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BIOENVISION INC  
Form SB-2/A  
June 21, 2004

Registration No. 333-115816  
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U.S. Securities and Exchange Commission  
Washington, D.C. 20549

AMENDMENT NO. 1 TO FORM SB-2  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

|  |  |  |
|--|--|--|
| Delaware<br>-----<br>(State or other jurisdiction of<br>incorporation or organization) | 2834<br>-----<br>(Primary Standard Industrial<br>Classification Code Number) | 13-4025857<br>-----<br>(I.R.S. Employer<br>Identification No.) |
|--|--|--|

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

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Approximate date of commencement of proposed sale to the public: As soon as practical after the effective date of this Registration Statement. If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act

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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<br>class of<br>securities to<br>be registered<br>----- | Number of<br>shares to be<br>registered<br>----- | Proposed<br>maximum<br>offering price<br>per share<br>----- | Proposed<br>maximum<br>aggregate<br>offering price<br>----- | Amount of<br>registration<br>fee<br>--- |
|--|--|---|---|---|
| Common Stock,<br>par value \$.001<br>per share                       | 3,618,768  | \$ 9.945(1)   | \$35,988,657(1)   | \$4,559.76(1)                           |
| Common Stock,<br>par value \$.001<br>per share                       | 34,131,931(2)                                    | (3)   | (3)   | (3)                                     |

(1) Calculated in accordance with Rule 457(c) under the Securities Act of 1933.

(2) Represents an aggregate of 34,131,931 shares of common stock previously registered on the registration statement on Form SB-2 (Registration No. 333-97443) that are being carried forward in the prospectus filed with this registration statement.

(3) This amount has previously been paid by the registrant as the registration fee for the 34,131,931 shares of common stock carried forward from the prior registration statement on Form SB-2 (Registration No. 333-97443).

Pursuant to Rule 429 under the Securities Act, the prospectus included as part of this registration statement shall be deemed a combined prospectus which shall also relate to our registration statement on Form SB-2 (Registration No. 333-97443) and constitutes a post-effective amendment to our registration statement on Form SB-2 (Registration No. 333-97443).

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

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

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offer to buy these securities in any state where such offer or sale is not permitted.

Subject to completion, June 21, 2004

### PROSPECTUS

BIOENVISION, INC.

37,750,699 Shares of Common Stock

Of the shares of stock covered by this prospectus: (i) 10,880,000 shares are issuable upon the conversion of 5,440,000 preferred shares issued in connection with a private placement consummated in May 2002; (ii) 5,440,000 shares are issuable upon the exercise of warrants issued to preferred stockholders in connection with a private placement consummated in May 2002; (iii) 6,650,867 shares were issued to former stockholders of Pathagon Inc. in February 2002 in connection with the consummation of the acquisition of Pathagon Inc.; (iv) 1,008,333 shares are issuable upon the exercise of warrants issued to our financial advisor in connection with a private placement consummated in May 2002; (v) 3,751,995 shares were issued and 3,974,544 shares are issuable upon the exercise of warrants and options issued to the co-founders, early round investors and certain former consultants and advisors for services rendered to or on behalf of us; (vi) 100,000 shares were issued and 200,000 shares are issuable upon the exercise of warrants issued to a former co-development partner for services rendered to us; (vii) 1,500,000 shares are issuable upon the exercise of warrants issued in connection with a credit facility secured by Bioenvision in November 2001; (viii) 160,000 shares are issuable upon the exercise of warrants issued to two former financial advisors in March, 2004; (ix) 175,000 shares issuable upon the exercise of warrants issued to a regulatory consultant in April of 2003 for services rendered; (x) 2,602,898 shares were issued in connection with a private placement consummated in March and May of 2004; and (xi) 780,870 shares are issuable upon the exercise of warrants issued in connection with the private placement consummated in March and May of 2004.

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

Our common stock is traded on the American Stock Exchange under the symbol "BIV". The last reported sales price of shares of our common stock on June 11, 2004, was \$8.60 per share.

