

Edgar Filing: BIOENVISION INC - Form SB-2

BIOENVISION INC  
Form SB-2  
July 31, 2002

As filed with the Securities  
and Exchange Commission on July 31, 2002 Registration No. 333-\_\_\_\_\_

=====

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

Form SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	2834	13-4025
-----	-----	-----
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Em Identificat

One Rockefeller Plaza  
Suite 1600  
New York, New York 10020  
(212) 445-6582  
(Address and telephone number of principal  
executive offices and principal place of business)

CHRISTOPHER B. WOOD, M.D.  
Chief Executive Officer  
Bioenvision, Inc.  
One Rockefeller Plaza  
Suite 1600  
New York, New York 10020  
(212) 445-6582  
(Name, address and telephone  
number of agent for service)

Copy to:  
Andrew J. Cosentino, Esq.  
Piper Rudnick LLP  
1251 Avenue of the Americas  
New York, NY 10020  
(212) 835-6000

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.  |X|

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 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

Edgar Filing: BIOENVISION INC - Form SB-2

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	Number of shares to be registered	Proposed maximum offering price per share (1)	Proposed maximum aggregate offering price
Common Stock, par value \$.001 per share	36,123,635	\$1.95	\$70,441,088.2

(1) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) on the basis of the average of the bid and ask prices per share of our common stock, as reported on the OTC Bulletin Board, on July 23, 2002.

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

Subject to completion, July 31, 2002

[GRAPHIC OMITTED]

PROSPECTUS

BIOENVISION, INC.

36,123,635 shares of common stock

## Edgar Filing: BIOENVISION INC - Form SB-2

This prospectus relates to the sale of up to an aggregate of 36,123,635 shares of our common stock, 10,285,760 of which are outstanding and 25,837,875 of which will be issued upon the exercise or conversion of outstanding convertible securities. The selling stockholders listed on page 63 may sell these shares from time to time.

Our common stock is quoted on the OTC Bulletin Board under the symbol "BIOV.OB." On July 23, 2002, the last reported sales price of our common stock as reported by the OTC Bulletin Board was \$1.90 per share.

We urge you to read carefully the "Risk Factors" section beginning on page 4 where we describe specific risks associated with an investment in 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 \_\_\_\_\_, 2002.

### TABLE OF CONTENTS

	Page
PROSPECTUS SUMMARY .....	1
RISK FACTORS .....	4
DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS .....	18
USE OF PROCEEDS .....	18
DIVIDENDS .....	19
MARKET FOR COMMON EQUITY AND DIVIDEND POLICY .....	19
MANAGEMENT'S DISCUSSION AND ANALYSIS .....	20
DESCRIPTION OF BUSINESS .....	27
CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE .....	46
MANAGEMENT .....	47
SCIENTIFIC COMMITTEE .....	49
EXECUTIVE COMPENSATION .....	50
DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES .....	54
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS .....	56

## Edgar Filing: BIOENVISION INC - Form SB-2

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT .....	57
DESCRIPTION OF SECURITIES .....	62
SELLING STOCKHOLDERS .....	63
PLAN OF DISTRIBUTION .....	68
LEGAL MATTERS .....	71
EXPERTS .....	71
WHERE YOU CAN GET MORE INFORMATION .....	72
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS .....	F-1

### 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. The summary highlights information contained elsewhere in this prospectus.

Bioenvision, Inc.

We are an emerging biopharma-ceutical company. Our primary business focus is the acquisition, development and distribution of drugs to treat cancer. We have a broad range of products and technologies under development, but our two lead drugs are clofarabine and Modrenal(R).

Based on third party studies conducted to date, we believe that clofarabine may be effective in the treatment of leukemia and lymphoma. Clofarabine is currently in Phase II clinical trials. In January, 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. The drug has also been granted orphan drug status in the United States.

We plan to launch Modrenal(R) by late 2002 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. We intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer.

We believe that we have the opportunity to become a leading oncology-focused pharmaceutical company in the next five years if we successfully bring our two lead drugs to market. We anticipate that revenues derived from the two lead drugs will permit us to further develop the twelve other products and potential products currently in our development portfolio. We intend to commence marketing Modrenal(R), and to continue developing our existing platform technologies with a primary business focus on drugs to treat cancer, and commercializing products derived from such technologies. A key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. As a result of the acquisition of Pathagon Inc. in February 2002, we have several anti-infective technologies which we believe have specific application for support of the cancer patient and oncology treatment. In addition, we believe that some of our

## Edgar Filing: BIOENVISION INC - Form SB-2

products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. However, we have established an animal healthcare division to exploit some of those opportunities.

### 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 One Rockefeller Plaza, Suite 1600, New York, New York 10020. Our telephone number is (212) 445-6582 and our fax number is (212) 265-4680. Our website is [www.bioenvision.com](http://www.bioenvision.com).

1

### The Offering

Shares offered by the selling stockholders.....	36,123,635 shares of common stock.
Shares outstanding prior to offering.....	16,887,786
Shares to be outstanding following offering.....	16,887,786
Use of proceeds.....	We will not receive any proceeds from the sale and issuance of the shares included in this offering. However, we will receive \$22,455,011.50 upon exercise of all the options and warrants held by the selling stockholders, if the same should be exercised, which would be used for general corporate and working capital.
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.
Dividend policy.....	We intend to retain any earnings to finance the development and growth of our business. Accordingly, we do not anticipate that we will declare any cash dividends on our common stock for the foreseeable future. See "Market For Common Equity and Dividend Policy" on page 19.

## Edgar Filing: BIOENVISION INC - Form SB-2

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 68.

OTC Bulletin Board symbol..... BIOV.OB

2

### Summary Financial Information

The following summary financial information is taken from our financial statements included elsewhere in this prospectus and should be read along with the financial statements and the related notes.

#### Income Statement Data

		Years Ended June 30, -----		Nine Months March 31, (unaudited) -----
	2001 ----		2000 ----	2002 ----
Contract revenue	\$ 245,455	\$	---	\$ 552,273
Operating expenses	2,367,719		1,495,509	2,329,814
Net loss	(2,122,264)		(1,495,509)	(1,777,541)
Net loss per share	\$ (0.26)	\$	(0.20)	\$ (0.17)
Average number of shares	8,121,255		7,430,965	10,435,997

#### Balance Data Sheet

	June 30, 2001 -----		March 31, 2002 (unaudited) -----
Total assets	\$ 762,885	\$	13,844,926
Cash	---		---
Total liabilities	3,245,401		2,554,763
Working capital (deficiency)	(1,629,038)		1,107,366
Stockholders' equity (deficit)	(2,482,516)		11,290,163

3

### RISK FACTORS

You should carefully consider the following risks before you decide to

## Edgar Filing: BIOENVISION INC - Form SB-2

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.

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

We were organized in November 1996. 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 \$1,777,541 for the nine months ended March 31, 2002. At March 31, 2002, we had a deficit accumulated in the development stage of \$7,516,192. 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 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:

## Edgar Filing: BIOENVISION INC - Form SB-2

- o inability 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 clinical and regulatory work in the United States and Canada under 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 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 do not anticipate that Ilex will fail to meet its obligations under the co-development agreement, but cannot provide assurance that it will meet these obligations. 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

5

limited operating history, as well as the limited resources, problems, expenses, risks and complications frequently encountered by similarly situated companies. To address these risks, we must, among other things,

- o maintain 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;



## Edgar Filing: BIOENVISION INC - Form SB-2

- o respond to industry and competitive developments; and
- o attract, retain, and motivate qualified personnel.

We may not be successful in addressing these risks. If we are unable to do so, our business prospects, financial condition and results of operations would be materially adversely affected. We have limited experience in developing products and may be unsuccessful in our efforts to develop products.

To achieve profitable operations, we, alone or with others, must successfully develop, clinically test, market and sell our products. 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 may not be obtained. 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

6

activities to result in any commercially viable products or technologies would materially adversely affect our future prospects.

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

Regulation in General. Virtually all aspects of our business are regulated by federal and state statutes and governmental agencies in the United States and other countries. Failure to comply with applicable statutes and government regulations could have a material adverse effect on our ability to develop and sell products which would have a negative impact on our cash flow. The development, testing, manufacturing, processing, quality, safety, efficacy,

## Edgar Filing: BIOENVISION INC - Form SB-2

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 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,

## Edgar Filing: BIOENVISION INC - Form SB-2

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,

## Edgar Filing: BIOENVISION INC - Form SB-2

therefore, generate revenue and cash flow.

We may not be successful in receiving orphan drug status for 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 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. We do not know whether any of these 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

9

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

## Edgar Filing: BIOENVISION INC - Form SB-2

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.

We rely on licensing or purchasing products and technologies to grow our product portfolio, and may not be effective in licensing or acquiring new products which would adversely affect our ability to grow our business and become profitable.

We have adopted a license and acquisition strategy to build our product portfolio. Unless and until we develop and introduce a sufficient number of our own products, we must rely upon the availability for licensing or purchasing of products or technologies of other pharmaceutical or biotechnology companies. Our success in executing this strategy depends on our continued ability to identify and acquire new pharmaceutical products targeted at niche markets within selected strategic therapeutic market segments. Other companies, including those with substantially greater financial, marketing and other resources than us, compete with us for the right to license or acquire these products. We may not be successful in identifying potential product licensing or acquisition opportunities. If any of these opportunities are identified, we may not be able to obtain these licenses or complete these acquisitions on acceptable terms. We may not be able to successfully integrate any licensed or acquired products or technologies into our product portfolio. Our failure to obtain licenses for, or complete acquisitions of, products or technologies within a selected strategic therapeutic market segment or to promote and market commercially successful products or technologies within an existing strategic therapeutic market segment could have a material adverse effect on our ability to grow our business and become

10

profitable. Once we have obtained rights to a product or technology and committed to payment terms, we may not be able to generate sales sufficient to create a profit or otherwise avoid a loss. Any inability to generate sufficient sales or any subsequent reduction of sales 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

## Edgar Filing: BIOENVISION INC - Form SB-2

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.

11

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

## Edgar Filing: BIOENVISION INC - Form SB-2

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 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.

12

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

The pharmaceutical industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend on our ability to obtain and enforce protection for products that we develop under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. 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

## Edgar Filing: BIOENVISION INC - Form SB-2

could have a material adverse effect on our ability to sell products or use patents in the future. In addition, we could be required to obtain licenses under patents or other proprietary rights of third parties. These licenses may not be made available on terms acceptable to us, or at all. If we are required to, and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more products.

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

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

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

We are highly dependent on the principal members of our scientific and management staff. We also rely on consultants and advisors, including our scientific advisors, to assist us in formulating our research and development strategy. Our success also depends upon retaining key management and technical personnel, as well as our ability to continue to attract and retain

13

additional highly-qualified personnel. We face intense competition for personnel from other companies, government entities and other organizations. We may not be successful in retaining our current personnel. We may not be successful in hiring or retaining qualified personnel in the future. If we lose the services of any of our scientific and management staff or key technical personnel, or if we fail to continue to attract qualified personnel, our ability to acquire, develop or sell products would be adversely affected.

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

If, as we anticipate, international operations will constitute a part of our business, we will be subject to the risks of conducting business in



## Edgar Filing: BIOENVISION INC - Form SB-2

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

We have recently 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

14

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 March 31, 2002, we had stockholders' deficit of \$11,290,163 and a net working capital deficit of \$1,107,366.

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

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

Our ability to commercialize products successfully depends in part on the price we may be able to charge for our products and on the extent to which reimbursement for the cost of our products and related treatment will be available from government health administration authorities, private health insurers and other third-party payors. Government officials and private health

## Edgar Filing: BIOENVISION INC - Form SB-2

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.

15

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 and our prospects.

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

We face exposure to product liability claims if the use of our technologies or products or those we license from third parties is alleged to have resulted in adverse effects to users thereof. 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. We may not be able to obtain 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 contraindications, which may adversely impact product sales. The pharmaceutical industry has experienced

## Edgar Filing: BIOENVISION INC - Form SB-2

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.

We may be liable for the use of hazardous materials.

Our research and development activities may involve the use of hazardous materials, chemicals and/or various radioactive compounds by our collaborative partners. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result and any liability could exceed our resources. Our future collaborative partners may incur substantial costs to comply with environmental regulations, which costs may be passed on to us.

We may encounter significant financial and operating risks if we grow our business through acquisitions.

As part of our growth strategy, we may seek to acquire or invest in complementary or competitive businesses, products or technologies. The process of integrating acquired assets into our operations may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. We may allocate a significant portion of our available working capital to

16

finance all or a portion of the purchase price relating to possible acquisitions although we have no immediate plans to do so. Any future acquisition or investment opportunity may require us to obtain additional financing to complete the transaction. The anticipated benefits of any acquisitions may not be realized. In addition, future acquisitions by us could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and amortization expenses related to goodwill and other intangible assets, any of which could materially adversely affect our operating results and financial position. Acquisitions also involve other risks, including entering markets in which we have no or limited prior experience.

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

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

The public trading market for our common stock is limited and may not be

## Edgar Filing: BIOENVISION INC - Form SB-2

developed or sustained which could limit the liquidity of an investment in our common stock.

There is a limited trading market for the common stock. Since January 1999, the common stock has been traded sporadically under the symbol "BIOV.OB" on the OTC bulletin board, an inter-dealer automated quotation system for equity securities. There can be no assurance that an active and liquid trading market will develop or, if developed, that it will be sustained which could limit your ability to sell our common stock at a desired price.

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

As of June 30, 2002, we had 16,887,786 shares of common stock outstanding, 5,916,666 shares of Series A preferred stock outstanding which are currently convertible into 11,833,332 shares of common stock and 14,004,543 common stock equivalents including warrants and stock options, other than the options granted under the co-development agreement with Ilex. The exercise and conversion prices of the common stock equivalents range from \$1.25 to \$2.33 per share. We have also reserved for issuance an aggregate of 7,473,082 shares of common stock for a stock option plan for our employees. 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

17

increase. If converted or exercised, these securities will result in a dilution to your percentage ownership 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.

### DISCLOSURE REGARDING forward-LOOKING STATEMENTS

We have made statements under the captions "Risk Factors," "Business" 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

## Edgar Filing: BIOENVISION INC - Form SB-2

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. However, we will receive approximately \$22,456,011.50 if all of the options and warrants to purchase an aggregate of 14,004,543 shares of common stock registered under this prospectus are exercised, which would be used for general, corporate and working capital purposes. There can be no assurance that any such options or warrants will be exercised.

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

18

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

### DIVIDENDS

We do not intend to pay cash dividends on our common stock for the foreseeable future. This is because we need to retain our cash for working capital and to finance our planned growth. However, our Board of Directors is free to change our dividend policy in the future, based upon factors such as our results of operations, financial condition, cash flow, cash needs and future prospects. We are obligated to pay dividends to holders of our outstanding preferred stock.

### MARKET FOR COMMON EQUITY AND DIVIDEND POLICY

	High	Low
	----	---
Fiscal Year Ended June 30, 2000		
First Quarter*	\$8.25	\$4.00
Second Quarter*	\$8.00	\$6.00
Third Quarter	\$9.00	\$6.25
Fourth Quarter	\$8.00	\$5.00
Fiscal Year Ended June 30, 2001		
First Quarter	\$4.25	\$2.50
Second Quarter	\$4.00	\$1.50
Third Quarter	\$2.625	\$0.875
Fourth Quarter	\$2.45	\$0.82
Fiscal Year Ended June 30, 2002		
First Quarter	\$2.50	\$1.60

## Edgar Filing: BIOENVISION INC - Form SB-2

Second Quarter	\$2.50	\$1.15
Third Quarter	\$3.00	\$2.25
Fourth Quarter	\$3.60	\$1.75

\* In accordance with the terms of the Acquisition Agreement between Old Bioenvision and Bioenvision dated December 21, 1998, Bioenvision effected a 1-for-15 reverse stock split, reducing its issued and outstanding shares of common stock from 3,450,000 to 230,000, immediately prior to issuing 7,013,897 shares of post 1-for-15 reverse stock split common stock at the closing of the acquisition on January 5, 1999.

On June 30, 2002, we had 403 stockholders of record.

We have never declared or paid cash dividends on our capital stock, and our board of directors does not intend to declare or pay any dividends on the common stock in the foreseeable future. Our earnings, if any, are expected to be retained for use in expanding our business. The declaration and payment in the future of any cash or stock dividends on the common stock will

19

be at the discretion of the board of directors and will depend upon a variety of factors, including our ability to service our outstanding indebtedness and to pay our dividend obligations on securities ranking senior to the common stock, our future earnings, if any, capital requirements, financial condition and such other factors as our board of directors may consider to be relevant from time to time.

### MANAGEMENT'S DISCUSSION AND ANALYSIS

The following discussion and analysis provides information which management believes is relevant to an assessment and understanding of our results of operations and financial condition. The discussion should be read together with our audited financial statements and notes included elsewhere in this prospectus.

#### Summary of Significant Accounting Policies

Financial Reporting Release No. 60, which was recently released by the SEC, requires all companies to include a discussion of critical accounting policies or methods used in the preparation of the consolidated financial statements. In addition, Financial Reporting Release No. 61 was recently released by the SEC, which requires all companies to include a discussion to address, among other things, liquidity, off-balance sheet arrangements, contractual obligations and commercial commitments. The following discussion is intended to supplement the summary of significant accounting policies as described in Note 1 of the Notes To Consolidated Financial Statements for the year ended June 30, 2001 included in our annual report on Form 10-K.

These policies were selected because they represent the more significant accounting policies and methods that are broadly applied in the preparation of the consolidated financial statements.

Revenue Recognition - Non-refundable up-front payments received in connection with research and development collaboration agreements are deferred and recognized on a straight-line basis over the relevant periods in the agreement, generally the research or development period. Milestone and royalty

## Edgar Filing: BIOENVISION INC - Form SB-2

payments, if any, are recognized pursuant to collaborative agreements upon the achievement of the specified milestones or sales transaction.

Stock Based Compensation - In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation, we apply Accounting Principles Board Opinion 25 and related interpretations in accounting for our stock option plan and, accordingly, we do not recognize compensation expense for employee stock options granted with exercise prices equal to or greater than fair market value. Non-employee stock-based compensation arrangements are accounted for in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Under EITF No. 96-18, as amended, where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument.

20

Use of Estimates - The preparation of financial statements in conformity with generally accepted accounting principles of the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates, and such differences may be material to the financial statements.

### Overview

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

### Clofarabine

Based on third party studies conducted to date, we believe that clofarabine may be effective in the treatment of leukemia and lymphoma. To expedite the commercialization of clofarabine, we have entered into a co-development agreement with Ilex Oncology, Inc. ("Ilex") under which Phase II clinical trials of clofarabine are currently being conducted. In January 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. The drug has also been granted orphan drug status in the United States of America ("United States").

Extensive preclinical and mechanistic studies have provided much of the rationale for the rapidly advancing clofarabine clinical development program. Published data and information presented at recent scientific meetings suggest that clofarabine has broader anti-cancer activity, and may be more potent than other currently marketed purine analogues such as Fludara(R) (fludarabine) and Leustatin(R) (cladribine).

Preliminary results from ongoing clinical studies indicate that clofarabine may be an effective treatment for acute leukemias in adult and pediatric patients that have become resistant, or refractory, to prior treatments. According to researchers at the MD Anderson Cancer Center, interim Phase I/II study results showed that 45 percent of adults with acute myelogenous leukemia (AML) achieved a complete remission (CR) rate, and acute lymphocytic leukemia (ALL) patients achieved a 20 percent CR rate when treated with

## Edgar Filing: BIOENVISION INC - Form SB-2

clofarabine as a single agent. Data from a separate Phase I dose-escalation study demonstrated a 25 percent CR rate, and an overall response rate of 40%, in children with acute leukemias who were refractory to previous therapy. Trials in adult and pediatric acute leukemias are currently ongoing in the US and are planned to commence in Europe later this year. Complete remission, in this context, means complete clearance of all leukemic cells from the blood and normalization of the blood count, sustained for a period of more than 4 weeks. In this context, a response, or partial response, has largely the same meaning, except that the bone marrow may still contain more than 5 percent but less than 25 percent blast cells (leukemic cells).

21

### Modrenal(R)

We plan to launch Modrenal(R) by late 2002 in the United Kingdom, where we have obtained regulatory approval for its use in the treatment of post-menopausal breast cancer. Our management believes that Modrenal(R) works by a unique action as compared with other commercially available drugs to treat post-menopausal breast cancer. We believe that Modrenal(R) alters the way in which the female hormone, estrogen, binds to the hormone receptor on the cell in a previously unrecognized fashion. In particular, it changes the way the hormone acts on a newly identified second estrogen receptor, ER beta (ER(beta)). Modrenal(R) is the first drug to be commercially available in a new class of agents that specifically target ER(beta). We intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone sensitive breast cancer. This would target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as Tamoxifen(R) or aromatase inhibitors. We believe that the potential market for Modrenal(R), based upon the sales of currently available drugs for hormonal therapy for breast cancers, is in excess of \$1.8 billion of sales per annum worldwide. The results of extensive clinical trials to date with Modrenal(R) show that it is at least as effective in second line or third line treatment of advanced breast cancer as the currently available hormonal treatments, such as selective estrogen receptor modulators, or SERMs, and aromatase inhibitors, and more effective than these agents in certain specific patient types, such as those who have become Tamoxifen(R) refractory. Furthermore, our management currently intends to price Modrenal(R) in such a way as to make treatment with Modrenal(R) compare very favorably, on a price basis, with the cost of treatment with the existing drugs used for second line or third line therapy. We believe that this should result in cost benefits for physicians, patients and health-care systems.

### Company Status

We have made solid progress in developing our product portfolio over the past twelve months, and have a several products in clinical trials for a variety of clinical indications. We have incurred losses during this development stage. Our management believes that we have the opportunity to become a leading oncology-focused pharmaceutical company if we successfully bring our two lead drugs to market. We anticipate that revenues derived from the two lead drugs, if they are successfully commercialized, will permit us to further develop the twelve other products and potential products currently in our development portfolio. We intend to commence marketing Modrenal(R), and to continue developing our existing platform technologies with a primary business focus on drugs to treat cancer, and commercializing products derived from such technologies. A key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. As a result of the acquisition of Pathagon Inc. in February 2002, we have several anti-infective technologies. These include the OLIGON(R) technology and



## Edgar Filing: BIOENVISION INC - Form SB-2

the use of thiazine dyes, such as methylene blue. OLIGON(R) is an advanced biomaterial that has been approved for certain indications by the FDA in the U.S. Certain products using the OLIGON(R) technology, for one clinical indication, are currently being sold by Edwards Lifesciences Corp. (NYSE:EW) pursuant to a license from us. Thiazine dyes, such as methylene blue, are used for in vitro and in vivo inactivation of pathogens (viruses, bacteria and fungus) in biological fluids. It is not the Company's strategy to sell devices or to

22

expand into the anti-infective market per se, but the technology obtained in the Pathagon acquisition has specific application for support of the cancer patient and oncology treatment. We have had discussions with potential product co-development partners from time to time, and plan to continue to explore the possibilities for co-development and sub-licensing in order to implement our development plans. In addition, we believe that some of our products may have applications in treating non-cancer conditions in humans and in animals. Those conditions are outside our core business focus and we do not presently intend to devote a substantial portion of our resources to addressing those conditions. However, we have established an animal healthcare division to exploit some of those opportunities.

