | Description<br>-----   |
|----------------------------|--|
| 2.1                        | Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1) |
| 2.2                        | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)                                    |
| 3.1                        | Certificate of Incorporation of Registrant. (2)  |
| 3.1(a)                     | Amendment to Certificate of Incorporation filed January 29, 1999. (3)  |
| 3.1(b)                     | Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)  |
| 3.1(c)                     | Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)   |
| 3.2                        | Amended and Restated By-Laws of the Registrant. (13)   |
| 3.2(a)                     | Amendment to Bylaws, effective April 30, 2002 (6)  |
| 4.1                        | Certificate of Designation (6)   |
| 4.2                        | Form of Warrant (6)  |
| 4.3                        | Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)   |
| 4.4                        | Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)  |
| 5.1*                       | Opinion of Paul, Hastings, Janofsky & Walker, LLP  |
| 10.1                       | Pharmaceutical Development Agreement, dated as of June 10, 2003, by and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories, Inc. (15)   |
| 10.2                       | Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)  |
| 10.3                       | Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited  |



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- and Bioenvision, Inc. (15)
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. And Bioenvision, Inc. dated July 15, 1998. (3)
- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by and between Bioenvision, Inc. and Dechra Pharmaceuticals, plc (15)
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D., dated December 31, 2002 (3)
- 10.8 Employment Agreement between Bioenvision, Inc. and David P. Luci, dated March 31, 2003. (14)
- II-8
- 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000. (4)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC. (7)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC. (7)
- 10.14 Registration Rights Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 10.15 Stockholders Lock-Up Agreement, dated as of February 1, 2002, by and among Bioenvision, Inc., the former shareholders of Pathagon, Inc. party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited. (8)
- 10.16 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of

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- May 7, 2002. (6)
- 10.17 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
- 10.18 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care division, and Implemed, dated as of May 6, 1997. (12)
- 10.19 License Agreement by and between Oklahoma Medical Research Foundation and bridge Therapeutic Products, Inc., dated as of January 1, 1998. (12)
- 10.20 Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002. (12)
- 10.21 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998. (12)
- 10.22 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999. (12)
- 10.23 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.24 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001. (12)
- 10.25 Co-Development Agreement, between Bioenvision, Inc. and ILEX Oncology, Inc., dated March 9, 2001. (12)
- 10.26 Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon Inc. (5)
- 10.27 Master Services Agreement, dated as of April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)
- 16.1 Letter from Graf Repetti & Co., LLP to the Securities and Exchange Commission, dated September 30, 1999. (9)
- II-9
- 16.2 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated July 6, 2001. (10)
- 16.3 Letter from Ernst & Young LLP to the Securities and Exchange Commission, dated August 16, 2001. (11)
- 21.1 Subsidiaries of the registrant (4)
- 23.1 Consent of Grant Thornton LLP

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

\* To be filed by amendment.  
-----

- (1) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on January 12, 1999.
- (2) Incorporated by reference and filed as an Exhibit to Registrant's Registration Statement on Form 10-12g filed with the SEC on September 3, 1998.
- (3) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB/A filed with the SEC on October 18, 1999.
- (4) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on November 13, 2000.
- (5) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K filed with the SEC on April 16, 2002.
- (6) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on May 28, 2002.
- (7) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on January 8, 2002.
- (8) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2002.
- (9) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on October 1, 1999.
- (10) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K/A, filed with the SEC on July 26, 2001.
- (11) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on December 6, 2001.
- (12) Incorporated by reference and filed as an Exhibit to Registrant's Current Report on Form 8-K, filed with the SEC on June 24, 2002.
- (13) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended December 31, 2002.
- (14) Incorporated by reference and filed as an Exhibit to Registrant's Quarterly Report on Form 10-QSB for the three-month period ended March 31, 2003.
- (15) Incorporated by reference and filed as an Exhibit to Registrant's Form 10-KSB filed with the SEC on September 29, 2003.