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

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

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

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### 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. The terms "Bioenvision," "the company," "we," "our" and "us" refer to Bioenvision, Inc. and its consolidated subsidiaries unless the context suggests otherwise. The term "you" refers to a prospective investor.

We are an emerging biopharmaceutical company that develops and markets drugs to treat cancer. Our two lead drugs are Clofarabine and Modrenal(R), although we have several other products and technologies under development. As of May 1, 2004, our internal staff consisted of nine employees based in New York, New York and Edinborough, Scotland.

Clofarabine is a purine nucleoside analogue, or a small molecule, which, based on our own clinical studies and studies conducted by others on our behalf, we believe is effective in the treatment of leukemia. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I/II clinical trials performed to date. In the United Kingdom, we are currently conducting clinical trials with Clofarabine for the treatment of pediatric and adult acute leukemias. In the U.S., Clofarabine is currently in Pivotal Phase II clinical trials for pediatric acute leukemias. In January, 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for Clofarabine. The drug has also been granted orphan drug status and "fast track" treatment by the United States Food and Drug Administration (the "FDA"). Further, in August 2003, we obtained the exclusive, irrevocable option to sell, market and distribute Clofarabine in Japan and Southeast Asia from the inventor of Clofarabine. These rights were not previously granted by Southern Research Institute and fall outside the scope of the Company's then current licensing and development contracts with respect to Clofarabine. We originally obtained an exclusive license from Southern Research Institute to sell, market and distribute Clofarabine throughout the world, except for Japan and Southeast Asia, for all human applications, pursuant to a co-development agreement, dated August 31, 1998, between the Company and Southern Research Institute. On March 12, 2001, we granted an exclusive option to sell, market and distribute Clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute Clofarabine in the U.S.

Modrenal(R) is a hormonal agent with a novel mode of action, that makes it an effective agent in patients with advanced breast cancer who have acquired resistance to other hormonal agents. We launched Modrenal(R) in May 2003 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. In the first half of 2004, we intend to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such territory. We anticipate receiving approval in each such territory in the first half of calendar year 2005. Further, we filed an IND for prostate cancer clinical trials in the US in February 2004 and intend to commence our first US clinical trial in the second quarter of calendar year 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.

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Our primary business strategy relates to our two lead drugs, Clofarabine and Modrenal(R). With Clofarabine, our strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory authorities to market and distribute Clofarabine for the treatment of pediatric and adult acute leukemias. We anticipate receiving approval early in 2005, subject to our obtaining approval of the regulatory authorities. We will continue clinical trials in other indications with the intention of seeking label extensions after Clofarabine's first approval. With Modrenal, our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to sell Modrenal(R) throughout Europe. We anticipate receiving mutual recognition from major European Community member states by mid-2005. Our secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from Clofarabine and Modrenal(R) will permit us to further develop our portfolio of ancillary products and technologies.

### Corporate Background

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

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### The Offering

Shares of common stock offered by the  
selling stockholders..... 37,750,699

Shares of common stock outstanding as of  
June 11, 2004..... 28,316,163

Shares to be outstanding following  
offering (assuming conversion of all  
preferred shares into common shares  
and the exercise of options and warrants,  
and assuming no sales of any securities  
pursuant to this offering)..... 48,483,737

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

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

Plan of Distribution..... The shares of common stock offered for resale may be sold by the selling stockholders pursuant to this prospectus in the manner described under "Plan of Distribution" on page 23.

Amex symbol..... BIV

RISK FACTORS

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

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

The market price of the securities of biotechnology companies has been, and can be, especially volatile. Thus, the market price of our common stock is likely to be subject to wide fluctuations. For the twelve month period ended June 11, 2004, our closing stock price has ranged from a high of \$11.75 to a low of \$1.75. If our revenues do not grow or grow more slowly, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our common stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in investor confidence or otherwise fails, the market price of our common stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us or for other reasons.