We are considered a development-stage company for accounting purposes because 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 are prone to all of the risks 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, among other things:

- o satisfy our future capital requirements for the implementation of our business plan;
- o commercialize our existing products;
- o complete development of products presently in our pipeline and obtain necessary regulatory approvals for use;
- o implement and successfully execute our business and marketing strategy to commercialize products;
- o establish and maintain our client base;
- 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 were unable to do so, our business prospects, financial condition and results of operations would be materially adversely affected. The likelihood of our success must be considered in light of the development cycles of new pharmaceutical products and technologies and the competitive and regulatory environment in which we operate.

## Results of Operations

Nine Months Ended March 31, 2002 Compared to Nine Months Ended March 31, 2001

We have acquired development and marketing rights to a portfolio of six platform technologies developed over the past fifteen years, from which a range of products have been derived and additional products may be developed in the future. Although we intend to commence marketing our lead product, Modrenal(R), and to continue developing our existing platform technologies and commercializing products derived from such technologies, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. Once a product or technology has been launched into the market for a particular disease indication, we plan to work with numerous collaborators, both pharmaceutical and clinical, in the oncology community to extend the permitted uses of the product to other indications. In order to market our products effectively, we intend to develop marketing alliances with strategic partners and may co-promote and/or co-market in certain territories.

For the nine months ended March 31, 2002 and 2001, we reported revenues of \$552,000 and \$1,358,000, respectively. Revenues reflect our agreement with Ilex. Research and development costs for the nine month period ended March 31, 2002 were \$687,000, compared to the nine month period ended March 31, 2001 of \$1,441,000. Administrative expenses for the nine-month period ended March 31, 2002 were \$489,000, a decrease of \$592,000 from the nine month period ended March 31, 2001 of \$870,000. The decrease reflects the reduction of our non-development expenses until additional funding is secured. Administrative expenses are comprised mainly of legal, accounting and other professional fees. We reported interest and finance charges of \$912,000 for the nine months ended March 31, 2002, an increase of \$900,000 from the nine months ended March 31, 2001. This increase reflects deferred charges related to our financing agreement in August 2001 with Kevin Leech and in November 2001 with SCO Capital. Depreciation and amortization expense totaled \$242,000 in the nine month period ended March 31, 2002, compared to \$8,000 in the nine month period ended March 31, 2001. The increase in amortization is related to the amortization of certain intangible assets we acquired in the Pathagon transaction.

Year Ended June 30, 2001 Compared to Year Ended June 30, 2000

Research and development costs increased to \$1,565,908 in the fiscal year ended June 30, 2001, from \$984,460 in the year ended June 30, 2000. The increase in research and development costs is a result of increasing our research activities during the fiscal year ended June 30, 2001 as we increased the pace of development of our products portfolio. General and administrative expenses totaled \$550,215 in the year ended June 30, 2001, as compared with \$486,627 in the year ended June 30, 2000. General and administrative expenses were comprised primarily of charges related to legal fees, accounting fees, investor relations and rent. Depreciation and amortization expense totaled \$22,809 in the fiscal year ended June 30, 2001, as compared with

\$11,644 in the fiscal year ended June 30, 2000. Interest and finance charges

## Edgar Filing: BIOENVISION INC - Form SB-2

totalled \$228,787 in the fiscal year ended June 30, 2001, as compared with \$12,778 in the fiscal year ended June 30, 2000. The majority of interest and finance charges relates to costs associated with the issuance of stock options related to our credit facility with Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, a United Kingdom citizen and one of our shareholders, which facility was terminated in August 2001. Reference is made to footnote 8 to our consolidated financial statements in Item 7 hereto, which consolidated financial statements are presented beginning at page F-1, for further details.

### Liquidity and Capital Resources

We anticipate that we may continue to incur significant operating losses for the foreseeable future. There can be no assurance as to whether or when we will generate material revenues or achieve profitable operations.

We are actively seeking strategic alliances in order to develop and market our range of products. In August 2001, we obtained a \$1 million unsecured line of credit facility from Jano Holdings Limited, bearing interest at 8% per annum. As of March 31, 2002, we have utilized \$290,000 of the facility. In November 2001, we entered into a senior, Secured Credit Facility with SCO Capital Partners LLC. The credit facility was established for up to \$1,000,000 in short term financing, in four tranches of \$250,000, subject to satisfaction of certain conditions, secured by the pledge of certain of our assets, and was established to bear interest on drawings at a rate of 6% per annum. As of March 31, 2002, we had utilized \$500,000 of the available facility. In addition, our officers agreed to defer salaries, and our former outside counsel agreed to defer certain fees, until we obtained sufficient long-term funding. Deferred salaries and fees amounted to approximately \$105,000 through March 31, 2002. In May 2001, our officers agreed to accept 705,954 shares of our common stock in settlement of \$910,681 of the outstanding accrued salaries through June 30, 2001. The shares were issued during the quarter ended March 31, 2002. On October 17, 2001, our officers agreed to accept 134,035 shares in settlement of \$154,140 of additional outstanding accrued salaries to September 30, 2001. On October 17, 2001, the board of directors approved a plan to repay certain trade debt with shares of our common stock, and a total of 146,499 shares of common stock were issued for the repayment of \$168,473.

We received an initial payment from Ilex of \$1,350,000 which became non-refundable in March 2001 upon execution of the agreement with Ilex to co develop clofarabine. That sum will be recognized as income for accounting purposes on a straight line basis over the period from March 2001, when the payment was received, through December 31, 2002, when Ilex is scheduled to complete Phase II trials of clofarabine and make another payment to us. A total of \$552,000 of that payment was recognized as contract revenue for the nine-month period ended March 31, 2002.

On May 7, 2002 we authorized the issuance and sale of up to 5,920,000 shares of Series A Preferred Stock. The Series A preferred stock may be converted into shares of common stock at an initial conversion price of \$1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A preferred stock also received, in respect of each share of Series A preferred stock purchased in a private placement which took place in May 2002, one warrant to purchase one

share of our common stock at an initial exercise price of \$2.00 subject to

## Edgar Filing: BIOENVISION INC - Form SB-2

adjustment. The purchasers of Series A Preferred Stock also received certain demand and piggyback registration rights.

Through May 16, 2002 we have sold an aggregate of 5,916,666 shares of Series A convertible participating preferred stock in the May 2002 private placement for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock, resulting in aggregate gross proceeds of approximately \$17,750,000. A portion of the proceeds were used to repay the Jano Holdings and SCO Capital obligations, upon which those facilities were terminated as well as to repay deferred salaries and fees amounting to \$105,000 and to pay fees and expenses related to the transaction.

### Plan of Operation

Our management believes that our net proceeds from the May 2002 private placement will be sufficient to continue currently planned operations over the next 12 months, and we will not intend to raise any additional funds during that period in order to fund operations. However, a key element of our business strategy is to continue to acquire, obtain licenses for, and develop new technologies and products that we believe offer unique market opportunities and/or complement our existing product lines. We are not presently considering any such transactions, and we do not presently expect to acquire or sell any significant assets over the coming 12 month period, but if any such opportunity presents itself and we deem it to be in our interests to pursue such an opportunity, it is possible that additional financing would be required for such a purpose.

We are a development stage biopharmaceutical company with a primary business focus on the acquisition, development and distribution of drugs to treat cancer. We plan to utilize a portion of the proceeds of the May 2002 private placement to conduct clinical trials of our receptor modulation drug, trilostane, in the treatment of breast and prostate cancer. Further laboratory studies will be conducted to examine the effect of the drug on the hormone receptor.

In addition, a provisional product license has been granted in the United Kingdom for the use of trilostane for the treatment of Cushing's disease in dogs. In November 2001, we granted to Arnolds Ltd., a major distributor of animal products in the United Kingdom, the right to market the drug for a six month trial period, after which time, if the results were satisfactory to Arnolds, we would enter into a licensing arrangement whereby Arnolds would pay royalties to us on sales from April 2002 onward. During the trial period, Arnolds has posted more than \$400,000 of sales of the drug, which is marketed in the United Kingdom as Veteryl(R). Arnolds has licensed the drug from us for sale in the United Kingdom market in consideration of a payment of a 5% royalty on sales.

We also plan to utilize a major portion of the proceeds of the May 2002 private placement to initiate clinical trials of clofarabine in Europe. The emphasis will be on the use of clofarabine in the treatment of refractory acute leukemia in children and adults. The drug has received orphan drug designation in Europe.

26

We plan to identify licensing partners for OLIGON(R) and to continue developing new aspects of the technology. We also plan to continue development of methylene blue and other products in our pipeline.

In order to implement our business plan, we anticipate utilizing a

## Edgar Filing: BIOENVISION INC - Form SB-2

portion of the proceeds of the May 2002 private placement to hire several key executives over the next few months, including a senior executive vice president of drug development and a director of finance, and to locate those individuals, as well as our President, in the United States. We also plan to gradually hire additional personnel to manage regulatory affairs, investor relations and certain administrative functions.

### Recent Accounting Pronouncements

In August 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This statement is effective for fiscal years beginning after December 31, 2001. This supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of," while retaining many of the requirements of such statement. We do not believe that this statement will have a material effect on our financial statements.

### DESCRIPTION OF BUSINESS

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

We believe that our two initial lead products have the following competitive advantages over existing products at market:

#### Modrenal(R) -----

- > Novel mode of action on estrogen receptor
- > Increases estrogen binding to ER(beta)
- > 46% response rate in international clinical trials of almost 800 patients with advanced breast cancer
- > Second line therapy for hormone sensitive breast cancer
- > Possible combination therapy with Tamoxifen(R)
- > Possible role in prostate and ovarian cancer
- > Favorable pricing compared to competitors

#### Clofarabine -----

- > Broader cellular activity than available nucleoside analogs, based on pre-clinical and clinical trials
- > Greater range of clinical activity than available nucleoside analogs
- > Good oral bio-availability
- > Pre-clinical activity against solid tumors.
- > Complete response in chronic myeloid leukemia, based on clinical trials

The following tables identify the state of development of the various products in our portfolio:

#### Anti-Cancer Product Portfolio

Edgar Filing: BIOENVISION INC - Form SB-2

-----

	Pre-clinical	Phase I	Phase II	Phase II
	-----	-----	-----	-----
Product/Condition:				
Modrenal(R)/Breast Cancer				
Abetafen/Prostate Cancer			Phase II	
Modrenal(R)/Analog	Pre-clinical			
Clofarabine/Leukemia			Phase II	
Clofarabine/Lymphoma			Phase II	
Clofarabine/Solid Tumors		Phase I		
Gene Albumin		Phase I		
TPO Gene		Phase I		
Gossypol/Prostate Cancer		Phase I		
Gossypol/Bladder Cancer		Phase I		
Summary	1	5	3	0
	=====	=====	=====	=====

Non-Cancer Product Portfolio

-----

	Pre-clinical	Phase I	Phase II	Phase II
	-----	-----	-----	-----
Product/Condition:				
Oligon(R) IV catheters (ST)				
Methylene Blue				
Veteryl(R)/Cushing's Disease				
Modrefen/Alzheimer's Disease	Pre-clinical			
Clofarabine/Transplantation	Pre-clinical			
Summary	2	0	0	0
	=====	=====	=====	=====

Animal Health Product Portfolio

-----

	Pre-clinical	Phase I	Phase II	Phase II
	-----	-----	-----	-----
Product/Condition:				
Modrastane(R) Cushing's Disease				
Modrastan(R)/Alopecia X			Phase II	
Clofarabine/Cancer	Pre-clinical			
Cytostatic Agents/Cancer	Pre-clinical			
Summary	2	0	1	0
	=====	=====	=====	=====

The animal healthcare market is a multi-billion dollar market (as demonstrated by publicly reported sales of large pharmaceutical companies and we intend to exploit the value of our products in the veterinary field. This business segment is not a part of our core business and will be managed separately from our core human pharmaceuticals business.

#### Products

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

##### Purine Nucleoside Technology

We have a license from Southern Research Institute, Birmingham, Alabama, to develop and market purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. The lead compound of these purine-based nucleosides is known as clofarabine. To facilitate its development, we entered into a co-development agreement with Ilex Oncology, Inc. ("Ilex") in March 2001. Clofarabine has successfully completed Phase I/II clinical trials at M.D. Anderson Cancer Center, Houston. Three Phase II clinical trials have begun at MD Anderson and will be extended to other leading centers in the United States and Europe. In addition, a clinical trial exemption certificate has been granted for clofarabine in the United Kingdom and approval for a Phase I/II trial of clofarabine in lymphoma has been obtained in Switzerland. In January 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. The drug also has been granted orphan drug status in the United States. The combination of the Phase II trials in acute leukemia at the MD Anderson and other leading centers in the U.S. and Europe and the encouraging results from the Phase I and early Phase II studies lead us, and Ilex, to be enthusiastic for the prospects of clofarabine reaching the market, possibly as soon as the 4th quarter of 2003 or the 1st quarter of 2004.

Under the terms of the agreement with Southern Research Institute, we were granted the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by us and by Southern Research Institute from the technology. Our management plans to develop clofarabine initially for the treatment of leukemia and lymphoma, but also to study its potential role in treatment of solid tumors.

Pre-clinical testing of clofarabine showed the drug to have anti-tumor activity against a range of human and animal cancers, including hematological malignancies and several solid tumors. In addition, clofarabine has been shown to have good oral bioavailability, and it is our intention to develop an oral preparation of the drug for clinical testing. Preliminary results from ongoing clinical studies indicate that clofarabine may be an effective treatment for relapsed acute leukemias in adult and pediatric patients, as well as acute leukemias in adult and pediatric patients that have become resistant, or refractory, to prior treatments. According to researchers at the MD Anderson Cancer Center, interim Phase II study results showed that 45 percent of adults with acute myelogenous leukemia (AML) achieved a complete remission (CR) rate, and acute lymphocytic leukemia (ALL) patients achieved a 20 percent CR rate when treated with

clofarabine as a single agent. Data from a separate Phase I dose-escalation study demonstrated a 25 percent CR rate, and an overall response rate of 40%, in children with acute leukemias who were refractory to previous therapy. Trials in pediatric acute leukemias are currently ongoing in the US and are planned to commence in Europe later this year. Complete remission, in this context, means complete clearance of all leukemic cells from the blood and normalization of the blood count, sustained for a period of more than 4 weeks. In this context, a response, or partial response, has largely the same meaning, except that the bone marrow may still contain more than 5 percent but less than 25 percent blast cells (leukemic cells).

Clofarabine appears to attack cancer cells in at least four ways:

- (1) damaging DNA in cancer cells;
- (2) preventing DNA repair by damaged cancer cells;
- (3) damaging the cancer cell's important control structures--the mitochondria; and
- (4) initiating the process of programmed cell death (apoptosis) in cancer cells.

Clofarabine combines many of the favorable properties of the two most commonly used nucleoside analog drugs, fludarabine(R) and cladribine(R), but has several-fold greater potency, when compared to fludarabine(R), at damaging the DNA of leukemia cells. Clofarabine appears to achieve this greater potency by a process of breaking DNA chains and inhibiting an important enzyme, ribonucleotide reductase. Clofarabine distinguishes itself from other drugs by its broader activity--in particular, the way in which it damages the cells mitochondria and initiates the process of programmed cell death (apoptosis). (See Blood 2000; volume 96, page 3537).

Because clofarabine is a potent inhibitor of DNA repair, we, along with our co-development partners in North America, ILEX, plan to explore the potential use of clofarabine in combination with DNA damaging agents. This strategy has already been validated through the combination of fludarabine(R) with cyclophosphamide in the treatment of chronic lymphocytic leukemia (CLL).

Purine Nucleoside--Solid Tumor. In pre-clinical tests, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the colon, kidney and prostate, as well as its action against leukemic cells. This activity against solid tumors distinguishes clofarabine from other drugs in its class which have shown relatively little activity against solid tumors. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon and prostate cancer. The development strategy for clofarabine as a solid tumor agent will run in conjunction with the program for hematological cancers, but is expected to take longer to complete clinical trials and will require a different marketing approach.

Cancer of the colon is one of the most common cancers in the Western world with approximately 200,000 new cases in the United States each year. Surgery is the most successful treatment for the primary tumor. Once the cancer has spread the results of chemotherapy are disappointing and long-term survival figures have changed very little in the past fifty years. There is a great need for an effective chemotherapeutic agent to treat this disease, and a huge



market potential exists for any drug that can induce tumor regression in patients with metastatic colon cancer. Prostate cancer affects 181,000 new patients in the United States each year. Initial treatment is directed at hormonal control of the disease, but in the event control is not achieved chemotherapy is usually required. We intend to develop clofarabine, or a derivative of clofarabine, for the treatment of advanced colon and prostate cancer.

#### Selective Steroid Receptor Modulation Technology

We have commercial rights to a selective steroid receptor modulation technology, the lead compound of which is currently approved by regulatory authorities in the United Kingdom for the treatment of advanced breast cancer in post-menopausal women, and by regulatory authorities in Germany, for the treatment of certain adrenal disorders, such as Cushing's Disease. The product had also received marketing approval for the treatment of Cushing's disease in certain other European countries and the United States. The lead product, trilostane, is currently approved for marketing under the names Modrenal(R) and Modrastan(R). Recent scientific data from Professor Gavin Vinson's laboratory at Queen Mary & Westfield College, London, England (part of the University of London) have shown that trilostane has a unique and previously unrecognized mode of action. The drug inhibits estrogen binding to the classical estrogen receptor (ER(alpha)) in an indirect (allosteric) fashion and also modulates estrogen binding to the newly-described second receptor, ER(beta). This action makes trilostane the first drug in a new class of agents that specifically modulate ligand binding to ER(beta). This novel action may explain the high clinical response rates seen when the drug was given to breast cancer patients with Tamoxifen(R) resistance.

Breast cancer is, in general, a hormone-dependent disease, with estrogen being the principal hormone driving cell growth. Consequently, a major part of modern treatment is directed at blocking the action of estrogen, either at the site of production in the body or at the cell's estrogen receptor. The most widely used drug in this area, Tamoxifen(R), has been very successful in improving response rates and survival in women with breast cancer. Until recently, it was believed that estrogen acted via a single receptor on the cancer cell. However, it is now known that more than one estrogen receptor exists. New data, from scientists at the University of London working on our behalf, have shown that trilostane alters the binding of estrogen to certain of the receptors, thereby altering and, in some cases, blocking the action of estrogen. Furthermore, trilostane's action is different from that of other known "hormonal agents" although its actions may be complementary to those of other drugs. Extensive clinical trials with the drug have shown that it is effective in a significant proportion of breast cancer patients, particularly those with hormone sensitive tumors. Trilostane has no aromatase inhibitor activity, which distinguishes it from some of the competitor hormonal products currently marketed for the treatment of breast cancer. We believe that the new data presents the drug with considerable market potential, although there can be no assurance that the medical profession or the FDA will accept this new data or that the drug will be successful in the marketplace.

Trilostane has been extensively studied in controlled trials in the United States, Europe and Australia, and almost 800 patients with breast cancer have received trilostane. Its anti-tumor activity has been well documented and the drug has been shown to produce tumor response rates of up to 55 percent in women with hormone sensitive breast cancer. In a sub-set analysis of the

clinical trial data, patients with hormone sensitive breast cancer who had responded to one or more hormonal therapies were given trilostane upon relapse of the cancer. The response rate was above 40 percent in this group of patients. This compares to a response rate of about 30-35 percent with currently marketed aromatase inhibitors and approximately 25 percent with herceptin given as second line therapy. Most of the patients in the sub-set had received Tamoxifen(R) as first-line therapy. Thus, trilostane given as follow-on, or salvage, therapy has a response rate in excess of those reported for the drugs currently in use for second-line treatment in this disease. Furthermore, trilostane has an acceptable side-effect profile. On the basis of these data, trilostane was granted a product license in the United Kingdom for the treatment of post-menopausal breast cancer.

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

We plan to launch Modrenal(R) by late 2002 in the United Kingdom for use in the treatment of post-menopausal breast cancer. We also intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone sensitive breast cancers. This would target patients that have hormone-sensitive cancers and have become resistant, or refractory, to prior hormone treatments, such as Tamoxifen(R) or aromatase inhibitors. We believe that the potential market for Modrenal(R), based upon the sales of currently available drugs for hormonal therapy for breast cancers, is in excess of \$1.8 billion of sales per annum worldwide. The results of extensive clinical trails to date with Modrenal(R) show that it is at least as effective in second line or third line treatment of advanced breast cancer as the currently available hormonal treatments, such as the selective estrogen receptor modulators, or SERMs, and aromatase inhibitors, and more effective than these agents in certain specific patient types, such as those who have become Tamoxifen(R)-refractory. Furthermore, our management currently intends to price Modrenal(R) in such a way as to make treatment with Modrenal(R) compare very favorably, on a price basis, with the cost of treatment with the existing drugs used for second line or third line therapy. We believe that this should result in cost benefits for physicians, patients and health-care systems.

Anti-Estrogen Prostate. We have received IRB [CHRIS WOOD] approval from the Massachusetts General Hospital for a Phase II study of trilostane for the treatment of androgen independent prostate cancer. The study will be conducted by The Dana Faber Cancer Institute.

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

currently available treatments to block all the receptors on the prostate cancer cells. The ability of trilostane to control prostate cell growth by altering hormone binding on important receptors could expand the treatment options for patients with prostate cancer.

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

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

#### OLIGON(R) Technology

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

The OLIGON(R) technology is based on the antimicrobial properties of silver ions. The broad spectrum activity of silver ions against bacteria, including antibiotic-resistant strains, has been known for decades. OLIGON(R) materials have application in a wide range of devices and products, including vascular access devices, urology catheters, pulmonary artery catheters and thoracic devices, renal dialysis catheters, orthopedic devices and several other medical and consumer product applications. One application of the OLIGON(R) technology has been licensed to Edwards Life Sciences, which is currently marketing the technology in its line of short-term vascular access catheters.

Six U.S. patents for the OLIGON(R) technology have been granted and additional patents have been filed. In addition, patents have been filed in Europe, Canada and Japan.

The OLIGON(R) technology specifically targets hospital-acquired infections, the rate of which tripled between 1980 and 1990 and which accounts for approximately \$11 billion of extra

expense to the U.S. healthcare system each year. According to the U.S. Centers for Disease Control 1992, \$6.5 billion of this expense is related to infections associated with medical devices, including vascular access and urology catheters, and is unreimbursable to hospitals. OLIGON(R) products and devices will be marketed as next generation into large existing markets with current sales aggregating \$2.6 billion worldwide. Manufacturers of existing products are aware of the seriousness of device related infections, but none has been able to develop technology that imparts antimicrobial efficacy to all surfaces of implanted devices over long periods of time. OLIGON(R) effectively addresses all these requirements.

Edwards Lifesciences has released OLIGON(R) catheters on a limited basis to Centers of Excellence in select European countries with very positive results. In addition, since there are no changes required in user procedures the anti-infective devices have been well accepted by the medical community.

#### Methylene Blue Technology

We have licensed from Oklahoma Medical Research Foundation the rights to the use of a range of thiazine dyes, the most well known of which is methylene blue, for the in vitro and in vivo inactivation of pathogens in biological fluids. Methylene blue, especially when irradiated by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Methylene blue is currently used commercially in Europe to inactivate pathogens found in blood transfusion products, with excellent safety and effectiveness.

Blood transfusions are required to treat a variety of medical conditions and, to meet that need, over 90 million blood donations occur each year. Of these, approximately 39 million donations occur in North America, Western Europe and Japan. Methylene blue is currently used in several European countries to inactivate pathogens in fresh frozen plasma (FFP). We intend to work closely with international blood collection agencies to maximize the value of our intellectual property position.