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

As of June 11, 2004, we had 28,316,163 shares of common stock outstanding, 3,341,666 shares of Series A preferred stock outstanding which are currently convertible into 6,683,332 shares of common stock and 13,484,242 common stock equivalents including warrants and stock options, other than the options granted under the co-development agreement with ILEX. The exercise and conversion prices of the common stock equivalents range from \$0.735 to \$7.50 per share. We have also reserved for issuance an aggregate of 3,000,000 shares of common stock for a stock option plan for our employees, of which approximately 1,900,000 have been issued. Historically, from time to time, we have awarded our

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common stock to officers of the Company, in lieu of cash compensation, although we do not expect to do so in the future. As of the date hereof, we are registering 37,750,699 shares under the Securities Act on this Form SB-2 and have registered options to purchase 4,500,000 shares under the Securities Act on Form S-8. The future resale of these shares and shares underlying stock options and warrants registered on this Form SB-2 and Form S-8 will result in a dilution to your percentage ownership of our common stock and could adversely affect the market price of our common stock.

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

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

Section 203 of the Delaware corporate statute

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

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substantially in response to actual or rumored takeover attempts. These provisions may also prevent changes in our management.

Issuance of Preferred Stock Without Stockholder Approval.

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



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or effect a change in control, thereby preserving the current stockholders' control.

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

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

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

To date, we have incurred significant net losses, including net losses of \$8,437,397 for the nine-month period ended March 31, 2004 and \$4,064,277 for the three month period ended March 31, 2004. At March 31, 2004, we had an accumulated deficit of \$37,676,811. We anticipate that we may continue to incur significant operating losses for the foreseeable future. We may never generate material revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

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

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

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

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

- o inability of vendors to manufacture sufficient quantities of materials for use in clinical trials;

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

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

Our ancillary products include OLIGON and Methylene Blue which are anti-microbial agents that we acquired in February 2002. As of March 31, 2004, our intangible assets associated with these products amounted to approximately \$14.8 million and constituted approximately 35% of our total assets and approximately 55% of our stockholders' equity. We amortize approximately \$1.3 million of this amount each year for the estimated useful life of these products of approximately 13 years.

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

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

ILEX, and any third party to which ILEX may grant a sublicense or in any way transfer its obligations, has primary responsibility for conducting clinical trials and administering regulatory compliance and approval matters in the United States and Canada pursuant to the terms of our co-development agreement with ILEX. While there are target dates for completion, that agreement allows ILEX time to continue working beyond those dates under certain circumstances. For example, under the co-development agreement, ILEX was required to complete Pivotal Phase II Trials not later than December 31, 2002, but ILEX failed to do so. In this situation the co-development agreement provides that the milestone shall be adjusted such that ILEX receives more time to complete the pivotal trials if the trials are ongoing at December 31, 2002 and progressing to completion within a reasonable time thereafter. Further, ILEX was required under the co-development agreement to have filed a New Drug Application by August 31, 2003, subject to extension if ILEX continues to use its reasonable efforts to promptly complete the filing after August 31, 2003. ILEX continued to use its reasonable efforts to complete the filing after August 31, 2003 and in March 2004, ILEX completed the filing.

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If ILEX fails to meet its obligations under the co-development agreement, we could lose valuable time in developing Clofarabine for commercialization both in the U.S. and in Europe. Because we intend to make use of clinical data from the clinical trials which ILEX conducted, and is conducting, to prepare and support our regulatory applications in Europe and elsewhere, ILEX's failure to expeditiously file the New Drug Application with FDA could adversely affect the timing of European approval. We can not provide assurance that ILEX will not fail to meet its obligations under the co-development agreement. Development of compounds to the stage of approval includes inherent risk at each stage of development that FDA in its discretion will mandate a requirement not foreseeable by us or by ILEX. There would also be testing delays if, for example, our sources of drug supply could not produce enough Clofarabine to support the then ongoing clinical trials being conducted. If this were to occur, it could have a material adverse effect on our ability to develop Clofarabine, obtain necessary regulatory approvals, and generate sales and cash flow from the sale of Clofarabine.