#### Gene Therapy Technology

Our product portfolio also includes a variety of gene therapy products which, we believe, may offer advancements in the field of cancer treatment and may have additional applications in certain non-cancer diseases such as diabetes, cystic fibrosis and other auto-immune disorders. Pursuant to a co-development agreement with the Royal Free and University College Medical School and a Canadian biotechnology company, we are developing DNA vector technologies which, based on pre-clinical research and early Phase I clinical trials, we believe are capable of elevating albumin levels in cancer and cirrhosis patients with hypo-albuminemia, a serious physiological disorder. We believe this has considerable market potential since low albumin levels are considered to be very dangerous consequences of many diseases, including cirrhosis and liver cancer.

#### Cytostatic Technology

We have acquired a license to develop a distinct group of compounds that we believe could play an important role in controlling the rate of growth of cancer cells. In some cancers,

such as cancer of the bladder and skin, drugs that stop cell growth (cytostatics) can be as effective as drugs that kill the cell by direct toxicity (cytotoxics). The cytostatic drugs we are developing are believed to work by blocking cell division and reversing the malignant process in the cancer cell. The first compound is a synthetic analog of a drug derived from a naturally grown plant, which has been widely tested for a variety of clinical indications. The results of this testing have been published in the medical literature. In particular, the drug has shown efficacy against certain cancers by, it is believed, preventing cell division and promoting cell differentiation.

We plan to develop more potent analogs and to study their role in the process of cell differentiation and the prevention of the spread of cancer cells. The first compound derived from this technology is currently approved for a Phase I clinical trial at a leading United Kingdom cancer center.

#### Animal Health Products

We also have one animal health product, Veteryl(R), at market in the United Kingdom for the treatment of Cushing's disease in dogs. In November 2001, we granted to Arnolds Ltd., a major distributor of animal products in the United Kingdom, the right to market the drug for a six month trial period, after which time, if the results were satisfactory to Arnolds, we would enter into a licensing arrangement whereby Arnolds would pay royalties to us on sales from April 2002 onward. During the trial period, Arnolds has posted more than \$400,000 of sales of the drug. Arnolds has licensed the drug from us for sale in the United Kingdom market in consideration of a payment of a 5% royalty on sales. We have established a separate division to market this product. The animal healthcare market is a multi-billion dollar market (as demonstrated by sales of large pharmaceutical companies and we intend to exploit the value of our products in the veterinary field. This business segment is not a part of our core business and will be managed separately from our core human pharmaceuticals business.

#### Patents and Proprietary Rights

Our success will depend, in part, upon our ability to obtain and enforce protection for our products under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Our policy is to file patent applications in the United States and/or foreign jurisdictions to protect technology, inventions and improvements to our inventions that are considered important to the development of our business. We will also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop a competitive position.

Through our current license agreements, we have acquired the right to utilize the technology covered by five issued patents and six patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. We evaluate the desirability of seeking patent or other forms of protection for our products in foreign markets based on the expected costs and relative benefits of attaining this protection. There can be no assurance that any patents will be issued from any applications or that any issued patents will afford adequate protection to us. Further, there can be no assurance

that any issued patents will not be challenged, invalidated, infringed or

## Edgar Filing: BIOENVISION INC - Form SB-2

circumvented or that any rights granted thereunder will provide competitive advantages to us. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. There can be no assurance that patents now in existence or hereafter issued to others will not adversely affect the development or commercialization of our products or that our planned activities will not infringe patents owned by others.

We could incur substantial costs in defending ourselves in infringement suits brought against us or any of our licensors or in asserting any infringement claims that we may have against others. We could also incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors or distributors. An adverse outcome in any litigation could have a material adverse effect on our business and prospects. In addition, we could be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any of these licenses would be made available on terms acceptable to us, or at all. If we are required to, and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more of our products.

We also rely upon trade secret protection for our confidential and proprietary information. There can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose this technology or that we can meaningfully protect our trade secrets.

It is our policy to require our employees, consultants, members of the Scientific Advisory Board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

### Sales and Marketing

Our success will depend, in part, upon our ability to obtain and enforce protection for our products under United States and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Our policy is to file patent applications in the United States and/or foreign jurisdictions to protect technology, inventions and improvements to our inventions that are considered important to the development of our business. We will also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop a competitive position.

Through our current license agreements, we have acquired the right to utilize the technology covered by five issued patents and six patent applications, as well as additional

intellectual property and know-how that could be the subject of further patent applications in the future. We evaluate the desirability of seeking patent or

## Edgar Filing: BIOENVISION INC - Form SB-2

other forms of protection for our products in foreign markets based on the expected costs and relative benefits of attaining this protection. There can be no assurance that any patents will be issued from any applications or that any issued patents will afford adequate protection to us. Further, there can be no assurance that any issued patents will not be challenged, invalidated, infringed or circumvented or that any rights granted thereunder will provide competitive advantages to us. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. There can be no assurance that patents now in existence or hereafter issued to others will not adversely affect the development or commercialization of our products or that our planned activities will not infringe patents owned by others.

We could incur substantial costs in defending ourselves in infringement suits brought against us or any of our licensors or in asserting any infringement claims that we may have against others. We could also incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors or distributors. An adverse outcome in any litigation could have a material adverse effect on our business and prospects. In addition, we could be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any of these licenses would be made available on terms acceptable to us, or at all. If we are required to, and do not obtain any required licenses, we could be prevented from, or encounter delays in, developing, manufacturing or marketing one or more of our products.

We also rely upon trade secret protection for our confidential and proprietary information. There can be no assurance that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose this technology or that we can meaningfully protect our trade secrets.

It is our policy to require our employees, consultants, members of the Scientific Advisory Board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements provide that all confidential information developed or made known during the course of the relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed by the individual during employment shall be our exclusive property to the extent permitted by applicable law.

### Manufacturing

We do not have and do not intend to establish any internal product testing, manufacturing or distribution capabilities. Our strategy is to enter into collaborative arrangements with other companies for the clinical testing, manufacture and distribution of its products. These collaborators are generally expected to be responsible for funding or reimbursing all or a portion of the development costs, including the costs of clinical testing necessary to obtain regulatory clearances and for commercial-scale manufacturing, in exchange for exclusive or semi-exclusive

rights to market specific products in particular geographic territories. Manufacturers of our products will be subject to Good Manufacturing Practices

## Edgar Filing: BIOENVISION INC - Form SB-2

prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities.

### Raw Materials

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

### Research and Development

In developing new products, we consider a variety of factors including: (i) existing or potential marketing opportunities for these products; (ii) our capability to arrange for the manufacture of these products on a commercial scale; (iii) whether these products complement our existing products; (iv) the opportunities to leverage these products with the development of additional products; and (v) the ability to develop co-marketing relationships with pharmaceutical and/or other companies with respect to the products. We intend to fund future research and development activities at a number of medical and scientific centers in Europe and the United States. Costs related to these activities are expected to include: clinical trial expenses; drug production costs; salaries and benefits of scientific, clinical and other personnel; patent protection costs; analytical and other testing costs; professional fees; and insurance and other administrative expenses. We currently have three employees that are involved in research and development activities. We estimate that that we have spent \$984,460 and \$1,565,908 on research and development activities in 2000 and 2001, respectively.

### Industry Overview

The biopharmaceutical industry has significantly evolved since its commercial inception in the 1970s and is currently approaching a period of sustained growth. We believe that this growth, coupled with the maturing state of the existing biotechnology sector, will strengthen the large pharmaceutical companies and result in the emergence of a new generation of biopharmaceutical companies. To be successful, this new breed of biopharmaceutical company must have the ability to harness rapidly advancing technology, provide solutions for previously unmet therapeutic needs, ensure faster development of new drugs and allow flexibility to exploit changing market conditions. We seek to be at the forefront of this new generation of biopharmaceutical companies, linking the technological skills of doctors and scientists in Europe and North America with the U.S. and European capital markets.

The World Health Organization (WHO) estimated in 2000 that globally, there were 3.5 million deaths and 5.3 million new cases of cancer annually. As would be expected the prevalent US cancer population at 3.2 million dwarfs those of other major markets. In addition, cancer causes a major drain on health-care resources. The Imperial Cancer Research Fund estimate that 1 in 3 people will contract some form of cancer at some point in their life. The World Health Organization estimate that over 7 million people will lose their lives to cancer this year alone.

The National Cancer Institute (NCI) estimated in 2000 the overall costs for cancer to be \$107 billion in the United States; \$37 billion for direct costs, \$11 billion for morbidity costs and \$59 billion for mortality costs.



## Edgar Filing: BIOENVISION INC - Form SB-2

Treatment of breast, lung and prostate cancer account for over half the direct medical costs.

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

### Forecast Global Cancer Treatment Market 2001 - 2007

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

Source: Reuters, 2002

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

#### Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our drug delivery products.

The process required by the FDA under the new drug provisions of the Federal Food, Drug and Cosmetics Act before our products may be marketed in the United States generally involves the following:

- o pre-clinical laboratory and animal tests,
- o submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin,
- o adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use,
- o submission to the FDA of a new drug application, and
- o FDA review and approval of the new drug application.

## Edgar Filing: BIOENVISION INC - Form SB-2

The testing and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approval will be granted on a timely basis, if at all.

Pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before we may begin human clinical trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. There is no certainty that pre-clinical trials will result in the submission of an IND or that submission of an IND will result in FDA authorization to commence clinical trials.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of a qualified principal investigator. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be conducted under the auspices of an independent institutional review board at the institution where the study will be conducted. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Human clinical trials are typically conducted in three sequential phases which may overlap:

- o PHASE I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion.
- o PHASE II: Studies are conducted in a limited patient population to identify possible short term adverse effects and safety risks, to determine the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- o PHASE III: Phase III trials are undertaken to further evaluate clinical efficacy and to further test for safety in an expanded patient population, often at geographically dispersed clinical study sites. Phase III or IIb/III trials are often referred to as pivotal trials, as they are used for the final approval of a product.

In the case of products for life-threatening diseases such as cancer, the initial human testing is often conducted in patients with disease rather than in healthy volunteers. Since these patients already have the targeted disease or condition, these studies may provide initial evidence of efficacy traditionally obtained in Phase II trials and so these trials are frequently referred to as Phase I/II trials. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Furthermore,

## Edgar Filing: BIOENVISION INC - Form SB-2

we, the FDA, the institutional review board or the sponsor may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application for approval of the marketing and commercial shipment of the product. The FDA may deny a new drug application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if the additional data is submitted, the FDA may ultimately decide that the new drug application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards for production and distribution is not maintained or if safety problems occur after the product reaches the market. In addition, the FDA requires surveillance programs to monitor approved products which have been commercialized, and the agency has the power to require changes in labeling or to prevent further marketing of a product based on the results of these post-marketing programs.

The FDA has a Fast Track program intended to facilitate the development and expedite the review of drugs that demonstrate the potential to address unmet medical needs for treatment of serious or life-threatening conditions. Under this program, if the FDA determines from a preliminary evaluation of clinical data that a fast track product may be effective, the FDA can review portions of a new drug application for a Fast Track product before the entire application is complete, and undertakes to complete its review process within six months of the filing of the new drug application. The FDA approval of a Fast Track product can include restrictions on the product's use or distribution such as permitting use only for specified medical procedures or limiting distribution to physicians or facilities with special training or expertise. The FDA may grant conditional approval of a product with Fast Track status and require additional clinical studies following approval.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially, based upon the type, complexity and novelty of the pharmaceutical product. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data from pre-clinical and clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications. Further, even after the FDA approves a product, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Any products manufactured or distribute under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the products. Drug manufacturers and their subcontractors are required to register with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with good manufacturing practices, which impose procedural and documentation requirements upon manufacturers and their third party manufacturers.

## Edgar Filing: BIOENVISION INC - Form SB-2

We are also subject to numerous other federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future. In addition, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

We also are subject to foreign regulatory requirements governing human clinical trials and marketing approval for pharmaceutical products which we sell outside the United States. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. Whether or not we obtain FDA approval, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for these approvals may differ substantially from that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that approval in one country will result in approval in any other country. For clinical trials conducted outside the United States, the clinical stages generally are comparable to the phases of clinical development established by the FDA.

### Competition

Competition in the pharmaceutical industry is intense. Potential competitors in the United States and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Although we seek to limit potential sources of competition by developing products that are eligible for orphan drug designation or other forms of protection, there can be no assurance that our competitors will not succeed in developing similar technologies and products more rapidly than are being or will be developed by us.

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

Listed below are other hormonal therapies currently at market.

Company -----	Brand -----	Generic -----	Class -----	1999 (\$m) ----	2000 (\$m) ----
TAP	Lupron	Leuprorelin	LHRH agonists	775	798
AstraZeneca	Zoladex	Goserelin	LHRH agonists	686	734
AstraZeneca	Nolvadex	Tamoxifen	Anti-estrogens	573	576
AstraZeneca	Casodex	Bicalutamide	Anti-estrogens	340	433
Takeda	Leuplin	leuprorelin	LHRH agonists	485	515
Barr	Tamoxifen	Tamoxifen	Anti-estrogens	297	322
Pharmacia	Depo-Provera	Medroxy	Progestagens	252	272
AstraZeneca	Arimidex	Anastrozole	Aromatase Inhibitors	140	156

Edgar Filing: BIOENVISION INC - Form SB-2

Company	Brand	Generic	Class	1999 (\$m)	2000 (\$m)
Abbott	Lupron	leuprorelin	LHRH agonsists	140	153
BMS	Megace	megestrol	Progestagens	114	180
Novartis	Femara	letrozole	Aromatase Inhibitors	57	74
Ipsen	Deccapepryl	triptorelin	LHRH agonsists	100	105
Aventis	Nilandron	nilutamide	Anti-androgens	72	87
Schering AG	Androcur	cyproterone	Anti-androgens	91	95
Aventis	Suprecur/ Suprefact	buserelin	LHRH agonsists	83	84
SP	Eulexin	flutamide	Anti-androgens	155	128
Pharmacia	Aromasin	exemestane	Aromatase Inhibitors	n/a	36
Nihun Kayaku	Odyne	flutamide	Anti-androgens	71	65
Teikoku Hormone	Prostal	chlormadinone	Progestagens	63	63
Novartis	Lentaron	formestane	Aromatase Inhibitors	47	45
Nihun Kayaku	Fareston	toremifene	Anti-estrogens	44	43
Novartis	Afema	tadrozole	Aromatase Inhibitors	22	25
Mitsui	Tasuomin	Tamoxifen	Anti-estrogens	10	9
Others				237	240
TOTAL				4,855	5,237

Source: Reuters, 2002

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

Company	Brand	Generic	Class	1999 (\$m)	2000 (\$m)
BMS	Taxol	Paclitaxel	Other Cytotoxics	1,481	1,592
Aventis	Taxotere	Docetaxel	Other Cytotoxics	461	686
Lilly	Gemzar	Gemcitabine	Antimetabolite	453	559
BMS	Paraplatin	Carboplatin	Other Cytotoxics	600	690
Pharmacia	Camptosar	irinorccan	Other Cytotoxics	293	441
Taiho	UFT	tegafur uracil	Antimetabolite	460	440
Pharmacia	Pharmorubicin /Ellence	cpirubein	Cytotoxic Antibiotics	206	199
Ivax	Paxene	paclitaxel	Other Cytotoxics	n/a	35
Roche	Furtulon	doxifluridine	Antimetabolite	166	201
Aventis	Campro	irinotecan	Other Cytotoxics	83	139
Sanofi	Eloxatine	oxilaplatin	Other Cytotoxics	72	130
SP	Temodar	temozolomide	Alkylating agents	36	121
Roche	Xeloda	capecitabine	Antimetabolite	53	89
GSK	Hycarntin	topotecan	Other Cytotoxics	141	144
Schering AG	Fludara	fludarabine	Antimetabolite	79	102
BMS	Ifex	ifosfamide	Alkylating agents	88	108
Alza US	Doxil/Caelyx	liposomal/	Cytotoxic Antibiotics	66	82

Edgar Filing: BIOENVISION INC - Form SB-2

doxorubicin

43

Company	Brand	Generic	Class	1999 (\$m)	2000 (\$m)
Pierre Fabre	Navelbine	vinorelbine	Vae	76	82
Wyeth	Novantrone	mitoxantrone	Cytotoxic Antibiotics	45	60
BMS	VcPesid	ctoposide	Vae	77	70
GSK	Navelbine	vinorelbine	Vae	67	65
Pharmacia	Adriamycin	doxorubicin	Cytotoxic Antibiotics	65	62
BMS	Hydrea	hydroxyurea	Alkylating agents	56	52
Others				1,824	1,776
TOTAL				6,948	7,925

Source: Reuters, 2002

The generic drug industry is intensely competitive and includes large brand name and multi-source pharmaceutical companies. Because generic drugs do not have patent protection or any other market exclusivity, our competitors may introduce competing generic products, which may be sold at lower prices or with more aggressive marketing. Conversely, as we introduce branded drugs into our product portfolio, we will face competition from manufacturers of generic drugs which may claim to offer equivalent therapeutic benefits at a lower price.

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

Employees

We have 8 full-time and 2 part-time employees. Of these, 5 are in management, 1 is in sales/marketing, 1 is in administration and 3 are in research and development. We believe our relationships with our employees are satisfactory.

## Edgar Filing: BIOENVISION INC - Form SB-2

### Properties

#### Facilities

As of the date of this report we do not own any interest in real property. We currently lease approximately 250 square feet of office space at our financial advisor at Suite 1600, One

44

Rockefeller Plaza, New York, New York 10020 for our principal executive offices for \$4,000 per month. We also rent 250 square feet of office space at 32 Haymarket, London SW1Y 4TP for (pound)3,000 per month. These offices spaces are used by management and administration. To date, most of our drug development programs have been conducted at scientific institutions around the world. It is our policy to continue development at leading scientific institutions in the United States and Europe. We intend to lease facilities that will serve as our corporate headquarters in the United States upon completion of a private financing. These facilities will be the center for all of our administrative and marketing functions in the United States. We do not plan to conduct laboratory research in such facilities in the near future, but, rather, will conduct research through collaborative arrangements with Southern Revenue Institute, M.D. Anderson and others.

#### Investment Policies

We do not currently have any investments in real estate or interests in real estate, nor in real estate mortgages nor in the securities of or interests in persons primarily engaged in real estate. We generally acquire our assets for the purpose of ultimately producing sales revenues from the exploitation of such assets in the development of our biopharmaceutical business. We do not currently have any surplus cash to invest, but we intend to invest any surplus cash we may have on hand in the future in interest-bearing deposit accounts, short-term certificates of deposit and governmental debt instruments.

#### Legal Proceedings

We are not a party to any material legal proceedings.

#### Business Development

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.

On February 1, 2002, we completed the acquisition of Pathagon Inc., the successor in interest to Bridge Blood Technologies L.L.C., d/b/a Pathagon, a privately held company focused on the development of novel anti-infective products and technologies. Pathagon's principal products, OLIGON(R) and methylene blue, are ready for market. Affiliates of SCO Capital Partners LLC, our financial advisor and consultant, owned 82% of Pathagon prior to the acquisition. We acquired 100% of the outstanding shares of Pathagon in exchange for 7,000,000 shares of our common stock. The acquisition has been accounted for as a purchase business combination in accordance with SFAS 141. With the acquisition, we added rights to OLIGON(R) and methylene blue to our portfolio of products.

45

## Edgar Filing: BIOENVISION INC - Form SB-2

### CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On September 30, 1999, we and our former auditors, Graf Repetti & Co., LLP agreed to terminate our relationship as of such date. As of October 1, 1999, we retained Ernst & Young (now Ernst & Young LLP) as our independent public accountants. The decision to terminate our relationship with Graf Repetti was recommended and approved by our board of directors and was based upon our need to have auditors with international auditing capability.

During the period from inception on August 16, 1996 through and including June 30, 1998, and for the interim period from July 1, 1998 through March 31, 1999, Graf Repetti's reports on our financial statements neither contained any adverse opinions or disclaimers of opinions nor were qualified or modified as to uncertainty, except that Graf Repetti's auditors' report on our consolidated financial statements for the fiscal period ended June 30, 1998 expressed substantial doubt about our ability to continue as a going concern due to our losses from operations and net capital deficiency.

During the fiscal period commencing with inception on August 16, 1996 and ended June 30, 1998, and for the interim period from July 1, 1998 through March 31, 1999, there were no disagreements with Graf Repetti on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Graf Repetti, would have caused it to make reference to the subject matter of the disagreements in connection with its reports.

On June 15, 2001, we received a letter from Ernst & Young (now Ernst & Young LLP) expressing its desire to resign as our independent auditors. On June 16, 2001 and again on June 19, 2001, our management had discussions with Ernst & Young LLP asking them to reconsider their resignation. On June 20, 2001, we received a letter from Ernst & Young LLP stating that it did not wish to reconsider its resignation.

The reports of Ernst & Young LLP on our financial statements for the past fiscal years ended June 30, 1999 and 2000 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles, except that the report for the years ended June 30, 1999 and 2000 included a paragraph expressing substantial doubt as to our ability to continue as a going concern.

In connection with the audits of our financial statements for the fiscal years ended June 30, 1999 and 2000 and in the subsequent interim period, there were no disagreements with Ernst & Young on any matters of accounting principles or practices, financial statement disclosure, or auditing scope or procedures which, if not resolved to the satisfaction of Ernst & Young LLP, would have caused Ernst & Young LLP to make reference to the matter in their report.

On July 23, 2001, pursuant to authorization of our board of directors, we engaged Grant Thornton LLP as our independent certified public accountants to audit our financial statements for the year ended June 30, 2001. During our fiscal years ended June 30, 1999 and 2000 and any subsequent interim period prior to engaging the new accountants, we did not consult with the



## Edgar Filing: BIOENVISION INC - Form SB-2

newly engaged accountants regarding any of the matters described in Regulation S-K Item 304(a)(2)(i) or (ii).

### MANAGEMENT

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

Name of Individual -----	Age ---	Position with Bioenvision and Subsidiaries -----
Christopher B. Wood, M.D.	56	Chairman of the Board and Chief Executive Officer (1)
Thomas Scott Nelson, C.A.	63	Chief Financial Officer and Director (1), (2)
Stuart Smith, Ph.D.	41	Senior Vice President and Secretary
David P. Luci	35	Director of Finance and General Counsel
Jeffrey B. Davis	39	Director
Steven A. Elms	38	Director
Andrew Schiff, M.D.	36	Director

- (1) Member of Compensation Committee  
 (2) Member of Audit Committee

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

Thomas Scott Nelson has served as our Chief Financial Officer since May 1998. From 1996 to 1999, Mr. Nelson served as the Director of Finance of the Management Board of the Royal & Sun Alliance Insurance Group. From 1991 to 1996, Mr. Nelson served as Group Finance Director of the Main Board of Sun Alliance Insurance Group. He has served as Chairman of the United Kingdom insurance industry committee on European regulatory, fiscal and accounting issues. He has also worked with Deloitte in Paris and as a consultant with PA Consultants Management. Mr. Nelson is a Member of Institute of Chartered Accountants of Scotland and a Fellow of the Institute of Cost and Management Accountants. Mr. Nelson holds a B.A. degree from Cambridge University.

Stuart Smith, Ph.D. has served as a Senior Vice President since May 1997 and served as a director from May 1997 until February 2002. Dr. Smith has considerable experience in the biotechnology and pharmaceutical fields. From June 1995 to May 1997, he served as Business

Development Manager of CRC Oxford. From July 1994 to June 1995, he served as

## Edgar Filing: BIOENVISION INC - Form SB-2

Marketing Manager (Oncology) of British Biotech Pharmaceuticals Ltd. From March 1992 to June 1994 as International Product Manager (Oncology) of Schering AG in Berlin, Germany. Prior thereto, Dr. Smith worked in the veterinary and public health fields, focusing on animal health research and parasitology. Dr. Smith holds a B.S. degree, with honors, in Biology and a Ph.D. degree in Philosophy from the University of Aberdeen.

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

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

Steven A. Elms was named a director in May 2002. Mr. Elms serves as a Managing Director of the Perseus-Soros BioPharmaceutical Fund. For five years prior to joining Perseus-Soros, Mr. Elms was a Principal in the Life Science Investment Banking group of Hambrecht & Quist (now J.P. Morgan H&Q). During his five years at H&Q, Mr. Elms was involved in over 60 financing and M&A transactions, helping clients raise in excess of \$3.3 billion of capital. Mr. Elms serves on a number of boards of private companies. He holds a B.A. in Human Biology from Stanford University and an M.B.A. from Northwestern University's Kellogg Graduate School of Management.

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

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

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

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

## Edgar Filing: BIOENVISION INC - Form SB-2

### SCIENTIFIC COMMITTEE

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

The current members of our Scientific Advisory Board and their primary professional or academic affiliations and qualifications are listed below.

Professor Emilio Montserrat is currently Professor of Oncology at the University of Barcelona. Professor Montserrat is a world-renowned expert in the management of blood disorders and is a member of several leading international scientific committees.

Nagy Habib, M.D., Ph.D. is currently Senior Lecturer in Surgery at the Royal Postgraduate Medical School, London. Dr. Habib has one of the largest liver resection practices in Europe and has pioneered a number of techniques in liver surgery. He has discovered a putative tumor suppressor gene in primary liver cancer and was the first to perform clinical trials of gene therapy in patients with liver cancer. Dr. Habib has published over 150 manuscripts and has presented over 250 papers at scientific meetings.

Michael Keating MD is a leading oncology specialist at the world-renowned MD Anderson Cancer Center in Houston, Texas.

Professor Cecilia Saccone, B.Sc. is Professor of Molecular Biology at the University of Bari, Italy and visiting Professor at the University of California at Berkeley. She is a member of the Advisory Committee of the European Bioinformatics Institute and is a member of the editorial boards of several leading peer-reviewed molecular biology journals.

Professor Wafik El-Deiry, M.D., Ph.D. is Assistant Professor of Medicine and Genetics at the Howard Hughes Medical Institute, University of Pennsylvania. Prior thereto, Dr. El-Deiry was Assistant Professor of Medicine and Director of the Laboratory of Molecular Oncology at the University of Pennsylvania School of Medicine. He has published extensively in the field of molecular biology and tumor suppressor genes.

Professor Anthony Davies, Ph.D., D.Sc. was formerly University of London Professor of Immunobiology at the Institute of Cancer Research, London. Dr. Davies has written extensively on cancer related topics, especially targeted chemotherapy. He received a Ph.D. degree from the University of Manchester and a D.Sc. degree from London University.

Professor Daniel Jaeck, M.D. is Professor of Surgery at the University of Strasbourg, France. Dr. Jaeck is one of the leading experts in the field of tissue transplantation and has published extensively on the subject.

## Edgar Filing: BIOENVISION INC - Form SB-2

Chief Medical Consultant

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

### EXECUTIVE COMPENSATION

The following table sets forth information for each of the fiscal years ended June 30, 2001, 2000 and 1999 concerning the compensation paid and awarded to all individuals serving as (a) our chief executive officer, (b) each of our four other most highly compensated executive officers (other than our chief executive officer) at the end of our fiscal year ended June 30, 2001 whose total annual salary and bonus exceeded \$100,000 for these periods, and (c) up to two additional individuals, if any, for whom disclosure would have been provided pursuant to (b) except that the individual(s) were not serving as our executive officers at the end of our fiscal year ended June 30, 2001:

Summary Compensation Table

Name & Principal Position	Year	Annual Compensation			Restricted Stock Awards	Long- Term Securi- ties underl- ying options
		Salary	Bonus	Other Annual Compensation		
		\$	\$	\$	\$	
Christopher B. Wood (3)	2001	180,000				
	2000	180,000				
	1999	180,000	(1)	(2)		
Stuart Smith (4)	2001	150,000				
	2000	150,000				
	1999	150,000	(1)	(2)		

(1) Salaries through January 4, 1999 were accrued by Eurobiotech Group, Inc., a wholly-owned subsidiary of Bioenvision.

50

(2) Accrued by Eurobiotech Group.

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

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

Stock Options

## Edgar Filing: BIOENVISION INC - Form SB-2

Our board of directors adopted our 2001 Stock Option Plan effective on April 30, 2001. The purpose of the option plan is to increase the employees', advisors', consultants' and non-employee directors' proprietary interest in us and to align more closely their interests with the interests of our stockholders. The purpose of the option plan is also to enable us to attract and retain the services of experienced and highly qualified employees and non-employee directors.

We reserved an aggregate of 5,104,544 shares of common stock for issuance pursuant to options granted under the 2001 Stock Option Plan. As of September 28, 2001 options to purchase an aggregate of 5,104,544 shares of our common stock have been granted under the 2001 Stock Option Plan. The board of directors or a committee of the board of directors (the Compensation Committee) will administer the Plan including, without limitation, the selection of the persons who will be granted options under the Plan, the type of options to be granted, the number of shares subject to each option and the option price.

Options granted under the option plan may either be options qualifying as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or options that do not so qualify (or are not intended to so qualify). Officers, directors and key employees of and consultants to us and our subsidiaries will be eligible to receive non-qualified options under the plan. Only our officers, directors and employees who are employed by us or by any of our subsidiaries as "common law employees" are eligible to receive incentive options. In addition, the option plan also allows for the inclusion of a "reload option" provision, which permits an eligible person to pay the exercise price of the option, and any withholding taxes that may be due on the exercise, with shares of common stock owned by the eligible person and to receive a new option to purchase shares of common stock equal in number to the tendered shares. Any incentive option granted under the option plan must provide for an exercise price of not less than 100% of the fair market value of the underlying shares on the date of such grant, but the exercise price of any incentive option granted to an eligible employee owning more than 10% of the total combined voting power of all classes of our common stock or the common stock of any of our subsidiary companies must be at least 110% of such fair market value as determined on the date of the grant.

The term of each option and the manner in which it may be exercised is determined by the board of directors or a committee, provided that no incentive stock option may be exercisable more than three years after the date of its grant. The exercise price of non-qualified options shall be determined by the board of directors or a committee.

The per share purchase price of shares subject to options granted under the option plan may be adjusted in the event of certain changes in our capitalization, but any such adjustment

shall not change the total purchase price payable upon the exercise in full of options granted under the option plan.

Incentive stock options are non-assignable and non-transferable, except by will or by the laws of descent and distribution and, during the lifetime of the optionee, may be exercised only by such optionee. Non-qualified options may be assignable to the optionee's spouse or children. If an optionee's employment is terminated for cause or without the approval of a committee of the board of directors (other than due to his death or disability), or if an optionee is not

## Edgar Filing: BIOENVISION INC - Form SB-2

our employee but is a member of our board of directors and his service as a director is terminated for cause, the option granted will be immediately forfeited. If the optionee's employment is terminated for any other reason, option(s) granted to him may be exercised to the extent provided in the agreement pursuant to which the option(s) were granted; provided, however, that incentive stock options must be exercised no later than three months after the optionee's termination of employment (other than due to death) and, if the optionee is permanently and totally disabled within the meaning of Section 22(c)(3) of the Code, the incentive stock options granted to him lapse to the extent unexercised on the earlier of the expiration date of the option or one year following the date of the disability.

The board of directors or a committee may amend, suspend or terminate the option plan at any time, except that no amendment will be made which:

- o increases the total number of shares subject to the plan or changes the minimum purchase price therefor (except in either case in the event of adjustments due to changes in our capitalization);
- o without the consent of the optionee, affects outstanding options or any exercise right thereunder;
- o extends the term of any option beyond ten years; or
- o extends the termination date of the option plan.

Unless the option plan is earlier suspended or terminated by the board of directors, the option plan will terminate on the third anniversary of the option plan's adoption by the board of directors. This termination of the option plan will not affect the validity of any options previously granted under the option plan.

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

52

### Option/SAR Grants in Last Fiscal Year [Individual Grants]

Name	Number of securities underlying options/ SARs granted (#)	Percent of total options/SARs granted to employees in fiscal year	Exercise or b price (\$/Shar
-----	-----	-----	-----
Christopher B. Wood	1,500,000 option shares	68.2%	\$1.25
Stuart Smith	500,000 option shares	22.7%	\$1.25

\* These options have been extended to April 30, 2006.

## Edgar Filing: BIOENVISION INC - Form SB-2

There were no options/SARs exercised in our fiscal year ended June 30, 2001 by the named executive officers.

### Employment Agreements

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

On September 1, 1999, we entered into an employment agreement with Christopher B. Wood, M.D. under which he serves as Chairman and Chief Executive Officer. The initial term of Dr. Wood's employment agreement is two years, with automatic one-year extensions thereafter unless either party gives written notice to the contrary. Dr. Wood's agreement provides for an initial base salary of \$180,000, a bonus as determined by the board of directors, life insurance benefits equal to his annual salary, health insurance and other benefits currently or in the future provided to our key employees. If Dr. Wood's employment is terminated for cause or if he terminates his employment for good reason, he will receive a lump sum payment in an amount equal to his then current annual base salary plus his average annual bonus for the preceding two years.

On January 1, 2000, we entered into an employment agreement with Stuart Smith under which he serves as our Senior Vice President. The initial term of Mr. Smith's employment agreement is two years, with automatic one-year extensions thereafter unless either party gives written notice to the contrary. Mr. Smith's agreement provides for an initial base salary of \$150,000, a bonus as determined by the board of directors, life insurance benefits equal to his annual salary, health insurance and other benefits currently or in the future provided to our key employees. If Mr. Smith's employment is terminated for cause or if he terminates his employment for good reason, he will receive a lump sum payment in an amount equal to his then current annual base salary plus his average annual bonus for the preceding two years.

### Director Compensation

Our non-management directors each receive a director's fee of \$1,000 per meeting for attendance at board of director's meetings, and are reimbursed for actual expenses incurred in respect of such attendance. We do not separately compensate employees for serving as directors.

53

We do not provide additional compensation for committee participation or special assignments of the board of directors.

### DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

#### Indemnification

The indemnification of officers and directors of the Registrant is

## Edgar Filing: BIOENVISION INC - Form SB-2

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

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

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

determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the applicable standard of conduct has been met by the party to be indemnified. Such determination must be made, with respect to a person who is a director or officer at the time of such determination, (1) by a majority vote of the directors who are no parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a 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)



## Edgar Filing: BIOENVISION INC - Form SB-2

by the stockholders. The statute authorizes the corporation to pay expenses incurred by an officer or director in advance of the final disposition of a proceeding upon receipt of an undertaking by or on behalf of the person to whom the advance will be made, to repay the advances if it shall ultimately be determined that he was not entitled to indemnification. DGCL Section 145 also provides that indemnification and advancement of expenses permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain liability insurance on behalf of its directors, officers, employees and agents regardless of whether the corporation would have the statutory power to indemnify such persons against the liabilities insured.

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

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

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

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

55

payment of dividends; or (4) any transaction in which the director received an improper personal benefit.

### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In May 1998, Bioheal Limited, one of our subsidiaries, entered into an agreement with Christopher B. Wood, our Chairman of the Board and Chief Executive Officer, to co-develop a gene marker and immunomodulator system for use in gene therapy and related technologies. Under the terms of the agreement, Bioheal was granted the exclusive license to make, use and sell products derived from technology, and to utilize technical information related to the technology

## Edgar Filing: BIOENVISION INC - Form SB-2

to obtain patent and other proprietary rights to products developed by Bioheal and its collaborators from the technology for a term expiring on the date of expiration of all current and future patents covered by the agreement, subject to earlier termination under certain circumstances. In consideration of the licenses granted to Bioheal, Bioheal agreed to pay to Dr. Wood, among other things, a royalty of 10% of the gross sales revenues of all products, less any discounts or deductions for value-added taxes. In addition, Bioheal has agreed to pay, among other things, certain costs associated with pre-clinical development and clinical trials of such products. Under the terms of the agreement, the pre-clinical costs are not to exceed \$1,500,000, and the clinical trial costs are not to exceed \$4,000,000, unless agreed by both parties.

In November 2000, we issued 272,500 shares of common stock valued at approximately \$1.00 per share to various consultants for work performed for and our behalf. The shares were issued to Andrew Turner (112,500), David Chester (112,500) and Shane Sutton (47,500).

In April 2001, we issued 5,104,544 options at an exercise price of \$1.25. The initial terms of the options are that each option can be exercised after April 30, 2001 for a period of three years, but were extended to five years.

Of these options, management were issued the following options:

Christopher Wood	1,500,000 options
Stuart Smith	500,000 options
Thomas Nelson	200,000 options

In April 2000, we received a \$2,000,000 equity investment from Bioaccelerate in exchange for the issuance of 727,272 shares of our common stock at a price of \$2.75 per share. The investment agreement, dated March 21, 2000, granted to Bioaccelerate the option to purchase two further tranches of 727,272 common shares each, also at a price of \$2.75 per share, upon achievement of certain specified milestones. We entered into the superceding arrangement with Bioaccelerate on April 30, 2001, to replace the outstanding option and eliminate the additional options in exchange for the new three-year option to purchase 1,454,544 shares at \$1.25 per share and amending certain other provisions of the investment agreement.

In April 2001, we granted to Phoenix Ventures 500,000 options to purchase shares of our common stock at an exercise price of \$1.25 per share. The options were issued in connection with a credit facility made available to us by Glen Investments Limited, a Jersey (Channel

56

Islands) corporation wholly owned by Kevin R. Leech, a United Kingdom citizen and one of our shareholders, which facility was terminated in August 2001.

As of June 30, 2000, our financial advisors held 342,468 shares of our common stock, which were issued in exchange for financial planning services rendered. These services are reflected in the statement of operations as administrative expense. They are valued at \$0.13 to \$0.67 per share, which reflected the most recent transaction for shares.

In May 2001, certain officers agreed to convert \$910,681 of the outstanding deferred salaries into 705,954 shares of common stock.

In August 2001, we issued 208,333 shares at the rate of \$1.25 per share

## Edgar Filing: BIOENVISION INC - Form SB-2

as follows: Christopher Wood, 98,684 shares; Thomas Nelson, 27,412 shares; and Stuart Smith, 82,237 shares.

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

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

On November 16, 2001, we entered into an engagement letter with SCO Capital, pursuant to which SCO would act as our financial advisor. In connection with the engagement letter, we issued a warrant to purchase 100,000 shares of common stock at an exercise price of \$1.25 per share, subject to certain anti-dilution adjustment.

In connection with securing the facility with SCO Capital, we issued warrants to purchase 1,500,000 shares of our common stock at a strike price of \$1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance.

Additional warrants to acquire 1,500,000 shares with similar terms were also granted to SCO Capital. The warrants expire on February 16, 2002 and can be exercised only if we failed to complete the acquisition of Pathagon, Inc. On February 5, 2002 we announced that we completed the acquisition of Pathagon. On February 1, 2002 we issued 7,000,000 shares of common stock related to the acquisition of Pathagon, Inc.

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of common stock, as of June 30, 2002, by (i) each person whom we know to beneficially own 5% or more of the common stock, (ii) each of our directors, (iii) each person listed on the Summary Compensation Table set forth under "Executive Compensation" and (iv) all of our directors and executive officers. The number of shares of common stock beneficially owned by each stockholder is determined in accordance with the rules of the Commission and does not necessarily indicate beneficial ownership for any other purpose. Under these rules, beneficial

57

ownership includes those shares of common stock over which the stockholder exercises sole or shared voting or investment power. The percentage ownership of the common stock, however, is based on the assumption, expressly required by the rules of the Commission, that only the person or entity whose ownership is being reported has converted or exercised common stock equivalents into shares of common stock; that is, shares underlying common stock equivalents are not included in calculations in the table below for any other purpose, including for the purpose of calculating the number of shares outstanding generally. The table below does not reflect the right of Ilex to purchase from us \$1.0 million of our common stock at the then applicable market price within 30 days of the completion of the Phase II trial, and an additional \$2.0 million of our common stock at the then applicable market price within 30 days of submittal to the FDA of the NDA for clofarabine.

Edgar Filing: BIOENVISION INC - Form SB-2

Name -----	Beneficial Ownership of Stock -----	Curre of --
Perseus-Soros Biopharmaceutical Fund, LP (2) 888 Seventh Avenue, 29th Floor New York, New York 10106.....	9,000,000	
OrbiMed Advisors Inc. (3) 767 Third Avenue, 30th Floor New York, New York 10017.....	3,000,000	
Merlin Biomed Private Equity Fund LP (4) 230 Park Avenue, Suite 928 New York, New York 10169.....	1,000,002	
DWS Investment GmbH (5) Gruneburgweg M3-M5 60323 Frankfurt Germany.....	1,299,999	
SCO Capital Partners LLC (6) 1285 Avenue of the Americas, 35th Floor New York, New York 10019.....	7,479,946	
Kevin Leech (7) The Old Chapel Sacre Couer Rouge Boullion St Helier Jersey, Channel Islands.....	1,900,000	
Lifescience Ventures Limited (8) Suite F8 International Commercial Centre Gibraltar.....	887,500	

Name -----	Beneficial Ownership of Stock -----	Curre of --
Estate of David Chester (9).....	887,500	
Bioaccelerate, Inc. (10) PO Box 3175 Road Town Tortolla British Virgin Islands.....	2,181,816	
Christopher B. Wood, M.D. (11) One Rockefeller Plaza Suite 1600		

Edgar Filing: BIOENVISION INC - Form SB-2

New York, New York 10020.....	3,957,342
Stuart Smith (12) One Rockefeller Plaza Suite 1600 New York, New York 10020.....	840,895
Thomas Scott Nelson (13) One Rockefeller Plaza Suite 1600 New York, New York 10020.....	287,523
Jeffrey B. Davis (14) 1285 Avenue of the Americas, 35th Floor New York, New York 10019.....	749,243
Steven A. Elms 888 Seventh Avenue, 29th Floor New York, New York 10106.....	0
Andrew Schiff, M.D. 888 Seventh Avenue, 29th Floor New York, New York 10106.....	0
All Executive Officers and Directors as a group (seven persons) (15).....	5,835,003

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

- (1) Based on a total of 16,887,786 shares of common stock outstanding as of June 30, 2002.
- (2) Includes 3,000,000 shares of Series A Preferred Stock currently convertible into 6,000,000 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 3,000,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Based upon information contained in its report on Schedule 13D filed with the Commission on May 20, 2002, Perseus-Soros BioPharmaceutical Fund, L.P. reported that Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners may be deemed to have sole power to direct the voting and disposition of the 9,000,000 shares of common stock. By virtue of the relationships between and among Perseus-Soros BioPharmaceutical Fund, L.P., Perseus-Soros Partners, LLC, Perseus BioTech Fund Partners, LLC, SFM Participation, L.P., SFM AH, Inc., Frank H. Pearl, George Soros, Soros Fund Management LLC, Perseus EC, LLC, Perseuspur, LLC, each of such entities, other than Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners, may be deemed to share the power to direct the voting and disposition of the 9,000,000 shares of common stock.
- (3) Includes 669,964 shares of Series A Preferred Stock currently convertible into 1,339,928 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 669,964 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, both of which are held by Caduceus Private Investments, LP; 13,945 shares of Series A Preferred Stock currently convertible into 27,980 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 13,945 shares of common stock

## Edgar Filing: BIOENVISION INC - Form SB-2

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

- (4) Includes 333,334 shares of Series A Preferred Stock currently convertible into 666,668 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 333,334 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Based upon information contained in its report on Schedule 13G filed with the Commission on June 28, 2002, Merlin BioMed Private Equity Fund, L.P. reported that it shares the power to direct the voting and disposition of the 1,000,002 shares of common stock with Merlin BioMed Private Equity, LLC, its general partner and Dominique Semon, who is the sole managing member of the general partner.
- (5) Includes 433,333 shares of Series A Preferred Stock currently convertible into 866,666 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 433,333 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002.
- (6) Includes a warrant to purchase 1,200,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001; a warrant to purchase 688,333 shares of

60

common stock exercisable at \$1.50 per share for five years from May 8, 2002; a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share Financial Group LLC for five years from November 16, 2001 held by SCO; a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 held by SCO Financial Group LLC; a warrant to purchase 150,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 held by the Sophie C. Rouhandeh Trust; and a warrant to purchase 150,000 shares of common stock exercisable at \$1.25 per share for five years from November 16, 2001 held by the Chloe H. Rouhandeh Trust. Steven H. Rouhandeh, in his capacity as President of SCO Capital Partners LLC and trustee of the trusts, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.

- (7) These shares are owned of record by Phoenix Ventures Limited, a Channel Islands (Jersey) corporation, which, to our knowledge, is wholly-owned by Kevin Leech. These shares include 500,000 options which are exercisable at \$1.25 per share for the benefit of Phoenix.
- (8) Lifescience Ventures is a Gibraltar limited company owned of record by a Gibraltar trust. Lee J. Cole, in his capacity as the trustee of the trust, has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.
- (9) These shares are owned of record by General Capital Limited, a Bermuda corporation which, to our knowledge, is wholly-owned by the Estate of David

## Edgar Filing: BIOENVISION INC - Form SB-2

Chester, a private investor.

- (10) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors and includes options to acquire 1,454,544 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001. Barbara Platts, in her capacity as Managing Director of Bioaccelerate, Inc., has investment power and voting power with respect to these shares, but disclaims any beneficial ownership thereof.
- (11) Includes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest, and 1,500,000 options which are exercisable at \$1.25 for five years from April 30, 2001.
- (12) Includes options to acquire 500,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (13) Includes options to acquire 200,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (14) 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.
- (15) Includes shares of common stock owned by Christopher B. Wood, Stuart Smith, David Luci, Thomas Nelson, Jeffrey Davis, Steven A. Elms and Andrew Schiff, M.D. Also includes (a) 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr.

61

Wood disclaims any beneficial interest, (b) Christopher Wood's options to acquire 1,500,000 shares of common stock, (c) Stuart Smith's options to acquire 500,000 shares of common stock, (d) Thomas Nelson's options to acquire 100,000 shares of common stock and (e) Jeffrey B. Davis's warrant to purchase 250,000 shares of common stock.

### 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 16,887,786 shares were outstanding on June 30, 2002. 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 in excess of 50% of the aggregate number of shares of common stock outstanding will be able to elect all of our directors and to approve or disapprove any other matter submitted to a vote of all stockholders.

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

## Edgar Filing: BIOENVISION INC - Form SB-2

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. Shares of preferred stock will be registered on our books. We currently anticipate that the preferred stock will not be registered with the SEC pursuant to the Exchange Act. 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.

We have designated 5,920,000 shares of our preferred stock as Series A convertible preferred stock, of which 5,916,666 shares were issued and outstanding as of May 31, 2002. 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 on which the holders of the common stock are entitled to

62

vote. Each outstanding share of Series A convertible preferred stock may currently be converted into two shares of common stock, at the conversion price of \$1.50 per share. The shares of Series A convertible preferred stock shall be automatically convertible into shares of common stock if the market price of the common stock after one year from the date of issuance is \$10.00 or more for 30 consecutive trading days and the trading volume is at least 150,000 shares per trading day during such 30-day period. Holders of Series A convertible preferred stock have a liquidation preference over holders of common stock of \$3.00 per share. Holders of the Series A preferred stock receive an annual 8% dividend which may be paid in cash or additional shares of common stock in our sole discretion.

### Warrants

As of June 30, 2002, 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 June 30, 2002, there were outstanding options to purchase an aggregate of 5,104,544 shares of our common stock at exercise prices of \$1.25 per share, of which, options to purchase 5,104,544 shares were exercisable.