If delays in completion constitute a breach by ILEX or there are certain other breaches of the co-development agreement by ILEX, then, at our discretion, the primary responsibility for completion would revert to

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us, but there is no assurance that we would have the financial, managerial or technical resources to complete such tasks in timely fashion or at all.

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

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

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

Generally, most products resulting from our or our collaborative partners' product development efforts are not expected to be available for sale for at least several years, if at all. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons, including:

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

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

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

Regulation in General. Virtually all aspects of our business are regulated by federal and state statutes and governmental agencies in the United States and other countries. Failure to comply with applicable statutes and government regulations could have a material adverse effect on our ability to develop and sell products which would have a negative impact on our cash flow. The development, testing, manufacturing, processing, quality, safety, efficacy, packaging, labeling, record-keeping, distribution, storage and advertising of pharmaceutical products, and disposal of waste products arising from these activities, are subject to regulation by one or more federal agencies. These activities are also regulated by similar state and local agencies and equivalent foreign authorities. In our material contracts with vendors providing any portion of these types of services, we seek assurances that our vendors comply and will continue to maintain compliance with all applicable rules and regulations. This is the case, for example, with respect to our contracts with Ferro

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Pfanstiehl and Penn Pharmaceuticals. No assurance can be given that our most significant vendors will continue to comply with these rules and regulations.

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

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

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- 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, 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

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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

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to the FDA. The clinical testing requirements and the time required to obtain foreign regulatory approvals may differ from that required for FDA approval. Although there is now a centralized European Union approval mechanism for new pharmaceutical products in place, each European Union country may nonetheless impose its own procedures and requirements, many of which are time consuming and expensive, and some European Union countries require price approval as part of the regulatory process. Thus, there can be substantial delays in obtaining required approval from both the FDA and foreign regulatory authorities after the relevant applications are filed.

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

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

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

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

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

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

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application approval. In addition, new drug application approval of a drug with an orphan drug designation does not provide any marketing exclusivity in foreign markets.

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

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

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

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

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

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

Competition in our industry is intense. Potential competitors in the United States and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than us. Potential competitors for certain indications of our lead drugs include, with respect to Clofarabine, Schering AG, which markets Fludarabine, and certain generic drug companies in Europe which could market Fludarabine upon expiry of the patent protections held by Schering. Potential competitors with respect to Modrenal include Astra-zeneca and Novartis, which market timoxifen and other aromatase inhibitors, which could be used by clinicians as first and second line therapies in patients with hormone sensitive advanced post-menopausal breast cancer prior to a Modrenal regimen of treatment. No assurance can be given that the ongoing business activities of our competitors will not have a material adverse effect on our business prospects and projections going forward.

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

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

If we fail to keep up with rapid technological change and evolving therapies,



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our technologies and products could become less competitive or obsolete.

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

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

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

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

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

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

The creation of infrastructure to commercialize oncology products is a difficult, expensive and time-consuming process. We may not be able to establish direct or indirect sales and distribution capabilities or be successful in gaining market acceptance for proprietary products or for other products. We currently have very limited sales and marketing capabilities. We currently employ one fulltime sales employee and two fulltime marketing employees. To market any products directly, we will need to develop a more fulsome marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. To the extent that we enter into co-promotion or other

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licensing arrangements, any revenues to be received by us will be dependent on the efforts of third parties. The efforts of third parties may not be successful. Our failure to establish marketing and distribution capabilities or to enter into marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

If we lose key management our business will suffer.

We are highly dependent on our Chief Executive Officer to develop our lead drug. Dr. Wood has an employment agreement with the Company dated December 31, 2002 for an initial term of one year which

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

Need for additional personnel.