### Transfer Agent

Our transfer agent is Liberty Transfer Company, Inc., 274B New York Avenue, Huntington, New York 11743.



## Edgar Filing: BIOENVISION INC - Form SB-2

### SELLING STOCKHOLDERS

The following table details the name of each selling stockholder, the number of shares owned by each selling stockholder and the number of shares that may be offered for resale under this prospectus. To the extent permitted by law, the selling stockholders which are not natural persons may distribute shares, from time to time, to one or more of their respective affiliates, which may sell shares pursuant to this prospectus. We have registered the shares to permit the selling stockholders and their respective permitted transferees or other successors in interest that receive their shares from the selling stockholders after the date of this prospectus to resell the shares. Because each selling stockholder may offer all, some or none of the shares it holds, and because there are currently no agreements, arrangements, or understandings with respect to the sale of any of the shares, no definitive estimate as to the number of shares that will be held by each selling stockholder after the offering can be provided. The selling stockholders may from time to time offer all or some of the shares pursuant to this offering. Pursuant to Rule 416 under the securities act, the registration statement of which this prospectus is a part also covers any additional shares of our common stock which becomes issuable in connection with such shares because of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of outstanding shares of our common stock. The following table has been prepared on the assumption that all

63

shares offered under this prospectus will be sold to parties unaffiliated with the selling stockholders. Except as indicated by footnote, none of the selling stockholders has had a significant relationship with us within the past three years, other than as a result of the ownership of our shares or other securities. Except as indicated by footnote, the selling stockholders have sole voting and investment power with their respective shares. Percentages in the table below are based on 16,887,786 shares of our common stock outstanding as of June 30, 2002.

Name -----	Shares Owned Prior to the Offering		Number of Shares Which May be Sold in	Num -----
	Number -----	Percent -----	This Offering -----	
Perseus-Soros BioPharmaceutical Fund, LP (1)	9,000,000	34.77	9,000,000	-
Caduceus Private Investments, LP (2)	2,009,892	10.64	2,009,892	-
OrbiMed Associates LLC (2)	41,835	*	41,835	-
PW Juniper Crossover Fund, L.L.C. (2)	948,273	5.32	948,273	-
Special Situations Private Equity Fund, L.P. (3)	750,000	4.25	750,000	-
Xmark Fund, L.P. (4)	144,999	*	144,999	-
Xmark Fund, Ltd. (5)	354,999	2.06	354,999	-
SDS Merchant Fund, LP (6)	500,001	2.88	500,001	-
Orion Biomedical Offshore	133,875	*	133,875	-

Edgar Filing: BIOENVISION INC - Form SB-2

Fund, LP (7)				
Orion Biomedical Fund, LP (8)	616,125	3.52	616,125	
Beaver Ltd. (9)	75,000	*	75,000	
CKH Invest Aps. (10)	50,001	*	50,001	
Merlin Biomed Private Equity Fund LP (11)	1,000,002	5.59	1,000,002	
Palladin Opportunity Fund LLC (12)	499,998	2.88	499,998	
DWS Investment GmbH (13)	1,299,999	7.15	1,299,999	
Michael Sistenich (14)	125,001	*	125,001	
Global Biotechnology Fund (15)	199,998	1.17	199,998	
Oklahoma Medical Research Foundation (16)	400,000	2.34	400,000	
Christopher B. Wood (17)	3,638,592	19.79	3,638,592	
Julie Wood (17)	318,750	1.89	318,750	
Stuart Smith (18)	840,895	4.84	840,895	
Thomas Nelson (19)	287,523	1.68	287,523	
Phoenix Ventures Limited (20)	1,900,000	10.93	500,000	1,400,000
Bioaccelerate, Inc. (21)	2,181,816	11.89	1,454,544	727,272
Jano Holdings, Ltd. (22)	250,000	1.46	250,000	
G. Margetts (23)	100,000	*	100,000	
N. Habib (24)	50,000	*	50,000	

64

Name	Shares Owned Prior to the Offering		Number of Shares Which May be Sold in This Offering	Num
	Number	Percent		
RLB Capital Limited (25)	100,000	*	100,000	
NAB Holdings Ltd. (26)	450,000	2.60	450,000	
SCO Capital Partners LLC (27), (29)	7,009,946	37.33	7,009,946	
SCO Financial Group LLC (27), (29)	170,000	*	170,000	
The Sophie C. Rouhandeh Trust (27)	150,000	*	150,000	
The Chloe H. Rouhandeh Trust (27)	150,000	*	150,000	
Jeffrey B. Davis (28), (29)	749,243	4.37	749,243	
Benefit Capital Management Corp. (29)	292,582	1.73	292,582	
David Bernstein (29)	282,900	1.68	282,900	
Eugene Zurlo (29)	282,900	1.68	282,900	
Hoegh Invest A/S (29)	29,258	*	29,258	
Robert J. Donohoe (29)	282,900	1.68	282,900	
Al-Mandani Investment (29)	14,629	*	14,629	
Community Investment Partners (29)	2,560	*	2,560	
Fredrick C. Schreuder (29)	10,533	*	10,533	
Oakwood Investors I, LLC (29)	10,240	*	10,240	
Gutrafin, Ltd. (29)	14,629	*	14,629	
Edward W. Kelly (29), (30)	356,013	*	356,013	

## Edgar Filing: BIOENVISION INC - Form SB-2

Paul Scharfer (31), (32)	115,000	*	115,000
David Bartash (33)	10,000	*	10,000
Preston Tsao (30), (34)	50,000	*	50,000
Total	38,250,907		36,123,635

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

- (1) See Note (2) to the table of Security Ownership of Certain Beneficial Owners and Management. After the company's May 2002 financing, Perseus-Soros named two individuals to the company's board of directors.
- (2) See Note (3) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (3) Includes 250,000 shares of Series A Preferred Stock currently convertible into 500,000 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 250,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.

65

- (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 166,667 shares of Series A Preferred Stock currently convertible into 333,334 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) See Note (4) to the table of Security Ownership of Certain Beneficial Owners and Management.

## Edgar Filing: BIOENVISION INC - Form SB-2

- (12) Includes 166,666 shares of Series A Preferred Stock currently convertible into 499,998 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 16,666 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (13) See Note (5) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (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 and a five-year warrant to purchase

66

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) See Note (11) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (18) See Note (12) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (19) See Note (13) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (20) See Note (7) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (21) See Note (10) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (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 100,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (26) Includes an option to purchase 450,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (27) SCO Financial Group LLC serves as financial advisor to the company. SCO

## Edgar Filing: BIOENVISION INC - Form SB-2

Capital Partners LLC extended a \$1 million secured credit line to the company in November 2001. SCO Securities LLC, a related entity, served as placement agent in the company's May 2002 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 individuals to the company's board of directors. See "Certain Relationships and Related Transactions." See also Note (6) to the table of Security Ownership of Certain Beneficial Owners and Management.

- (28) See Note (14) to the table of Security Ownership of Certain Beneficial Owners and Management.
- (29) Indicates the selling stockholder was a former stockholder of Pathagon.

67

- (30) Mr. Kelly has executed a consulting agreement with us pursuant to which we will issue to him 200,000 shares of common stock which will vest over an eighteen month period.
- (31) Indicates the selling stockholder is a current employee of SCO Financial Group LLC.
- (32) Includes a warrant to purchase 115,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002.
- (33) Includes a warrant to purchase 10,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002.
- (34) Includes a warrant to purchase 50,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002.

### 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 OTC Bulletin Board 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;

## Edgar Filing: BIOENVISION INC - Form SB-2

- o purchases by a broker or dealer as principal and resale by the broker or dealer for its account pursuant to this prospectus;
- o ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- o in public or privately-negotiated transactions;
- o through the writing of options on the shares;

68

- o 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
- 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.

## Edgar Filing: BIOENVISION INC - Form SB-2

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

69

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;

## Edgar Filing: BIOENVISION INC - Form SB-2

- 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;

70

- o any discount, commission or concession allowed or reallocated or paid to any dealer;
- o the proposed selling price to the public; and
- o other facts material to the transaction.

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

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

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

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

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

### 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 Piper Rudnick LLP, New York, New York.

### EXPERTS



## Edgar Filing: BIOENVISION INC - Form SB-2

Our auditors are Grant Thornton LLP. Our consolidated financial statements as at and for the year ended June 30, 2001 have been included in this prospectus and in the registration statement in reliance upon the report of Grant Thornton LLP, and upon the authority of Grant Thornton LLP as experts in accounting and auditing.

71

Ernst & Young LLP, independent auditors, have audited our consolidated financial statements for the year ended June 30, 2000 and for the period from August 16, 1996 (inception) through June 30, 2000 included in the cumulative period from August 16, 1996 to June 30, 2001, as set forth in their report. We have included these financial statements in the prospectus in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

### WHERE YOU CAN GET MORE INFORMATION

This prospectus is part of a registration statement on Form SB-2 that we are filing with the SEC. Certain information in the registration statement has been omitted from this prospectus in accordance with the rules of the SEC.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our File Number is 000-24875.

You may read and copy materials that we have filed with the SEC, including the registration statement, at the following SEC public reference rooms:

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

Copies of such material, when filed, may also be obtained from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549 at prescribed rates. You may call the SEC at 1-800-732-0330 for further information about the public reference room. We are also required to file electronic versions of these documents with the SEC, which may be accessed through the SEC's web site at <http://www.sec.gov>.

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.

72

### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

BIOENVISION, INC. - as of June 30, 2001 and for the years ended June 30, 2001 and 2000

## Edgar Filing: BIOENVISION INC - Form SB-2

Report of Independent Certified Public Accountants.....	F-2
Report of Independent Auditors.....	F-3
Consolidated Balance Sheet as of June 30, 2001.....	F-4
Consolidated Statements of Operations for the years ended June 30, 2001 and 2000 and the period from August 16, 1996 (inception) to June 30, 2001.....	F-5
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2001 and 2000 and the period from August 16, 1996 (inception) to June 30, 2001.....	F-6
Consolidated Statements of Cash Flows for the years ended June 30, 2001 and 2000 and the period from August 16, 1996 (inception) to June 30, 2001.....	F-8
Notes to Consolidated Financial Statements for the year ended June 30, 2001.....	F-9
BIOENVISION, INC. - as of March 31, 2002 and for the nine months ended March 31, 2002 and 2001 (Unaudited)	
Consolidated Statements of Operations for the nine months ended March 31, 2002 and 2001 and the period from August 16, 1996 (inception) to March 31, 2002.....	F-16
Consolidated Balance Sheet as of March 31, 2002.....	F-17
Consolidated Statements of Cash Flows for the nine months ended March 31, 2002 and 2001 and the period from August 16, 1996 (inception) to March 31, 2002.....	F-18
Notes to Consolidated Financial Statements for the nine months ended March 31, 2002.....	F-19
BRIDGE BLOOD TECHNOLOGIES, L.L.C. - as of and for the years ended December 31, 2001 and 2000	
Report of Independent Auditors.....	F-25
Report of Independent Auditors.....	F-26
Balance Sheet as of December 31, 2001.....	F-27
Statement of Operations and Member's Equity (Deficiency) for the year ended December 31, 2001.....	F-28
Statement of Cash Flows for the year ended December 31, 2001.....	F-29
Schedule of Expenses for the year ended December 31, 2001.....	F-30
Notes to Financial Statements.....	F-31
Balance Sheet as of December 31, 2000.....	F-32
Statement of Operations and Member's Equity (Deficiency) for the year ended December 31, 2000.....	F-33
Statement of Cash Flows for the year ended December 31, 2000.....	F-34

Edgar Filing: BIOENVISION INC - Form SB-2

Schedule of Expenses for the year ended December 31, 2000..... F-35  
Notes to Financial Statements..... F-36  
PRO FORMA FINANCIAL INFORMATION..... F-37

F-1

REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors and Stockholders of  
Bioenvision, Inc.

We have audited the accompanying consolidated balance sheet of Bioenvision, Inc. (a development stage Company) as of June 30, 2001, and the related consolidated statements of operations, stockholders' equity (deficiency), and cash flows for the year then ended and the 2001 amounts included in the cumulative period from August 16, 1996 (inception) through June 30, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Bioenvision, Inc. and subsidiaries as of June 30, 2001, and the results of their operations and their cash flows for the year then ended and the 2001 amounts included in the cumulative period from August 16, 1996 (inception) through June 30, 2001 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has sustained losses and negative cash flows from operations since inception, and the Company's ability to obtain future financing is uncertain. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 1. The financial statements do not include any adjustments to the recoverability and classifications of asset carrying amounts or the amount and classification of liabilities that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

GRANT THORNTON LLP  
New York, New York

Edgar Filing: BIOENVISION INC - Form SB-2

October 11, 2001

F-2

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders  
Bioenvision, Inc. (a development stage company)

We have audited the accompanying consolidated statements of operations, stockholders' equity (deficit), and cash flows of Bioenvision, Inc. (a development stage company) for the year ended June 30, 2000 and for the period from August 16, 1996 (inception) through June 30, 2000 included in the cumulative period from August 16, 1996 to June 30, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and consolidated cash flows of Bioenvision, Inc. (a development stage company) for the year ended June 30, 2000 and for the period from August 16, 1996 (inception) to June 30, 2000, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 of notes to the consolidated financial statements, the Company's recurring losses from operations, working capital deficit and stockholder's deficit raise substantial doubt about its ability to continue as a going concern. Management's plans as to this matter are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young

ERNST & YOUNG

November 9, 2000  
Reading, England

F-3

Edgar Filing: BIOENVISION INC - Form SB-2

Bioenvision, Inc..  
 (A Development Stage company)  
 -----

CONSOLIDATED BALANCE SHEET

	June 30, 2001
	-----
ASSETS	
Current assets:	
Deferred costs	\$ 337,500
	-----
Total current assets	337,500
Property, plant and equipment, net	18,097
Other assets:	
Intangible assets, net	15,698
Deferred costs	184,091
Deferred financing costs	207,500
	-----
	\$ 762,885
	=====
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current liabilities:	
Bank overdraft	\$ 127,241
Accounts payable	785,134
Other accrued liabilities	317,799
Deferred revenue	736,364
	-----
Total current liabilities	1,966,538
Long term liabilities:	
Deferred revenue	368,182
Officers' salaries	910,681
	-----
Total long term liabilities	1,278,863
Stockholders' deficit:	
Common stock, \$0.001 par value	8,249
Authorised: 25,000,000 shares	
Issued and outstanding: 8,248,919	
Additional paid in capital	3,165,540
Accumulated other comprehensive income	152,346
Deficit accumulated during development stage	(5,808,651)
	-----
Total stockholders' deficit	(2,482,516)
	-----
	\$ 762,885
	=====

The accompanying footnotes are an integral part of these financial statements.

Edgar Filing: BIOENVISION INC - Form SB-2

Bioenvision, Inc.  
 (A Development Stage company)  
 -----

CONSOLIDATED STATEMENT OF OPERATIONS

	Year ended June 30, 2001	Year ended June 30, 2000	Period from August 16, 1996 (inception through June 30, 2001)
Contract revenue	\$ 245,455	\$ --	\$ 280,970
Costs and expenses:			
Research and development	1,565,908	984,460	2,714,610
General and administrative	550,215	486,627	3,022,290
Interest and finance charges	228,787	12,778	267,640
Depreciation and amortization	22,809	11,644	85,050
Total costs and expenses	2,367,719	1,495,509	6,089,620
Net loss	\$ (2,122,264)	\$ (1,495,509)	\$ (5,808,650)
Basic and diluted net loss per share	(\$0.26)	(\$0.20)	
Weighted average shares used in computing basic and diluted basic and diluted net loss per share	8,121,255	7,430,965	

The accompanying footnotes are an integral part of these financial statements.

F-5

Bioenvision, Inc.  
 (A Development Stage company)  
 -----

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

Deficit

Edgar Filing: BIOENVISION INC - Form SB-2

	Share	Amount	Additional Paid in Capital	Accumulated Int Development Stage	Accumulated Other Comprehensive Income (Loss)	St (
	No.	\$	\$	\$	\$	
Issuance at inception (August 1996)	167,899	5,147	-	-	-	
Issuance of shares in exchange for cash in October 1996	97,348	2,894	26,041	-	-	
Shares issued in November 1996 in exchange for services	71,429	4,780	43,027	-	-	
Shares issued in November 1996 in exchange for cash	21,428	1,433	10,027	-	-	
Shares issued in January 1997 in exchange for services	271,039	3,622	32,579	-	-	
Surrender of 1,050,000 shares of common stock in January 1997	(35,247)	(1,013)	1,013	-	-	
Shares issued in April 1997 on the inception of Biotechnology & Healthcare Ventures Ltd.	3,315,000	6	-	-	-	
Shares issued in April 1997 on the Inception of Eurobiotech Group Inc.	1,375,000	9,833	158,049	-	-	
Net loss for the period	-	-	-	(117,697)	-	
Foreign currency translation adjustment for the period	-	-	-	-	(67,371)	
Comprehensive loss for the period	-	-	-	-	-	
Balance at June 30, 1997	5,283,896	26,702	270,736	(117,697)	(67,371)	
Stock issued on the acquisition of Biomed UK Ltd in May 1998	300,000	3	-	-	-	
Stock issued on the acquisition of Bioheal Ltd on May 1998	535,000	3	-	-	-	
Net loss for the year	-	-	-	(1,259,826)	-	
Foreign currency translation adjustment for the year	-	-	-	-	59,886	
Comprehensive loss for the year	-	-	-	-	-	
Balance at June 30, 1998	6,118,896	26,708	270,736	(1,377,523)	(7,485)	

Edgar Filing: BIOENVISION INC - Form SB-2

Bioenvision, Inc.  
(A Development Stage company)

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock			Deficit	Accumulated	St
	Share	Amount	Additional Paid in Capital	Accumulated Int Development Stage	Other Comprehensive Income (Loss)	(
	-----	-----	-----	-----	-----	-----
Shares issued on the purchase of the minority interest in Eurobiotech Group, Inc. in September 1998	1,125,000	1,212	25,199	-	-	
Issuance of shares in exchange for services in April 1999	5,250	5	9,263	-	-	
Net loss for the year	-	-	-	(813,355)	-	
Foreign currency translation adjustment for the year	-	-	-	-	86,811	
Comprehensive loss for the year	-	-	-	-	-	
Balance as at June 30, 1999	7,249,146	27,925	305,198	(2,190,878)	79,326	
Shares issued in March 2000 in exchange for cash	727,273	727	1,999,273	-	-	
Contribution of rent	-	-	28,665	-	-	
Net loss for the year	-	-	-	(1,495,509)	-	
Foreign currency translation adjustment for the year	-	-	-	-	41,681	
Comprehensive loss for the year	-	-	-	-	-	
Balance as at June 30, 2000	7,976,419	28,652	2,333,136	(3,686,387)	121,007	
Adjustments to par value at beginning of year		(20,676)	20,676			
Common stock issued to consultants	272,500	273	272,228	-	-	
Compensation related to stock options issued to non-employees			124,500			
Finance charge related to stock options issued to Phoenix Ventures			415,000			
Net loss for the year				(2,122,264)		
Foreign currency translation	-	-	-	-	31,339	



Edgar Filing: BIOENVISION INC - Form SB-2

Total comprehensive loss

Balance at June 30, 2001	8,248,919	\$8,249	\$3,165,540	\$(5,808,651)	\$152,346
--------------------------	-----------	---------	-------------	---------------	-----------

The accompanying footnotes are an integral part of these financial statements.

F-7

Bioenvision, Inc.  
(A Development Stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended June 30, 2001	Year ended June 30, 2000	Period from August 16, 1996 (inception) through June 30, 2001
Cash flows from operating activities:			
Net loss	\$ (2,122,264)	\$ (1,495,509)	\$ (5,808,651)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	22,809	11,644	85,058
Financing costs---non-cash	207,500		207,500
Gain on sale of fixed assets	--	(8,228)	(8,228)
Provision of free rent	--	28,665	28,665
Compensation cost for options issued to non-employees	124,500		124,500
Compensation cost for shares issued to non-employees	272,500		365,776
Changes in assets and liabilities, net:			
Accounts receivable	75,695	(78,649)	(11,750)
Deferred costs	(521,589)	--	(521,589)
Deferred revenue	1,104,545	--	1,104,545
Accounts payable	(268,405)	(412,080)	789,216
Officers' salaries for equity conversion	910,681		910,681
Other accrued expenses and liabilities	37,193	--	37,193
Net cash used in operating activities	(156,835)	(1,954,157)	(2,697,084)
Cash flows from investing activities:			
Capital expenditures, net	(1,760)	(51,473)	(165,596)
Proceeds from sale of fixed assets, net	--	63,089	63,089
Purchase of intangible assets	--	--	(24,500)
Net cash (used in) provided by investing activities	(1,760)	11,616	(127,007)
Cash flows from financing activities:			
Bank overdraft	127,241		127,241

Edgar Filing: BIOENVISION INC - Form SB-2

Proceeds from issuance of common stock	--	2,000,000	2,268,512
Other liabilities--related party	--	(57,304)	292,317
		-----	-----
Net cash provided by financing activities	127,241	1,942,696	2,688,070
Effect of exchange rate on cash	31,339	(156)	136,021
		-----	-----
Net decrease in cash and cash equivalents	(15)	(1)	0
Cash and cash equivalents, beginning of period	15	16	0
		-----	-----
Cash and cash equivalents, end of period	\$ 0	\$ 15	\$ 0
	=====	=====	=====
Supplemental disclosure of cash flow information			
Interest paid	\$21,287	\$12,778	\$119,295

The accompanying footnotes are an integral part of these financial statements.

F-8

Bioenvision, Inc.  
(A Development Stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
Year Ended June 30, 2001

1 Organization and significant accounting policies

Description of business

Bioenvision, Inc. ("Bioenvision" or the "Company") is a development stage, biopharmaceutical company primarily focused in the research and development of products and technologies for the treatment of cancer. The Company has acquired development and marketing rights to a portfolio of four platform technologies. These platforms have resulted in the development of the Company's two (2) leading products, Modrenal(R) and clofarabine, as well as 12 other products which are in various stages of development.

The Company was incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed its name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998.

Basis of presentation

In January 1999 the Company merged with Bioenvision, Inc. ('Old Bioenvision') a development stage Company primarily engaged in the research and development of products and technologies for the treatment of cancer. The transaction was accounted for as a reorganization of companies under common control in a manner similar to a pooling of interests as they had a common majority shareholder.

## Edgar Filing: BIOENVISION INC - Form SB-2

In September 1998, Old Bioenvision merged with Eurobiotech Group, Inc., a development stage company involved in the research and development of products and technologies for the treatment of cancer. The transaction was accounted for as a combination of a reorganization of companies under common control in a manner similar to a pooling as they had a common majority shareholder, and the purchase of a minority interest.

In July 1998, Old Bioenvision merged with Biotechnology & Healthcare Ventures, Limited, ('BHV') a development stage company involved in the research and development of products and technologies for the treatment of cancer. The transaction was accounted for as a reorganization of companies under common control in a manner similar to a pooling of interests as they had a common majority shareholder.

BHV acquired Bioheal Limited and Biomed UK Limited in May 1998, both of which are development stage companies involved in the research and development of products and technologies for the treatment of cancer. Both of the transactions were accounted for as purchases and the results of Biomed UK Limited and Bioheal Limited have been included in the financial statements of BHV from the date of acquisition.

Where mergers have been accounted for as reorganizations under common control in a manner similar to a pooling of interests, no fair value have been attributed to any tangible or intangible assets, including technology rights.

### Operations to date and financing plans

The Company has incurred significant losses from operations and is not generating cash from operations. The Company also had a working capital deficit and stockholders' deficiency as of June 30, 2001 of \$1,629,038 and \$2,482,516, respectively. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Operations to date have been funded principally by equity capital and loans. The Company's ability to continue to develop and implement its business strategy depends on its ability to obtain additional capital. The Company plans to continue to fund its development expenses through additional capital raising activities, including one or more offerings of equity and/or debt through private placements and/or public offerings. The Company is also actively seeking strategic alliances in order to develop and market its range of products. In November 2000, the Company obtained a financing facility for up to \$2 million, from a major shareholder, Kevin Leech, which would be available through November 30, 2001. The facility was terminated in August, 2001 and replaced by similar facility with Jano Holding (reference is made to Note 10, Subsequent events). In addition, the Company's officers and former outside counsel have agreed to defer salaries and certain fees, respectively, until sufficient long-term funding has been obtained by the Company. Deferred salaries and fees amounted to approximately \$1,031,698 through June 30, 2001. The Company's officers agreed to accept shares in settlement of \$910,681 of the outstanding accrued

F-9

Bioenvision, Inc.  
(A Development Stage company)

-----  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Edgar Filing: BIOENVISION INC - Form SB-2

Year Ended June 30, 2001

salaries. The shares were not yet issued as of June 30, 2001. At June 30, 2001, the balance due officers of \$1,031,698 is included in accrued liabilities in the accompanying balance sheet, \$910,681 in long term liabilities.

The Company's management believes that the anticipated equity financing, the \$1 million credit facility, and the deferral of the officers' salaries and of legal fees, will enable the Company to meet its cash requirements at least until June 30, 2002. However, if the additional equity funding does not occur as anticipated, the Company's management believes that the Company will be able to reduce its rate of expenditures in order to meet cash requirements at least until June 30, 2002; however, the Company's management believes that if there were to be any such reduction, the Company's development strategy would be delayed and the Company's marketing campaign for Modrenal(R) would be curtailed or delayed. There can be no assurances that these plans will be successfully implemented.

### Principles of consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Inter-company accounts and transactions have been eliminated.

### Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles of the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates, and such differences may be material to the financial statements.

### Revenue Recognition

Non-refundable up-front payments received in connection with research and development collaboration agreements are deferred and recognized on a straight-line basis over the relevant periods in the agreement, generally the research or development period. Milestone and royalty payments, if any, are recognized pursuant to collaborative agreements upon the achievement of the specified milestones or sales transaction.

### Research and development

Research and development costs are charged to expense as incurred.

### Stock based compensation

In accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 123, Accounting for Stock-Based Compensation, the Company applies Accounting Principles Board Opinion 25 and related interpretations in accounting for its stock option plan and, accordingly, does not recognize compensation expense for employee stock options granted with exercise prices equal to or greater than fair market value. Note 9 to the financial statements contains a summary of the pro-forma effects to reported net loss and loss per share for 2001 as if the Company had elected to recognize compensation expense based on the fair value of the options granted at grant date as described by SFAS No.123. Non-employee stock-based

## Edgar Filing: BIOENVISION INC - Form SB-2

compensation arrangements are accounted for in accordance with the provisions of SFAS No. 123, and Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Under EITF No. 96-18 where the fair value of the equity instrument is more reliably measurable than the fair value of services received, such services will be valued based on the fair value of the equity instrument.

### Income taxes

The Company accounts for income taxes under Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (FAS 109). Under FAS 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse.

F-10

Bioenvision, Inc.  
(A Development Stage company)

-----  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
Year Ended June 30, 2001

### Net loss per share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the periods. Diluted net loss per share is computed using the weighted average number of common shares and potentially dilutive common shares outstanding during the periods. Options to purchase 4,854,444 shares of common stock have not been included in the calculation of net loss per share as their effect would have been anti-dilutive.

### Foreign currency translation

The functional currency of the Company is the pound sterling and its reporting currency is the United States dollar. Assets and liabilities are translated at year-end rates and income and expenses and cash flows are translated at average rates prevailing during the period. Translation adjustments arising from differences in exchange rates from period to period have been reported as other comprehensive income or loss in stockholders' equity (deficit).

### Advertising costs

Costs related to advertising and other promotional expenditures are expensed as incurred. Advertising costs totaled \$0 for the year ended June 30, 2001 and 2000.

### Deferred costs

Payments for certain royalties incurred pursuant to collaborative agreement are recognized as deferred charges and amortized to research and development costs, ratably on a straight-line basis over the applicable development periods.

### Property, plant and equipment

## Edgar Filing: BIOENVISION INC - Form SB-2

Property, plant and equipment are stated at cost, net of accumulated depreciation and amortization. Property, plant and equipment are depreciated on a straight-line basis over an estimated three year useful life for book and tax.

### Intangible assets

Intangible assets consist of acquired development and marketing rights to platform technologies. Acquired development and marketing rights are stated at their cost less accumulated amortization. Amortization is provided on a straight-line basis over 10 years.

### Cash and cash equivalents

The Company considers all highly liquid financial instruments with a maturity of three months or less when purchased to be cash equivalents.

### Impact of recently issued accounting pronouncements

On July 20, 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001, SFAS 142 is effective for fiscal years beginning after December 15, 2001; however, certain provisions of this Statement apply to goodwill and other intangible assets acquired between July 1, 2001 and the effective date of SFAS 142. Major provisions of these Statements and their effective dates for the Company include:

All business combinations initiated after June 30, 2001 must use the purchase method of accounting.

Intangible assets acquired in a business combination must be recorded separately from goodwill if they arise from contractual or other legal rights or separable from the acquired entity and can be sold, transferred, licensed, rented or exchanged, either individually or as part of a related contract, asset or liability.

Goodwill, as well as intangible assets with indefinite lives, acquired after June 30, 2001, will not be amortized. All previously recognized goodwill and intangible assets with indefinite lives will no longer be subject to amortization.

F-11

Bioenvision, Inc.  
(A Development Stage company)

-----  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
Year Ended June 30, 2001

Effective July 1, 2002, goodwill and intangible assets with indefinite lives will be tested for impairment annually and whenever there is an impairment indicator.

The Company does not believe that these statements will have a material affect on the Company's financial statements.

## Edgar Filing: BIOENVISION INC - Form SB-2

In December 1999, the SEC issued Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements ("SAB 101"). SAB 101 summarizes the SEC's views in applying generally accepted accounting principles to revenue recognition. The adoption of SAB 101 had no impact on the Company's operating results or financial position.

### 2 Property, plant and equipment

Property, plant and equipment consists of the following:

	June 30, 2001
Office equipment	\$ 4,303
Motor vehicles	36,603
	-----
	40,906
Less: accumulated depreciation	22,809
	-----
	\$18,097
	=====

### 3 INTANGIBLE ASSETS

	June 30, 2000
Purchased technology	\$19,622
Less: accumulated amortization	3,924
	-----
	\$15,698
	=====

### 4 License and co-development agreements

Ilex Oncology, Inc.

The Company entered into a Co-Development Agreement with Ilex Oncology, Inc. ("Ilex") on March 9, 2001 for the development of clofarabine. Under the terms of the co-development agreement, Ilex is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the U.S. and Canada (excluding Japan and Southeast Asia). Ilex is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada. The Company retains the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia). The Company retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. The Company has agreed to pay Ilex a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. Ilex, which has U.S. and Canadian distribution rights, will pay the Company a royalty on sales in the U.S. and Canada. In addition, the Company is entitled to certain milestone payments. The Company also granted Ilex an option to purchase \$1 million of Common Stock after completion of the pivotal Phase II clinical trial, and Ilex has an additional option to purchase \$2 million of Common Stock after the filing of a new drug application in the United States for the use of clofarabine in the treatment of lymphocytic leukemia. The exercise price

## Edgar Filing: BIOENVISION INC - Form SB-2

per shares for each option is determined by a formula based around the date of exercise. Under the co-development agreement, Ilex also pays royalties to Southern

F-12

Bioenvision, Inc.  
(A Development Stage company)

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Year Ended June 30, 2001

Research Institute based on certain milestones. The Company continues to pay royalties to Southern Research Institute in respect to clofarabine.

#### Southern Research Institute

The Company has an agreement with Southern Research Institute, Birmingham, Alabama, to co-develop purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. Under the terms of a co-development agreement with Southern Research Institute, the Company has been granted the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by the Company and by Southern Research Institute from the technology. The lead compound of these purine-based nucleosides is known as clofarabine.

#### Deferred revenue

As of June 30, 2001, the Company reported deferred revenue of \$1,104,546 related to the contract with Ilex Oncology Inc. The Company is amortizing the deferred revenue, and recognizing revenues ratably, on a straight-line basis concurrent with certain development activities described in the contract, through December 2002.

#### Deferred costs

Deferred costs represents royalty payments that became due and payable upon the Company's execution of the co-development agreement with Ilex Oncology. Since the revenue related to the co-development agreement will be realized over the life of the agreement, the Company has deferred the costs related to the Ilex agreement. The Company will amortize such costs ratably, on a straight-line basis concurrent with development activities through December 2002. As of June 30, 2001, the Company has deferred costs of \$521,590.

#### 5 Rent expense

The Company uses office space provided by its financial advisors for its executive offices at a cost of \$4,000 per month in the United States and at a cost of 3,000 pounds per month in the United Kingdom on a month-to-month agreement.



## Edgar Filing: BIOENVISION INC - Form SB-2

Rent expenses for the fiscal year ended June 30, 2001 totaled approximately \$110,000.

### 6 Income taxes

The Company accounts for income taxes pursuant to Statement of Financial Accounting Standards No.109, "Accounting for Income Taxes." SFAS No. 109 requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Future tax benefits, such as operating loss carry forwards, are recognized to the extent that realization of these benefits is considered more likely than not. As of June 30, 2001, the Company has not filed certain of its corporate income tax returns.

### 7 Stockholders' transactions

In January 1997, the Board of Directors and Stockholders approved a 1 for 1.986 reverse split of the Company's common stock and in January 1999 effected a 1 for 15 reverse stock split. All share and per share amounts in the accompanying financial statements have been adjusted for these stock splits retroactively.

F-13

Bioenvision, Inc.  
(A Development Stage company)  
-----

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Year Ended June 30, 2001

Under an agreement between the Company and Bioaccelerate Inc, a BVI company, of Switzerland, dated 21 March, 2000, Bioaccelerate purchased 727,273 common shares of the Company at \$2.75 per share. The agreement also provided Bioaccelerate options to purchase two further tranches of 727,272 common shares each at \$2.75 per share upon certain specified milestones being achieved. The specified milestones have not yet been achieved. In April 2001, Bioaccelerate amended certain provisions of its investment agreement with the Company, including eliminating the outstanding option and the right to purchase additional options upon achievement of milestones and, in consideration, received 1,454,444 options to purchase shares of the Company's common stock.

In December 2000, the Company issued 272,500 shares of common stock to outside consultants. Consultants expense of \$272,500 based on the fair value of the Company's stock trading at \$1.00 at the time the shares were issued has been recognized in the Company's financial statements.

In May 2001, the Company's officers agreed to convert \$910,681 of the outstanding deferred salaries into 705,954 shares of the Company's common stock. The shares were not issued as of June 30, 2001; accordingly the

## Edgar Filing: BIOENVISION INC - Form SB-2

amount is recorded as a non-current liability.

### 8 Related party transactions

On September 8, 1998 the Company entered to an agreement with Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, whereby Glen Investments agreed to loan funds to the Company on an as-needed basis based upon previously agreed budgets. Mr. Leech is a private investor who is also the sole owner of Phoenix Ventures Limited, a Guernsey (Channel Islands) corporation and the holder of approximately 19% of the outstanding shares of common stock of the Company. The loan facility was not utilized during the year and was terminated in August 2001.

Included in accounts payable and accrued liabilities are interest free loans payable to Christopher B. Wood, the Company's Chairman of the Board and Chief Executive Officer, amounting to \$124,405 as of June 30, 2001.

In May 1998, Bioheal Limited, a subsidiary of Bioenvision, entered into an agreement with Mr. Wood to co-develop a gene marker and immunomodulator system for use in gene therapy and related technologies. Under the terms of the agreement, Bioheal was granted the exclusive license to make, use and sell products derived from technology, and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by Bioheal and its collaborators from the technology for a term expiring on the date of expiration of all current and future patents covered by the agreement, subject to earlier termination under certain circumstances. In consideration of the licenses granted to Bioheal, Bioheal agreed to pay to Dr. Wood, among other things, a royalty of 10% of the gross sales revenues of all products, less and discounts or deductions for value-added taxes. In addition, Bioheal has agreed to pay, among other things, certain costs associated with pre-clinical development and clinical trials of such products. Under the terms of the agreement, the pre-clinical costs are not to exceed \$1,500,000, and the clinical trial costs are not to exceed \$4,000,000, unless agreed by both parties

### 9 Stock options

The Company has adopted it's 2001 Stock Option Plan (the "Plan") on April 30, 2001. The purchase price of stock options under the Plan is determined by the Compensation Committee of the Board of Directors of the Company (the "Committee"). The term is fixed by the Committee, but no incentive stock option is exercisable after 3 years from the date of grant.

In April 2001, in accordance with the terms of the Company's stock option plan, the Company issued a total of 2,200,000 options to employees at an exercise price of \$1.25 per option share and which immediately vested. The terms of the options are that each option can be exercised after April 30, 2001 for a period of three years, whereby the options will no longer be able to be exercised after April 30, 2004 unless otherwise agreed with the Company.

F-14

Bioenvision, Inc.  
(A Development Stage company)

-----

## Edgar Filing: BIOENVISION INC - Form SB-2

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Year Ended June 30, 2001

A summary of the Company's stock option activity for options issued to employees and related information for the year ended June 30, 2001 follows:

	2001	
	Common Stock Options	Option Exercise Price
Outstanding at beginning of year	0	n/a
Granted	2,200,000	\$1.25
Exercised	0	
Canceled	0	
Outstanding at end of year	2,200,000	
Exercisable at end of year	2,200,000	
Weighted average fair value of options granted during the year		\$0.83

The Company accounts for stock-based compensation in accordance with the provisions of APB No. 25. Had compensation expense been determined based on the fair value of the options at the grant dates, as prescribed in SFAS No. 123, the Company's results would have been as follows:

	Year ended June 30, 2001
Net loss as reported	\$ (2,122,264)
Pro forma net loss	\$ (3,948,264)

In April 2001, in connection with the \$2,000,000 loan facility outstanding with Kevin Leech, the Company granted to Phoenix Ventures 500,000 options to purchase shares of the Company's common stock at an exercise price of \$1.25. The options immediately vested and expire in April 2004. These options resulted in a finance charge of \$415,000 being recorded and amortized over the remaining life of the loan facility that expired August 2001.

In April 2001, the Company granted 150,000 options to two consultants in exchange for certain services received to purchase shares of the Company's common stock at any exercise price of \$1.25 per share. The options originally expire in April 2004 and are immediately vested. The issuance of these options resulted in a charge to consulting expenses of \$124,500 in the Company's financial statements.

#### 10 Subsequent events

On August 20, 2001 the Company entered into a (3) three year agreement with Dana-Farber/Partners Cancer Care, Inc., (DF/PCC). The agreement calls for DF/PCC to conduct a clinical study of trilostone. The Company holds an exclusive license, until the expiry of existing and new patents related to trilostone, to market trilostone in major international territories, and an agreement with a U.K. company to co-develop trilostone for other therapeutic indications. The DF/PCC study will be a Phase II study of

## Edgar Filing: BIOENVISION INC - Form SB-2

trilostone for androgen -- independent prostate cancer. The Company has agreed to provide DF/PCC with a \$40,000 grant in support of the study.

In August 2001, the Company entered into an agreement with Jano Holdings Limited ("Jano"), whereby Jano made available to the Company a \$1,000,000 unsecured facility-bearing interest at a rate of 8% per annum. Jano Holdings Limited is a shareholder of the Company. The facility expires in September 2002. As of October 2001, the Company had utilized \$143,000 of the facility.

F-15

Bioenvision, Inc. and Subsidiaries  
(a Development Stage company)

-----  
Condensed Consolidated Statements of Operations  
(Unaudited)

	Nine Months Ended March 31, 2002	Peri 1996 (
Contract revenue	\$ 552,273	\$ 1,350,000
	-----	-----
Costs and expenses		
Research & development costs	687,020	1,441,164
Administrative expenses	488,837	869,900
Interest and finance charges	912,258	12,279
Depreciation and amortization	241,699	8,103
	-----	-----
	2,329,814	2,331,446
	-----	-----
Net loss	\$ (1,777,541)	\$ (981,446)
	=====	=====
Basic & diluted net loss per share	\$ (0.17)	\$ (0.12)
Weighted average shares used in computing basic and diluted net loss per share	10,435,997	7,976,419

The accompanying footnotes are an integral part of these financial statements.

F-16

Bioenvision, Inc. and Subsidiaries  
(a Development Stage company)

-----  
Consolidated Balance Sheet

Edgar Filing: BIOENVISION INC - Form SB-2

	March 31, 2002 (Unaudited)
ASSETS	
Current assets	
Cash	\$ -
Deferred costs	245,455
Deferred financing costs	1,096,875
	-----
Total current assets	1,342,330
Property, plant and equipment, net	4,012
Other assets	
Patents and licensing rights, net	12,498,584
Deferred costs	-
Deferred financing costs	-
	-----
	\$ 13,844,926
	=====
LIABILITIES & STOCKHOLDERS' EQUITY (DEFICIT)	
Liabilities	
Current liabilities	
Bank overdraft	\$ 160,335
Accounts payable	622,786
Other accrued liabilities	316,365
Deferred revenue	552,273
Loan payable	797,937
	-----
Total current liabilities	2,449,696
Long term liabilities	
Deferred revenue	-
Officers' salaries	105,067
	-----
Total long term liabilities	105,067
Stockholders' equity (deficit)	
Common stock, \$.001 par value	16,688
Authorized 25,000,000 shares	
Issued and outstanding : 16,687,786	
shares at March 31, 2002	
and 8,248,919 shares at June 30, 2001	
Additional paid in capital	18,637,321
Accumulated other comprehensive income	152,346
Deficit accumulated during development stage	(7,516,192)
	-----
Total stockholders equity (deficit)	11,290,163
	-----
	\$ 13,844,926
	=====

The accompanying footnotes are an integral part of these financial statements.

Edgar Filing: BIOENVISION INC - Form SB-2

Bioenvision, Inc. and Subsidiaries  
(a Development Stage company)

-----  
Consolidated Statements of Cash Flows  
(Unaudited)

	Nine months ended March 31, 2002	N mo en Marc 2
Cash flows from operating activities		
Net loss	\$ (1,777,541)	\$ (
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	241,699	
Financing charges - non-cash	906,125	
Gain on sale of fixed assets	-	
Provision of free rent	-	
Compensation cost for options issued to non employees	-	
Compensation cost for shares issued to non employees	-	
Changes in operating assets and liabilities		
Accounts receivable	-	
Deferred costs	276,136	
Deferred revenue	(552,273)	
Accounts payable	(28,810)	
Officers' salaries	105,067	
Other accrued expenses and liabilities	(1,434)	
Net cash used in operating activities	(831,031)	(
Cash flows from investing activities		
Capital expenditures, net	-	
Proceeds from sale of fixed assets, net	-	
Purchase of intangible assets	-	
Net cash used in investing activities	-	
Cash flows from financing activities		

Edgar Filing: BIOENVISION INC - Form SB-2

Bank overdraft	33,094	
Proceeds from issuance of common stock	-	
Loan financing	797,937	
Net cash provided by financing activities	831,031	
Effect of exchange rate on cash	-	
Net increase in cash and equivalents	-	
Cash and equivalents, beginning of year	-	
Cash and equivalents, end of year	-	
Supplemental disclosure of cash flow information		
Interest paid	\$ 1,625	\$
Supplemental disclosure of non-cash financing and investing activities:		
Non cash issuance of warrants related to Jano financing agreement	\$ -	\$
Non cash conversion of officers salary into common stock	910,681	
Non cash conversion of trade payables into common stock	322,613	
Non cash issuance of warrants related to SCO financing agreement	1,755,000	
Non cash issuance of stock related to Pathagon acquisition	12,600,000	

The accompanying footnotes are an integral part of these financial statements.

F-18

BIOENVISION, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001  
(Unaudited)

NOTE A - ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Description of business:

Bioenvision, Inc. ("Bioenvision" or "the Company") is a development stage biopharmaceutical company whose primary business focus is the acquisition, development and distribution of products and technologies for the treatment of cancer. The Company has acquired development and marketing rights to a portfolio

## Edgar Filing: BIOENVISION INC - Form SB-2

of four platform technologies. These platforms have resulted in the development of the Company's two leading products, Modrenal(R) and clofarabine, as well as twelve other products that are in various stages of development. The Company has received regulatory approval in the United Kingdom to market Modrenal(R) for the treatment of post-menopausal breast cancer. In January 2002, the Company's European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. A co-development partner has also applied for orphan drug status in the United States of America for clofarabine. The application is currently pending.

The Company was incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed its name to Ascot Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998.

On February 1, 2002, the Company completed the acquisition of Pathagon Inc. ("Pathagon"), the successor in interest to Bridge Blood Technologies L.L.C., d/b/a Pathagon, a privately held company focused on the development of novel anti-infective products and technologies. Pathagon's principal products, OLIGON(R) and methylene blue, are ready for market. Affiliates of SCO Capital Partners LLC, the Company's financial advisor and consultant, owned 82% of Pathagon prior to the acquisition. The Company acquired 100% of the outstanding shares of Pathagon in exchange for 7,000,000 shares of the Company's common stock. The acquisition has been accounted for as a purchase business combination in accordance with SFAS 141. With the acquisition, the Company adds rights to OLIGON(R) and methylene blue to its portfolio of products.

### Basis of presentation:

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Inter-company accounts and transactions have been eliminated. The financial information included in these financial statements is unaudited but, in the opinion of management, reflects all normal recurring adjustments necessary for a fair presentation of the results for the interim periods. The interim results of operations and cash flows are not necessarily indicative of those results and cash flows for the entire year. These financial statements should be read in conjunction with the financial statements and notes to the financial statements contained in the Annual Report on Form 10-K for the fiscal year ended June 30, 2001 of the Company. The balance sheet information as of June 30, 2001 has been derived from audited statements at that date.

### Operations to date and financing plans:

The Company plans to continue to fund its development expenses through additional capital raising activities, including one or more offerings of equity and/or debt through private placements and/or public offerings. The Company is also actively seeking strategic alliances in order to develop and market its range of products.

In August 2001, the Company obtained an unsecured financing facility with Jano Holdings for \$1,000,000, bearing interest at a rate of 8% per annum. The Company had utilized approximately \$290,000 of the available facility as of March 31, 2002. Accrued interest on the facility utilized amounted to \$9,811 as of March 31, 2002.

In November 2001, the Company announced the appointment of SCO Financial Group LLC as its financial advisor, and that SCO Capital Partners LLC ("SCO Capital") extended a \$1 million secured credit line (the "Facility") to the Company. The Facility provides for up to \$1,000,000 in short term financing available in four tranches of \$250,000, subject to criteria, conditions, and covenants set forth in the agreement. The Facility is secured by the pledge of



# Edgar Filing: BIOENVISION INC - Form SB-2

F-19

BIOENVISION, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001  
(Unaudited)

certain assets of the Company and bears interest at a rate of 6% per annum. The Company had utilized the maximum availability through March 31, 2002 of \$500,000 as of March 31, 2002. Accrued interest on the facility utilized amounted to \$8,125 as of March 31, 2002

The Company's officers and former outside counsel have agreed to defer salaries and certain fees, respectively, until the Company has obtained sufficient long-term funding. Deferred salaries and fees amounted to approximately \$105,000 through March 31, 2002. In May 2001, the Company's officers agreed to accept 705,954 shares of the Company's common stock in settlement of \$910,681 of the outstanding accrued salaries through June 30, 2001. The shares were issued during the quarter ended March 31, 2002. On October 17, 2001, the Company's officers agreed to accept 134,035 shares in settlement of \$154,140 of additional outstanding accrued salaries to September 30, 2001. On October 17, 2001, the Company's Board approved a plan to repay certain trade debt with shares of the Company's common stock, and a total of 146,499 shares of common stock were issued for the repayment of \$168,473.