The Company will be required to hire additional qualified scientific and technical personnel, as well as personnel with expertise in clinical testing and government regulation to expand our research and development programs and pursue our product development plans. There is intense competition for qualified personnel in the areas of the Company's activities, and there can be no assurance that the Company will be able to attract and retain the qualified personnel necessary for the development of its business. The Company faces competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and research institutions. The failure to attract and retain key scientific and technical personnel would have a material adverse effect on the development of the Company's business and our ability to develop, market and sell our products.

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

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

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procedures, controls and resources is further heightened by the fact that our executive office and operational development facilities are located in separate time zones (New York and Edinburgh, Scotland, respectively).

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

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

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is directed to the treatment of chronic myelogenous leukemia ("CML") using specific doses of Clofarabine. We do not believe that we will infringe this patent. If this patent is asserted against us, even though we may be successful in defending against such an assertion, our defense would require substantial financial and human resources. And, we may need a license to this patent to use the claimed dose in the treatment of CML. However, we do not know if such a license is available at commercially reasonable terms, if at all.

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

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delays in, developing, manufacturing or marketing one or more products.

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

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

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

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

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

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

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

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

We consummated a private placement transaction on March 22, 2004,

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pursuant to which we raised \$12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of \$7.50 per share. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional \$3.5 million in the second tranche closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of \$7.50 per share. However, we may need additional financing to continue to fund the research and development of our products and to generally expand and grow our business. For example, we will need to employ a European sales force within the next twelve months to capitalize on the commercial potential for Clofarabine and Modrenal if and to the extent our lead drugs are at market in Europe in the first half of 2005. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders 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, 2004, we had stockholders' equity of \$26,743,344 and net working capital of \$17,197,041.

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 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.

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

Our products may be subject to recall.

Product recalls may be issued at our discretion or by the FDA, the FTC or other government agencies having regulatory authority for product sales. Product recalls, if any in the future, may harm our reputation and cause us to

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lose development opportunities, or customers or pay refunds. Products may need to be recalled due to disputed labeling claims, manufacturing issues, quality defects, or other reasons. We do not carry any insurance to cover the risk of potential product recall. Any product recall could have a material adverse effect on us, our prospects, our financial condition and results of operations.

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

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

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### DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

We have made statements under the captions "Risk Factors," and in other sections of this prospectus that are forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue," the negative of these terms and other comparable terminology. These forward-looking statements which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, or anticipated growth strategies and anticipated trends in our business. These statements are only predictions based on our current expectations and projections about future events. There are important factors that could cause our actual results, level

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of activity, performance or achievements to differ materially from the results, level of activity, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed under the section entitled "Risk Factors." You should specifically consider the numerous risks outlined under "Risk Factors." Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness or any of these forward-looking statements.

### USE OF PROCEEDS

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

Expenses we are expected to incur in connection with this registration are estimated at approximately \$150,000. The selling stockholders will pay all of their underwriting commissions and discounts and counsel fees and expenses in connection with the resale of the shares covered by this prospectus.

### DESCRIPTION OF SECURITIES

#### Description of Common Stock

Number of Authorized and Outstanding Shares. Our Certificate of Incorporation authorizes the issuance of 50,000,000 shares of common stock, \$.001 par value per share, of which 28,316,163 shares were outstanding on June 11, 2004. All of the outstanding shares of common stock are fully paid and non-assessable.

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

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

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

#### Description of Preferred Stock

Number of Authorized Shares. Our certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, par value \$.001 per share, in one or more series with such limitations and restrictions as may be determined in the sole discretion of our board of directors, with no further authorization by stockholders required for the creation and issuance thereof.

We have designated 5,920,000 shares of our preferred stock as Series A convertible preferred stock, of which 3,341,666 shares were issued and outstanding as of June 11, 2004. The holders of the Series A convertible preferred stock vote as a single class with the common stock, on an as-converted basis, on all matters upon which the holders of the common stock are entitled to vote. Each outstanding share of Series A convertible preferred stock may currently be converted into two shares of common stock, at the conversion price of \$1.50 per share. The shares of Series A convertible preferred stock shall be automatically convertible into shares of common stock if the market price of the common stock after one year from the date of issuance is \$10.00 or more for 30 consecutive trading days and the trading volume is at least 150,000 shares per trading day during such 30-day period. Holders of Series A convertible preferred stock have a liquidation preference over holders of common stock of \$3.00 per share. Holders of the Series A convertible preferred stock are entitled to an annual 5% dividend which may be paid in cash or additional shares of common stock in our sole discretion.