In May 2002, the Company sold shares of its newly-created Series A Convertible Participating Preferred Stock to raise capital (the "May 2002 Private Placement"). Through May 14, 2002, the Company has sold 5,683,332 shares of Series A Convertible Participating Preferred Stock in the May 2002 Private Placement for aggregate gross proceeds of \$17,049,999. A portion of the proceeds were used to repay the Jano Holdings and SCO Capital obligations as well as the deferred salaries and fees amounting to \$105,000 and fees related to the transaction. (See note G)

#### Foreign currency translation

Through June 30, 2001, the functional currency of the Company was the Pound Sterling and its reporting currency was the United States dollar. Translation adjustments arising from differences in exchange rates from these transactions were reported as accumulated other comprehensive income in stockholders' equity (deficit). Effective July 1, 2001, the functional and reporting currency is the United States dollar.

#### Impact of recently issued accounting pronouncements

In August 2001, the FASB issued SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets". This statement is effective for fiscal years beginning after December 31, 2001. This supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of", while retaining many of the requirements of such statement. The Company does not believe that this statement will have a material effect on the Company's financial statements.

#### NOTE B - PROPERTY, PLANT AND EQUIPMENT

## Edgar Filing: BIOENVISION INC - Form SB-2

Property, plant and equipment consists of the following:

	March 31, 2002
Office equipment	\$ 4,303
Motor vehicles	36,603
	40,906
Less: Accumulated depreciation	36,894
	\$ 4,012

F-20

BIOENVISION, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001  
(Unaudited)

NOTE C - PATENT AND LICENSING RIGHTS

	March 31, 2002
Patent and licensing rights	\$ 12,660,122
Less: Accumulated amortization	161,538
	\$ 12,498,584

On February 1, 2002, the Company completed the acquisition of Pathagon. The acquisition was accounted for as a purchase business combination in accordance with SFAS 141. The Company issued 7,000,000 shares of common stock to complete the acquisition, which was valued at \$12,600,000 based on the 5-day average trading price of the stock (\$1.80) from November 22, 2001, the day of the Company's announcement of the agreed upon acquisition. The purchase price was allocated to the acquired patent and licensing rights of OLIGON(R) and methylene blue, respectively, net of assumed liabilities of \$108,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of these assets. No goodwill was recorded on the transaction. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro-forma results and balances since the beginning of the fiscal year are not materially different. Amortization of patents and licensing rights amounted to \$161,538 for the three months ended March 31, 2002, and for the next five fiscal years will amount to approximately: June 30, 2002, \$406,000; 2003, \$974,000; 2004, \$974,000; 2005, \$974,000; 2006, \$974,000.

The Company now has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro and in vivo inactivation of pathogens in biological fluids. Methylene blue is one of only two compounds used commercially to inactivate pathogens in blood products, and is currently used in many European countries to inactivate pathogens in fresh frozen plasma. The Company believes that, as a result of the mechanism of action of its proprietary technology, its systems also have the potential to inactivate many new pathogens before they are

## Edgar Filing: BIOENVISION INC - Form SB-2

identified and before tests have been developed to detect their presence in the blood supply. Because the Company's systems are being designed to inactivate rather than merely test for pathogens, the Company's systems also have the potential to reduce the risk of transmission of pathogens that would remain undetected by testing.

The OLIGON(R) technology is a patented antimicrobial technology that can be incorporated into the manufacturing process of many implantable devices. The patented process, involving two dissimilar metals (silver and platinum) creates an electrochemical reaction that releases silver ions which destroy bacteria, fungi and other pathogens. The Company intends to commercialize the technology in partnership with leading medical devices manufacturers.

### NOTE D - LICENSE AND CO-DEVELOPMENT AGREEMENTS

#### Southern Research Institute

In August 1998, Southern Research Institute, Birmingham, Alabama, entered into an agreement with a wholly-owned subsidiary of the Company, which was subsequently assigned to the Company, to co-develop purine nucleoside analogs which, based on third-party studies conducted to date, may be effective in the treatment of leukemia and lymphoma. Under the terms of a co-development agreement with Southern Research Institute, the Company acquired the exclusive worldwide license, excluding Japan and Southeast Asia, to make, use and sell products derived from the technology for a term expiring on the date of expiration of the last patent covered by the license (subject to earlier termination under certain circumstances), and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by the Company and by Southern Research Institute from the technology. The lead compound of these purine-based nucleosides is known as clofarabine.

F-21

BIOENVISION, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001  
(Unaudited)

#### Ilex Oncology, Inc.

In March 2001, the Company entered into a co-development agreement with Ilex Oncology, Inc. ("Ilex") on March 9, 2001 for the development of clofarabine. Under the terms of that co-development agreement, Ilex is required to pay all development costs of clofarabine in the United States of America ("United States") and Canada, and 50% of approved development costs worldwide outside the United States and Canada (excluding Japan and Southeast Asia). Ilex is responsible for conducting all clinical trials and the filing and prosecution of applications with applicable regulatory authorities in the United States and Canada. The Company has retained the right to handle those matters in all territories outside the United States and Canada (excluding Japan and Southeast Asia). The Company also retained the exclusive manufacturing and distribution rights in Europe and elsewhere worldwide, except for the United States, Canada, Japan and Southeast Asia. Assuming completion of development responsibilities by Ilex, the Company will pay Ilex a royalty on sales of clofarabine outside the United States, Canada, Japan and Southeast Asia, and Ilex will have United States and Canadian distribution rights and will pay the Company a royalty on

## Edgar Filing: BIOENVISION INC - Form SB-2

sales of clofarabine in the United States and Canada. In addition, the Company is entitled to receive certain milestone payments from Ilex. The Company also granted Ilex an option to purchase \$1 million of common stock after completion of the pivotal Phase II clinical trial, and Ilex has an additional option to purchase \$2 million of common stock after the filing of a new drug application in the United States for the use of clofarabine in the treatment of lymphocytic leukemia. The exercise price per share for each option is determined by a formula based upon an average price of the Company's common stock around the date of exercise. Under the co-development agreement, Ilex also pays royalties to Southern Research Institute based upon achievement of certain milestones. The Company continues to pay royalties to Southern Research Institute in respect to clofarabine.

As of March 31, 2002, the Company has reported deferred revenue of \$552,273 related to the contract with Ilex Oncology Inc. The Company is amortizing the deferred revenue, and recognizing revenues ratably, on a straight-line basis concurrent with certain development activities described in the contract, through December 2002.

Deferred costs represents royalty payments that became due and payable upon the Company's execution of the co-development agreement with Ilex Oncology. Since the revenue related to the co-development agreement will be realized over the life of the agreement, the Company has deferred the costs related to the Ilex agreement. The Company will amortize such costs ratably, on a straight-line basis concurrent with development activities through December 2002. As of March 31, 2002, the Company has deferred costs of \$245,455.

In January 2002, the Company's European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Ilex has also applied for orphan drug status in the United States for clofarabine. The application is currently pending.

Dana Farber

On August 20, 2001 the Company entered into a three year agreement with Dana-Farber/Partners Cancer Care, Inc., ("DF/PCC"). The agreement calls for DF/PCC to conduct a clinical study of trilostane. The Company holds an exclusive license, until the expiration of existing and new patents related to trilostane, to market trilostane in major international territories, and an agreement with a United Kingdom company to co-develop trilostane for other therapeutic indications. The DF/PCC study will be a Phase II study of trilostane for androgen independent prostate cancer. The Company has agreed to provide DF/PCC with a \$40,000 grant in support of the study.

### Note E - STOCKHOLDERS' TRANSACTIONS

In August 2001, the Company issued 208,333 shares to officers of the Company.

In August 2001, the Company converted 150,000 of options previously issued to outside consultants to 150,000 shares of common stock.

F-22

BIOENVISION, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001  
(Unaudited)

## Edgar Filing: BIOENVISION INC - Form SB-2

In October 2001, the Company issued 134,035 shares to officers as payment for salaries accrued to September 30, 2001. In October 2001, the Company issued 146,499 shares as payment for trade payables to certain creditors.

In connection with securing the Facility with SCO Capital in November 2001, the Company issued warrants to purchase 1,500,000 shares of the Company's common stock at a strike price of \$1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The Company measured the fair market value of the warrants and recorded deferred financing costs of \$1,755,000, which will be amortized over the term of the Facility. During the quarter ended March 31, 2002, the Company recorded interest expense of \$438,750 relating to the amortization of such costs. Unamortized costs amounted to \$1,096,875 as of March 31, 2002.

Additional warrants to acquire 1,500,000 shares with similar terms were also granted to SCO Capital. The warrants expired unexercised on February 16, 2002 and could only have been exercised if the Company had failed to complete the acquisition of Pathagon. On February 1, 2002 the Company completed the acquisition of Pathagon.

On February 1, 2002, in connection with the Company's acquisition of Pathagon, the Company issued 7,000,000 shares of its common stock. In connection with the closing of the acquisition of Pathagon, the Company also entered into Registration Rights Agreements with the persons or entities, who were shareholders of Pathagon registering the offer and resale of the shares of common stock issued in the acquisition. The Company is required to prepare and file with the U.S. Securities and Exchange Commission a registration statement on Form SB-1 or such other form as may then be available and appropriate for use by the Company to register the offer and resale of those shares upon the earlier to occur of (a) the date which is six (6) months after February 1, 2002, or (b) the Company's preparation and filing of a registration statement to register the offer and resale of securities of the Company in connection with any other financing. Those shareholders also have certain demand registration and piggyback registration rights. However, each shareholder party to the Registration Rights Agreement also agreed not to dispose of any securities in a market transaction, if so requested by the Company or any underwriters managing an underwritten offering of the Company's securities, or any regulatory authority, for 180 days from the effective date of such registration with respect to the underwriter's request or such longer period as requested by any such regulatory authority.

On March 12, 2002, a majority of the Company's shareholders delivered a written consent to authorize amendment of the Company's certificate of incorporation, approved by the Company's Board of Directors, to increase the number of authorized shares of common stock from 25,000,000 to 50,000,000 and to authorize the issuance of 10,000,000 shares of the Company's Preferred Stock. The shareholder action became effective, and the amendment was filed and became effective, on April 30, 2002.

In March 2002, the Company issued 735,984 shares of common stock to its officers and directors as payment for salaries accrued through June 30, 2001 of \$910,000.

### NOTE F - RELATED PARTY TRANSACTIONS

On September 8, 1998, the Company entered to an agreement with Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, whereby Glen Investments agreed to loan funds to the Company on an as-needed basis based upon previously agreed budgets. Mr. Leech is a private investor who is also the sole owner of Phoenix Ventures Limited, a Guernsey (Channel Islands)

## Edgar Filing: BIOENVISION INC - Form SB-2

corporation and the holder of approximately 19% of the outstanding shares of common stock of the Company. The loan facility was not utilized during the year and was terminated in August 2001. In connection with this facility, the residual finance charge of \$207,500 related to the remaining life of the facility was amortized through August 2001.

F-23

BIOENVISION, INC. AND SUBSIDIARIES  
(A Development Stage Company)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2001  
(Unaudited)

Included in accounts payable and accrued liabilities are interest free loans payable to Christopher B. Wood, the Company's Chairman of the Board and Chief Executive Officer, amounting to \$124,338 as of March 31, 2002.

In May 1998, Bioheal Limited, a subsidiary of Bioenvision, entered into an agreement with Mr. Wood to co-develop a gene marker and immunomodulator system for use in gene therapy and related technologies. Under the terms of the agreement, Bioheal was granted the exclusive license to make, use and sell products derived from technology, and to utilize technical information related to the technology to obtain patent and other proprietary rights to products developed by Bioheal and its collaborators from the technology for a term expiring on the date of expiration of all current and future patents covered by the agreement, subject to earlier termination under certain circumstances. In consideration of the licenses granted to Bioheal, Bioheal agreed to pay to Dr. Wood, among other things, a royalty of 10% of the gross sales revenues of all products, less and discounts or deductions for value-added taxes. In addition, Bioheal has agreed to pay, among other things, certain costs associated with pre-clinical development and clinical trials of such products. Under the terms of the agreement, the pre-clinical costs are not to exceed \$1,500,000, and the clinical trial costs are not to exceed \$4,000,000, unless agreed by both parties.

### NOTE G - SUBSEQUENT EVENTS

On May 7, 2002 the Company authorized the issuance and sale of up to 5,920,000 shares of Series A Convertible Participating Preferred Stock, par value \$0.001 per share ("Series A Preferred Stock"). Series A Preferred Stock may be converted into shares of common stock at an initial conversion price of \$1.50 per share of common stock, subject to adjustment for stock splits, stock dividends, mergers, issuances of cheap stock and other similar transactions. Holders of Series A Preferred Stock also received, in respect of each share of Series A Preferred Stock purchased in the May 2002 Private Placement by the Company, one warrant to purchase one share of the Company's common stock at an initial exercise price of \$2.00, subject to adjustment. The purchasers of Series A Preferred Stock also received certain demand and piggyback registration rights.

Through May 14, 2002, the Company has sold 5,683,332 shares of Series A Convertible Participating Preferred Stock in the May 2002 Private Placement \$3.00 per share, resulting in aggregate gross proceeds of \$17,049,999. A portion of the proceeds to the Company were used to retire the outstanding loan obligations to Jano Holdings and SCO Capital, and the related credit facilities were terminated. A portion of the proceeds were also used to repay deferred salaries and fees to officers of the Company amounting to \$105,000.

## Edgar Filing: BIOENVISION INC - Form SB-2

On May 7, 2002, the Company executed an amendment to the original license agreement between Oklahoma Medical Research Foundation ("OMRF") and Bridge Therapeutic Products, Inc. ("BTP"), a predecessor of Pathagon, relating to the licensing of methylene blue. Under the terms of the amendment, OMRF agreed to the assignment of the original license agreement by BTP to Pathagon. The Company is required to pay OMRF \$100,000 and issue 200,000 shares of the Company's common stock and a five-year warrant to purchase an additional 200,000 shares of common stock and an annual license fee of \$10,000. The exercise price of the warrant is \$2.33 per share, subject to adjustment.

F-24

### REPORT OF INDEPENDENT AUDITORS

To the Board of Directors: Bridge Blood Technologies, L.L.C

I have audited the accompanying Balance Sheet of Bridge Blood Technologies, L.L.C as of December 31, 2001 and the related statement of operations and Member's Equity (Deficiency) and Statement of Cash Flows for the year then ended. These financial statements are the responsibility of the Company's management. My responsibility is to express an opinion on these financial statements based on my audit.

I conducted my audit in accordance with generally accepted auditing standards. Those standards require that I plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. I believe that my audit provides a reasonable basis for my opinion.

In my opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Bridge Blood Technologies, L.L.C as of December 31, 2001 and the results of operations and cash flows for the year then ended in conformity with generally accepted accounting principles.

/s/ Frank E. Hanson, C.P.A

-----  
Frank E. Hanson, C.P.A  
Arlington Virginia  
April 12, 2002

F-25

### REPORT OF INDEPENDENT AUDITORS

To the Board of Directors: Bridge Blood Technologies, L.L.C

I have audited the accompanying Balance Sheet of Bridge Blood Technologies, L.L.C as of December 31, 2000 and the related statement of operations and Member's Equity (Deficiency) and Statement of Cash Flows for the year then

Edgar Filing: BIOENVISION INC - Form SB-2

ended. These financial statements are the responsibility of the Company's management. My responsibility is to express an opinion on these financial statements based on my audit.

I conducted my audit in accordance with generally accepted auditing standards. Those standards require that I plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. I believe that my audit provides a reasonable basis for my opinion.

In my opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Bridge Blood Technologies, L.L.C as of December 31, 2000 and the results of operations and cash flows for the year then ended in conformity with generally accepted accounting principles.

/s/ Frank E. Hanson, C.P.A

-----  
Frank E. Hanson, C.P.A  
Arlington Virginia  
April 12, 2002

F-26

BRIDGEBLOOD TECHNOLOGIES L.L.C., DBA PATHAGON, INC.  
CONSOLIDATED BALANCE SHEET  
DECEMBER 31, 2001

ASSETS

INTANGIBLE ASSETS: Net of accumulated amortization of \$13,334 \$36,666  
-----

LIABILITIES AND MEMBER'S EQUITY

LIABILITIES: Accounts Payable \$108,074  
-----

MEMBER'S DEFICIENCY: (71,408)  
-----

NET LIABILITIES AND MEMBER'S DEFICIENCY: \$36,666  
-----



Edgar Filing: BIOENVISION INC - Form SB-2

The accompanying notes are an integral part of these financial statements.

F-27

BRIDGEBLOOD TECHNOLOGIES L.L.C. DBA PATHAGON, INC.  
STATEMENT OF OPERATIONS AND MEMBER'S EQUITY (DEFICIENCY)  
FOR THE YEAR ENDED DECEMBER 31, 2001

REVENUE:	\$-0-
-----	
EXPENSES:	
-----	
Amortization Expense	3,333
Expenses (See Schedule)	207,885
	-----
Total Expenses	211,218
-----	
NET (LOSS):	(211,218)
-----	
MEMBER'S DEFICIENCY - JANUARY 1, 2001:	(666,786)
-----	
ACCOUNTS PAYABLE CONVERTED TO EQUITY:	(806,596)
-----	
MEMBER'S DEFICIENCY-DECEMBER 31, 2001:	\$ (71,408)
-----	

The accompanying notes are an integral part of these financial statements.

F-28

BRIDGEBLOOD TECHNOLOGIES L.L.C., DBA PATHAGON, INC.  
STATEMENT OF CASH FLOWS  
YEAR ENDED DECEMBER 31, 2001

CASH FLOWS FROM OPERATING ACTIVITIES	
Net (Loss)	\$ (211,218)
Adjustments to reconcile net (loss) to net cash provided (used) by operating activities:	

Edgar Filing: BIOENVISION INC - Form SB-2

Amortization	3,333
Changes in assets and liabilities	
Due to affiliate	207,885
	-----
CASH-JANUARY 1, 2001	-0-
CASH-DECEMBER 31, 2001	-0-

The accompanying notes are an integral part of these financial statements.

F-29

BRIDGEBLOOD TECHNOLOGIES L.L.C. DBA PATHAGON, INC.  
SCHEDULE OF EXPENSES  
YEAR ENDED DECEMBER 31, 2001

EXPENSES:

-----

Consulting	\$72,342
Professional Fees	132,768
Storage	2,865
Total Expenses	\$207,885
	-----

## Edgar Filing: BIOENVISION INC - Form SB-2

The accompanying notes are an integral part of these financial statements.

F-30

BRIDGEBLOOD TECHNOLOGIES L.L.C. DBA PATHAGON, INC.  
NOTES TO FINANCIAL STATEMENTS  
YEAR ENDED DECEMBER 31, 2001

Note 1 : DESCRIPTION OF OPERATIONS  
-----

Bridge Blood Technologies L.L.C. (BBT or the "Company") was established to develop and acquire biotech and medical technologies. BBT is developing systems designed to improve the safety of blood transfusions by inactivation of infectious pathogens in blood components (fresh from frozen plasma of "FFP", platelets and red blood cells) used for transfusion. BBT has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro inactivation of pathogens in biological fluids. Methylene blue is only two compounds used commercially to inactivate pathogens in blood products, and is currently used in many European countries to inactivate pathogens in FFP. The Company believes that, as a result of the mechanism of action of its proprietary technology, its systems also have the potential to inactivate many new pathogens before they are identified and before tests have been developed to detect their presence in the blood supply. Because the Company's systems are being designed to inactivate rather than merely test for pathogens, the Company's systems also have the potential to reduce the risk of transmission of pathogens that would remain undetected by testing.

In February 2000, BBT acquired the OLIGON(R) technology from creditors to Implemed, Inc. The OLIGON(R) technology is a patented antimicrobial technology that can be incorporated into the manufacturing process of many implantable devices. The patented process, involving two dissimilar metals (silver and platinum) creates an electrochemical reaction that releases silver ions which destroy bacteria, fungi and other pathogens. BBT intends to commercialize the technology in partnership with leading medical devices manufacturers.

NOTE 2 : BASIS OF PRESENTATION:  
-----

The financial statements are prepared on an accrual basis of accounting where revenue is recognized when earned and expenses when incurred.

NOTE 3 : SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:  
-----

INTANGIBLE ASSET  
-----

Intangible asset represents a license and is being amortized using the straight line basis over 15 years

ESTIMATES AND ASSUMPTIONS  
-----

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

NOTE 4 RELATED PARTY TRANSACTIONS:  
-----

Edgar Filing: BIOENVISION INC - Form SB-2

The Company was charged \$207,885 for the year ended in December 31, for related expenses paid by an affiliate on its behalf.

NOTE 5. CONTIGENT LIABILITES:

-----  
The Company has a \$300,000 demand note payable contingent on the receipt by the Company of at least \$5,000,000 of qualified financing. The note bears interest at 1.5% per month. Total accrued interest at December 31, 2001 amounted to \$313,044.

F-31

BRIDGEBLOOD TECHNOLOGIES L.L.C., DBA PATHAGON, INC.  
BALANCE SHEET  
DECEMBER 31, 2000

ASSETS	
INTANGIBLE ASSETS: Net of accumulated amortization of \$10,001	\$39,999
-----	-----
LIABILITIES AND MEMBER'S CAPITAL	
LIABILITIES : Due to Affiliate	\$706,785
-----	
MEMBER'S DEFICIENCY:	(666,786)
-----	
NET LIABILITIES AND MEMBER'S DEFICIENCY:	\$39,999
-----	-----

The accompanying notes are an integral part of these financial statements.

F-32

BRIDGEBLOOD TECHNOLOGIES L.L.C., DBA PATHAGON, INC.  
STATEMENT OF OPERATIONS AND MEMBER'S EQUITY (DEFICIENCY)  
FOR THE YEAR ENDED DECEMBER 31, 2000

Edgar Filing: BIOENVISION INC - Form SB-2

REVENUE:		\$-0-
-----		
EXPENSES:		
-----		
	Amortization Expense	3,333
	Expenses (See Schedule)	537,574
	Total Expenses	540,907
	-----	
NET (LOSS):		(540,907)
-----		
MEMBER'S DEFICIENCY - JANUARY 1, 2000:		(125,879)
-----		
MEMBER'S DEFICIENCY-DECEMBER 31, 2000:		\$666,786
-----		

The accompanying notes are an integral part of these financial statements.

F-33

BRIDGEBLOOD TECHNOLOGIES L.L.C. DBA PATHAGON, INC.  
STATEMENT OF CASH FLOWS  
YEAR ENDED DECEMBER 31, 2000

CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)		\$ (540,907)
Adjustments to reconcile net (loss) to net cash provided (used) by operating activities:		
	Amortization	3,333
	Changes in assets and liabilities	
	Due to affiliate	537,574
CASH-JANUARY 1, 2000		-0-
CASH-DECEMBER 31, 2000		-0-

The accompanying notes are an integral part of these financial statements.