#### Warrants

As of June 11, 2004, there were outstanding warrants to purchase an aggregate of 9,079,242 shares of our common stock, exercisable at prices ranging from \$1.25 to \$7.50 per share. The weighted average exercise price of the warrants is \$2.51.

#### Stock Options

As of June 11, 2004, there were outstanding options to purchase an aggregate of 4,405,000 shares of our common stock, exercisable at prices ranging from \$0.735 to \$6.50 per share, of which, options to purchase 3,103,334 shares were exercisable. The weighted average exercise price of the options is \$1.64.

#### SELLING STOCKHOLDERS

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

the name of each selling stockholder;

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

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

the number and percentage of shares of common stock that will be



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beneficially owned by each selling stockholder following the offering to which this prospectus relates.

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

For purposes of the table below, the number of shares "beneficially owned" are those beneficially owned as determined under the rules of the SEC. Such information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power and any shares for which the person has the right to acquire such power within 60 days through the exercise of any option, warrant or right, through conversion of any security or pursuant to the automatic termination of a power of attorney or revocation of a trust, discretionary account or similar arrangement. Percentages in the table below are based on 28,316,163 shares of our common stock outstanding as of June 11, 2004.

| Name  | Shares<br>Owned Prior to<br>the Offering<br>----- |                  | Number of Shares<br>which may be Sold<br>in This Offering<br>----- |
|---|---|------------------|--|
|   | Number<br>-----                                   | Percent<br>----- |  |
| Perseus-Soros BioPharmaceutical<br>Fund, LP (1)     | 9,450,053   | 25.27%           | 9,450,053  |
| Caduceus Private Investments,<br>LP (2)             | 2,110,410   | 6.96%            | 2,110,410  |
| OrbiMed Associates LLC (2)                          | 43,928  | *                | 43,928   |
| PW Juniper Crossover Fund,<br>L.L.C. (2)            | 995,698   | 3.40%            | 995,698  |
| Special Situations Private<br>Equity Fund, L.P. (3) | 250,000   | *                | 250,000  |
| Xmark Fund, L.P. (4)                                | 144,999   | *                | 144,999  |
| Xmark Fund, Ltd. (5)                                | 354,999   | 1.24%            | 354,999  |
| SDS Merchant Fund, LP (6)                           | 380,001   | 1.32%            | 380,001  |
| Orion Biomedical Offshore<br>Fund, LP (7)           | 133,875   | *                | 133,875  |
| Orion Biomedical Fund, LP (8)                       | 616,125   | 2.13%            | 616,125  |
| Beaver Ltd. (9)                                     | 75,000  | *                | 75,000   |
| CKH Invest Aps. (10)                                | 50,001  | *                | 50,001   |
| Merlin Biomed Private Equity<br>Fund LP (11)        | 1,025,617   | 3.50%            | 1,025,617  |
| Alexandra Global Master Fund, ltd. (12)             | 310,666   | 1.09%            | 310,666  |
| DWS Investment GmbH (13)                            | 1,360,600   | 4.59%            | 1,360,600  |
| Michael Sistenich (14)                              | 125,001   | *                | 125,001  |
| Global Biotechnology Fund (15)                      | 209,369   | *                | 209,369  |
| Oklahoma Medical Research<br>Foundation (16)        | 300,000   | 1.05%            | 300,000  |
| Christopher B. Wood (17)                            | 3,805,258   | 13.60%           | 3,638,592  |
| Julie Wood (17)                                     | 318,750   | 1.13%            | 318,750  |
| Stuart Smith (18)                                   | 700,000   | 2.43%            | 700,000  |
| Thomas Nelson (19)                                  | 287,523   | 1.01%            | 287,523  |
| Kevin Leech (20)                                    | 1,900,000   | 6.59%            | 500,000  |