F-34

BRIDGEBLOOD TECHNOLOGIES L.L.C. DBA PATHAGON, INC.  
SCHEDULE OF EXPENSES  
YEAR ENDED DECEMBER 31, 2000

EXPENSES:

-----

Consulting	\$81,387
Professional Fees	20,152
Acquisition Cost	173,250
Storage	2,565
Variable and Fixed Costs	260,220
Total Expenses	\$537,574

-----

The accompanying notes are an integral part of these financial statements.

F-35

BRIDGEBLOOD TECHNOLOGIES L.L.C. DBA PATHAGON, INC.  
NOTES TO FINANCIAL STATEMENTS  
YEAR ENDED DECEMBER 31, 2000

Note 1 : DESCRIPTION OF OPERATIONS

-----

Bridge Blood Technologies L.L.C. (BBT or the Company") was established to

## Edgar Filing: BIOENVISION INC - Form SB-2

develop and acquire biotech and medical technologies.

BBT is developing systems designed to improve the safety of blood transfusions by inactivation of infectious pathogens in blood components (fresh from frozen plasma of "FFP", platelets and red blood cells) used for transfusion. BBT has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro inactivation of pathogens in biological fluids. Methylene blue is only two compounds used commercially to inactivate pathogens in blood products, and is currently used in many European countries to inactivate pathogens in FFP. The Company believes that, as a result of the mechanism of action of its proprietary technology, its systems also have the potential to inactivate many new pathogens before they are identified and before tests have been developed to detect their presence in the blood supply. Because the Company's systems are being designed to inactivate rather than merely test for pathogens, the Company's systems also have the potential to reduce the risk of transmission of pathogens that would remain undetected by testing.

In February 2000, BBT acquired the OLIGON(R) technology from creditors to Implemed, Inc. The OLIGON(R) technology is a patented antimicrobial technology that can be incorporated into the manufacturing process of many implantable devices. The patented process, involving two dissimilar metals (silver and platinum) creates an electrochemical reaction that releases silver ions which destroy bacteria, fungi and other pathogens. BBT intends to commercialize the technology in partnership with leading medical devices manufacturers.

### NOTE 2 : BASIS OF PRESENTATION:

-----  
The financial statements are prepared on an accrual basis of accounting where revenue is recognized when earned and expenses then incurred.

### NOTE 3 : SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

#### ----- INTANGIBLE ASSET

-----  
Intangible asset represents a license and is being amortized using the straight line basis over 15 years

#### ESTIMATES AND ASSUMPTIONS

-----  
The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates.

### NOTE 4 RELATED PARTY TRANSACTIONS:

-----  
The Company was charged \$537,574 for the year ended in December 31, for related expenses paid by an affiliate on its behalf.

### NOTE 5. CONTIGENT LIABILITES:

-----  
The Company has a \$300,000 demand note payable contingent on the receipt by the Company of at least \$5,000,000 of qualified financing. The note bears interest at 1.5% per month. Total accrued interest at December 31, 2000 amounted to \$212,742.

F-36

## PRO FORMA FINANCIAL INFORMATION

The following unaudited pro forma consolidated statements of income for the year

## Edgar Filing: BIOENVISION INC - Form SB-2

ended June 30, 2001 and for the nine months ended March 31, 2002 (collectively. The "Pro Forma Statements") are based on the historical Consolidated Financial Statements of Bioenvision, Inc. and Subsidiaries (the "Company") and Bridgeblood Technologies L.L.C. DBA Pathagon Inc. ("Pathagon") included elsewhere in this prospectus, adjusted to give effect to the acquisition of Pathagon (the "Pathagon Acquisition") using the purchase method of accounting and the assumptions and adjustments in the accompanying Notes to the Unaudited Pro Forma Consolidated Financial Statements. The unaudited pro forma consolidated statements of income for the year ended June 30, 2001 and the nine months ended March 31, 2002 give effect to the transaction as if it occurred on July 1, 2000, the first day of the Company's 2001 fiscal year and July 1, 2001, the first day of the Company's 2002 fiscal year, respectively.

The pro forma adjustments are based upon available information and certain assumptions that the Company believes are reasonable. The Pro Forma Statements are provided for informational purposes only and do not purport to represent what the Company's financial position and results of operations would actually have been had the Pathagon Acquisition in fact occurred on such date or to project the Company's financial position or results of operations for any future period. Additionally, the Pro Forma Statements do not include any cost savings or other synergies expected to be realized as a result of the integration of the two companies.

The Pro Forma Statements and the Notes thereto should be read in conjunction with the historical Consolidated Financial Statements of the Company and Pathagon included elsewhere in this prospectus.

F-37

Bioenvision, Inc and Subsidiaries  
Pro Forma Consolidated Statement of Income-Unaudited  
For the Nine Months Ended March 31, 2002

	BIOV For the nine months ended March 31, 2002 (See Note C)	Pathagon For the period from July 1, 2001 to February 1, 2002	Pro Forma Adjustments For the nine months ended March 31, 2002
Contract revenue	\$ 552,273	\$ -	\$ -
	-----	-----	-----
Costs and expenses			
-----			
Research & development costs	687,020	-	-
Administrative expenses	488,837	103,385	-
Interest and finance charges	912,258	-	-
Depreciation and amortization	241,699	71,666	571,227



Edgar Filing: BIOENVISION INC - Form SB-2

Total costs and expenses	2,329,814	175,051	571,227
Net loss	(1,777,541)	(175,051)	(571,227)
Basic & diluted net loss per share	(0.17)	-	-
Weighted average shares used in computing basic and diluted net loss per share	10,435,997	-	7,000,000

The accompanying footnotes are an integral part of these financial statements

F-38

Bioenvision, Inc and Subsidiaries  
 Pro Forma Consolidated Statement of Operations-Unaudited  
 For the Twelve Months Ended June 30, 2001

	BIOV For the twelve months ended June 30, 2001	Pathagon For the twelve months ended June 30, 2001	Pro Forma Adjustments For the two months ended June 30, 2001 (unaudited)
Contract revenue	\$ 245,455	\$ -	\$ -
Costs and expenses			
Research & development costs	1,565,908	-	-
Administrative expenses	550,215	372,155	-
Interest and finance charges	228,787	-	-
Depreciation and amortization	22,809	3,333	969,000
Total costs and expenses	2,367,719	375,488	969,000
Net loss	(2,122,264)	(375,488)	(969,000)
Basic & diluted net loss per share	(0.26)	-	-
Weighted average shares used in computing basic and diluted net loss per share	8,121,255	-	7,000,000

## Edgar Filing: BIOENVISION INC - Form SB-2

The accompanying footnotes are an integral part of these financial statements

F-39

Bioenvision, Inc and Subsidiaries  
Notes to Pro Forma Consolidated Financial Statements - Unaudited  
March 31, 2002 and June 30, 2001

- a. Record amortization of intangible assets related to patents and licensing rights acquired in the acquisition which were valued at approximately \$12,600,000 and will be amortized over their estimated useful life of 13 years.
- b. Record amortization of intangible assets related to acquisition for the period from July 1, 2001 through the date of acquisition.
- c. The historical financial information for Bioenvision, Inc. includes the results of operations of Pathagon since February 1, 2002, the date of acquisition.

F-40

### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

Item 24. Other Expenses of Issuance and Distribution.

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

Securities and Exchange Commission Registration Fee.....	\$6,481
*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.....	7,519
	-----
*Total.....	\$150,000
	=====

-----  
\* Estimated.

Item 25. 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,

## Edgar Filing: BIOENVISION INC - Form SB-2

criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in the manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful.

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

II-1

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

## Edgar Filing: BIOENVISION INC - Form SB-2

permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain liability insurance on behalf of its directors, officers, employees and agents regardless of whether the corporation would have the statutory power to indemnify such persons against the liabilities insured.

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

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

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

II-2

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 26. Recent Sales of Unregistered Securities.

In April 2000, we received a \$2,000,000 equity investment from Bioaccelerate, Inc., a BVI company, of Switzerland, in exchange for the issuance of 727,272 shares of our common stock at a price of \$2.75 per share. The investment agreement, dated March 21, 2000, granted to Bioaccelerate the option to purchase two further tranches of 727,272 common shares each, also at a price of \$2.75 per share, upon achievement of certain specified milestones. On April 30, 2001, 1,454,444 options were issued Bioaccelerate in consideration for amending certain provisions of the investment agreement and terminating the outstanding options. The issuance of these shares and options was exempt from registration under Regulation S and/or Section 4(2) of the securities act and/or Regulation D promulgated under the securities act based upon representations and warranties made by the purchaser as to its status as an accredited investor.

## Edgar Filing: BIOENVISION INC - Form SB-2

As of June 30, 2000, our financial advisors held 342,468 shares of our common stock, which were issued in exchange for financial planning services rendered to the Company. These services are reflected in the statement of operations as administrative expense. They are valued at \$0.13 to \$0.67 per share, which reflected the most recent transaction for shares.

In November 2000, we issued 272,500 shares of common stock valued at approximately \$1.00 per share to various consultants for work performed for and our behalf. The shares were issued to Andrew Turner (112,500), David Chester (112,500) and Shane Sutton (47,500). The issuance of these shares was exempt from registration under Regulation S promulgated under the securities act and/or section 4(2) of the securities act.

In March 2001, we entered into a co-development agreement with Ilex, pursuant to which Ilex will have a thirty-day option to purchase \$1 million of our common stock upon completion by Ilex of the pivotal Phase II clinical trial of clofarabine, and an additional 30 day option to purchase \$2 million of our common stock after the filing by Ilex of a new drug application in the United States for the use of clofarabine in the treatment of lymphocytic leukemia. The exercise price per share for each option is based upon the average market price of our common stock at the time of exercise. The issuance of these shares was exempt from registration under Regulation S promulgated under the securities act and/or section 4(2) of the securities act.

In April 2001, we issued 5,104,544 options at an exercise price of \$1.25 per option share. The initial terms of the options are that each option can be exercised after April 2001 for a period of three years, but were extended for five years.

Of these options, 2,200,000 were issued to the following members of our management:

Christopher Wood	1,500,000 options
Stuart Smith	500,000 options
Thomas Nelson	200,000 options

The issuance of these options was exempt from registration under Section 4(2) of the Securities Act with respect to the optionees.

### II-3

In April 2001, we granted to Phoenix Ventures 500,000 options to purchase shares of our common stock at an exercise price of \$1.25 per share. The options were issued in connection with a credit facility made available to us by Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, a United Kingdom citizen and one of our shareholders, which facility was terminated in August 2001. The options originally expired in April 2004 and are immediately vested but were extended to April 2006. That issuance of options were exempt from registration under Regulation S under the Securities Act or Section 4(2) of the Securities Act.

In April 2001, we granted 150,000 options to purchase shares of our common stock at an exercise price of \$1.25 per share. The options were issued to two consultants in exchange for certain services rendered. In August 2001, these options were converted into 150,000 shares of common stock. Those issuances of options and shares of common stock were exempt from registration under Regulation S promulgated under the Securities Act and/or Section 4(2) of the Securities Act.

## Edgar Filing: BIOENVISION INC - Form SB-2

In May 2001, certain officers agreed to convert \$910,681 of the outstanding deferred salaries into 705,954 shares of common stock. The shares were issued in March 2002 and their issuance was exempt from registration under Regulation S promulgated under the Securities Act and/or Section 4(2) of the Securities Act.

In October 2001, we issued 134,035 shares to officers as payment for salaries accrued to September 30, 2001. The issuance of these securities was exempt from the registration requirements of the securities act under Section 4(2) and/or Regulation D of the securities act, as a transaction by an issuer not involving a public offering.

In October 2001, we issued 146,499 shares as payment for trade payables to certain creditors. The issuance of these securities was exempt from the registration requirements of the securities act under Section 4 (2) and/or Regulation D of the securities act, as a transaction by an issuer not involving a public offering.

On November 16, 2001, we entered into an engagement letter with SCO Financial Group LLC, pursuant to which SCO would act as our financial advisor. In connection with the engagement letter, we issued a warrant to purchase 100,000 shares of common stock at an exercise price of \$1.25 per share, subject to certain anti-dilution adjustment.

In connection with securing the facility with SCO Capital, we issued warrants to purchase 1,500,000 shares of our common stock at a strike price of \$1.25 per share, subject to certain anti-dilution adjustments. The warrants expire five years from the date of issuance. The issuance of these securities was exempt from the registration requirements of the securities act under Section 4 (2) and/or Regulation D of the securities act, as a transaction by an issuer not involving a public offering.

Additional warrants to acquire 1,500,000 shares with similar terms were also granted to SCO Capital. The warrants expire on February 16, 2002 and can be exercised only if we failed to complete the acquisition of Pathagon, Inc. On February 5, 2002 we announced that we completed the acquisition of Pathagon. The issuance of these securities was exempt from the registration requirements of the securities act under Section 4(2) and/or Regulation D of the securities act, as a transaction by an issuer not involving a public offering.

II-4

In August 2001 we issued 208,333 shares of common stock at the rate of \$1.25 per share as follows: Christopher Wood 98,684 shares; Thomas Nelson, 27,412 shares and Stuart Smith, 82,237 shares. That issuance of shares was exempt from registration under Section 4(2) of the Securities Act.

On February 1, 2002 we issued 7,000,000 shares of common stock related to the acquisition of Pathagon, Inc. The issuances of these securities were exempt from the registration requirements of the Securities Act under Section 4 (2) and/or Regulation D of the Securities Act, as a transaction by an issuer not involving a public offering.

In May 2002, we sold an aggregate of 5,916,666 shares of Series A Convertible Participating Preferred Stock for \$3.00 per share, resulting in aggregate gross proceeds of \$17,750,000 and warrants to purchase an additional 5,916,666 shares of common stock at an exercise price of \$2.00 per share. Each share of Series A Preferred Stock is initially convertible into two shares of common stock. The issuance of shares was exempt from register under Section 4 (2) of the Securities Act and/or Regulation D preferred Stock under the Securities Act.

## Edgar Filing: BIOENVISION INC - Form SB-2

On May 7, 2002, we executed an amendment to the original license agreement between Oklahoma Medical Research Foundation and Bridge Therapeutic products, Inc., a predecessor of Pathagon, relating to the licensing of methylene blue. Under the terms of the amendment, OMRF agreed to the assignment of the original license agreement by BTP to Pathagon. We paid OMRF \$100,000 and issued 200,000 shares of common stock and a five-year warrant to purchase an additional 200,000 shares of common stock and an annual license fee of \$10,000. The exercise price of the warrant is \$2.33 per share, subject to adjustment. The issuance of these shares was exempt from registration under Regulation S promulgated under the securities act and/or section 4(2) of the securities act.

Item 27. Exhibits and Schedules.

### Exhibit

Number	Description of Document
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc., dated as of 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 (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)
II-5	
3.2	By-Laws (2)
3.2(a)	Amendment to Bylaws, effective April 30, 2002 (6)
4.1	Certificate of Designations of Series A Preferred Stock (6)
4.2	Form of Warrant (6)
5.1*	Opinion of Piper Rudnick LLP
10.1	Sponsored Research Agreement between Eurobiotech Corporation, Ltd. and University of Texas, MD Anderson Cancer Center dated February 26, 1998 (3)
10.2	Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998 (3)
10.3	Co-Development Agreement between Biomed (UK) Ltd. and EuroLifesciences, Ltd. dated May 20, 1998 (3)
10.4	Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998 (3)

## Edgar Filing: BIOENVISION INC - Form SB-2

- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998 (3)
- 10.5a Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998 (3)
- 10.6 Loan Agreement between Glen Investments Ltd. and Bioenvision, Inc. dated September 8, 1998 and affirmed July 15, 1999 (3)
- 10.7 Co-Development and Licensing Agreement between Orion Pharmaceuticals Canada and Bioenvision, Inc. dated November 1998 (3)
- 10.8 License Agreement between Bioenvision, Inc. and Royal Free and University College Medical School, London dated March 11, 1999 (3)
- 10.9 License Agreement between Bioenvision, Inc. and University College Cardiff Consultants Limited dated June 21, 1999 (3)
- 10.10 Research Agreement between Bioenvision, Inc. and Cardiff University dated July 8, 1999 (3)
- 10.11 Employment agreement between Bioenvision, Inc. and Stuart Smith dated January 1, 2000 (4)
- 10.12 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D. dated September 1, 1999 (4)
- 10.13 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000 (4)

II-6

- 10.14 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC (7)
- 10.15 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC (7)
- 10.16 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.17 Senior Secured Grid Note, dated November 16, 2001 by Bioenvision, Inc. in favor of SCO Capital Partners LLC (7)
- 10.18 Registration Rights Agreement dated as of February 1, 2002 by and between Bioenvision, Inc. and the former shareholders of Pathagon. party thereto (8)
- 10.19 Stockholders Lock Up Agreement dated as of February 1, 2002 by and among Bioenvision, Inc., the former shareholders of Pathagon party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited (8)
- 10.20 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002 (6)
- 10.21 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002 (6)
- 10.22 Exclusive License Agreement by and between Baxter Healthcare



## Edgar Filing: BIOENVISION INC - Form SB-2

Corporation, acting through its Edwards Critical-Care Division, and Implemented, dated as of May 6, 1997 (12)

- 10.23 License Agreement by and between Oklahoma Medical Research Foundation and Bridge Therapeutic Products, Inc., dated as of January 1, 1998 (12)
- 10.23(a) Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002 (12)
- 10.24 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998 (12)
- 10.25 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999 (12)
- 10.26 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.27 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001 (12)
- 10.28 Co-Development Agreement between Bioenvision, Inc. and Ilex Oncology, Inc., dated March 9, 2001 (12)

### II-7

- 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 Subsidiaries of the registrant (4)
- 23.1 Consent of Grant Thornton LLP
- 23.2 Consent of Ernst & Young LLP
- 23.3 Consent of Frank Hanson, C.P.A.
- 23.4\* Consent of Piper Rudnick 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

## Edgar Filing: BIOENVISION INC - Form SB-2

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/A 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.

II-8

- (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.

Item 28. Undertakings.

The undersigned Registrant undertakes:

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

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or taken as a whole, represent a fundamental change in the information detailed in the Registration Statement; and
- (iii) To include any significant information with respect to the plan of distribution not previously disclosed in the Registration Statement or any significant change to such information in the Registration Statement.

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

(e) Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling

## Edgar Filing: BIOENVISION INC - Form SB-2

persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as express in the Act and is, therefore, unenforceable.

II-9

### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form SB-2 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 19th day of July, 2002.

BIOENVISION INTERNATIONAL, 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 -----	Title -----
/s/ Christopher B. Wood ----- Christopher B. Wood, M.D.	Director, Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
/s/ Thomas Scott Nelson ----- Thomas Scott Nelson, C.A.	Director and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Jeffrey B. Davis	

Edgar Filing: BIOENVISION INC - Form SB-2

-----  
 Jeffrey B. Davis Director

/s/ Steven A. Elms  
 -----

Steven A. Elms Director

/s/ Andrew Schiff  
 -----

Andrew Schiff, M.D. Director

EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Acquisition Agreement between Registrant and Bioenvision, Inc., dated as of 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 (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	By-Laws (2)
3.2(a)	Amendment to Bylaws, effective April 30, 2002 (6)
4.1	Certificate of Designations (6)
4.2	Form of Warrant (6)
5.1*	Opinion of Piper Rudnick LLP
10.1	Sponsored Research Agreement between Eurobiotech Corporation, Ltd. and University of Texas, MD Anderson Cancer Center dated February 26, 1998 (3)
10.2	Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998 (3)
10.3	Co-Development Agreement between Biomed (UK) Ltd. and EuroLifesciences, Ltd. dated May 20, 1998 (3)
10.4	Co-Development Agreement between Stegram Pharmaceuticals, Ltd. and Bioenvision, Inc. dated July 15, 1998 (3)

## Edgar Filing: BIOENVISION INC - Form SB-2

- 10.5 Co-Development Agreement between Southern Research Institute and Eurobiotech Group, Inc. dated August 31, 1998 (3)
- 10.5a Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998 (3)
- 10.6 Loan Agreement between Glen Investments Ltd. and Bioenvision, Inc. dated September 8, 1998 and affirmed July 15, 1999 (3)
- 10.7 Co-Development and Licensing Agreement between Orion Pharmaceuticals Canada and Bioenvision, Inc. dated November 1998 (3)
- 10.8 License Agreement between Bioenvision, Inc. and Royal Free and University College Medical School, London dated March 11, 1999 (3)
- 10.9 License Agreement between Bioenvision, Inc. and University College Cardiff Consultants Limited dated June 21, 1999 (3)
- 10.10 Research Agreement between Bioenvision, Inc. and Cardiff University dated July 8, 1999 (3)
- 10.11 Employment agreement between Bioenvision, Inc. and Stuart Smith dated January 1, 2000 (4)
- 10.12 Employment Agreement between Bioenvision, Inc. and Christopher B. Wood, M.D. dated September 1, 1999 (4)
- 10.13 Securities Purchase Agreement with Bioaccelerate Inc dated March 24, 2000 (4)
- 10.14 Engagement Letter Agreement, dated as of November 16, 2001, by and between Bioenvision, Inc. and SCO Securities LLC (7)
- 10.15 Security Agreement, dated as of November 16, 2001, by Bioenvision, Inc. in favor of SCO Capital Partners LLC (7)
- 10.16 Commitment Letter, dated November 16, 2001, by and between SCO Capital Partners LLC and Bioenvision, Inc. (7)
- 10.17 Senior Secured Grid Note, dated November 16, 2001 by Bioenvision, Inc. in favor of SCO Capital Partners LLC (7)
- 10.18 Registration Rights Agreement dated as of February 1, 2002 by and between Bioenvision, Inc. and the former shareholders of Pathagon. party thereto (8)
- 10.19 Stockholders Lock Up Agreement dated as of February 1, 2002 by and among Bioenvision, Inc., the former shareholders of Pathagon party thereto, Christopher Wood, Bioaccelerate Limited, Jano Holdings Limited and Lifescience Ventures Limited (8)
- 10.20 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002 (6)
- 10.21 Form of Registration Rights Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002 (6)
- 10.22 Exclusive License Agreement by and between Baxter Healthcare Corporation, acting through its Edwards Critical-Care Division, and

## Edgar Filing: BIOENVISION INC - Form SB-2

Implemed, dated as of May 6, 1997 (12)

- 10.23 License Agreement by and between Oklahoma Medical Research Foundation and Bridge Therapeutic Products, Inc., dated as of January 1, 1998 (12)
- 10.23(a) Amendment No. 1 to License Agreement by and among Oklahoma Medical Research Foundation, Bioenvision, Inc. and Pathagon, Inc., dated May 7, 2002 (12)
- 10.24 Inter-Institutional Agreement between Sloan-Kettering Institute for Cancer Research and Southern Research Institute, dated as of August 31, 1998 (12)
- 10.25 License Agreement between University College London and Bioenvision, Inc., dated March 1, 1999 (12)
- 10.26 Research Agreement between Stegram Pharmaceuticals Ltd., Queen Mary and Westfield College and Bioenvision, Inc., dated June 8, 1999 (12)
- 10.27 Research and License Agreement between Bioenvision, Inc., Velindre NHS Trust and University College Cardiff Consultants, dated as of January 9, 2001 (12)
- 10.28 Co-Development Agreement between Bioenvision, Inc. ad Ilex Oncology, Inc., dated March 9, 2001 (12)
- 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 Subsidiaries of the registrant (4)
- 23.1 Consent of Grant Thornton LLP
- 23.2 Consent of Ernst & Young LLP
- 23.3 Consent of Frank Hanson, C.P.A.
- 23.4\* Consent of Piper Rudnick 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

## Edgar Filing: BIOENVISION INC - Form SB-2

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/A 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.