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|                               |           |       |         |
|-------------------------------|-----------|-------|---------|
| Bioaccelerate, Inc. (21)      | 1,227,272 | 4.26% | 500,000 |
| Sterling Securities Ltd. (21) | 74,045    | *     | 74,045  |
| Carpe DM, Inc. (21)           | 59,058    | *     | 59,058  |

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|   |           |        |           |
|---|-----------|--------|-----------|
| Michelle Tidball (21)                           | 254,114   | *      | 254,114   |
| Weil Consulting Corporation (21)                | 75,000    | *      | 75,000    |
| Kingsley Securities Ltd. (21)                   | 124,544   | *      | 124,544   |
| Fontenelle LLC (21)                             | 50,000    | *      | 50,000    |
| Jano Holdings, Ltd. (22)                        | 250,000   | *      | 250,000   |
| George Margetts (23)                            | 100,000   | *      | 100,000   |
| Nagy Habib (24)                                 | 50,000    | *      | 50,000    |
| NAB Holdings Ltd. (21) (25)                     | 478,247   | 1.68%  | 478,247   |
| SCO Capital Partners LLC (26), (28)             | 7,009,946 | 24.67% | 7,009,946 |
| SCO Financial Group LLC (26), (28)              | 100,000   | *      | 100,000   |
| SCO Securities LLC (26), (28)                   | 260,290   | *      | 260,290   |
| Daniel DiPietro (30)                            | 50,000    | *      | 50,000    |
| Jeremy Kaplan                                   | 10,000    | *      | 10,000    |
| Joshua Golumb                                   | 10,000    | *      | 10,000    |
| The Sophie C. Rouhandeh Trust (26)              | 150,000   | *      | 150,000   |
| The Chloe H. Rouhandeh Trust (26)               | 150,000   | *      | 150,000   |
| Jeffrey B. Davis (27), (28), (30)               | 749,243   | 2.62%  | 749,243   |
| David Berstein (28)                             | 269,200   | *      | 269,200   |
| Eugene Zurlo (28)                               | 282,900   | 1.00%  | 282,900   |
| Robert J. Donohoe (28)                          | 282,400   | 1.00%  | 282,400   |
| Al-Midani Investment Company Limited (28)       | 14,629    | *      | 14,629    |
| Community Investment Partners (28)              | 2,560     | *      | 2,560     |
| Oakwood Investors I, LLC (28)                   | 10,240    | *      | 10,240    |
| Gutrafin, Ltd. (28)                             | 14,629    | *      | 14,629    |
| Edward W. Kelly (28), (29)                      | 356,013   | 1.26%  | 356,013   |
| RRD International, Inc. (31)                    | 175,000   | *      | 175,000   |
| RLB Capital, Inc. (32)                          | 100,000   | *      | 100,000   |
| Stamford Capital (33)                           | 60,000    | *      | 60,000    |
| Palladin Opportunity Fund LLC                   | 13,632    | *      | 13,632    |
| SDS Capital Group SPC, Ltd. (34)                | 159,802   | *      | 159,802   |
| Baystar Capital II, L.P. (35)                   | 60,000    | *      | 60,000    |
| North Sound Legacy Fund, LLC (36)               | 1,440     | *      | 1,440     |
| North Sound Legacy Institutional Fund, LLC (37) | 15,840    | *      | 15,840    |
| North Sound Legacy International Fund, LLC (38) | 30,720    | *      | 30,720    |
| Vertical Ventures, LLC (39)                     | 115,200   | *      | 115,200   |
| Iroquois Capital LP (40)                        | 76,800    | *      | 76,800    |
| Alpha Capital AG (41)                           | 96,000    | *      | 96,000    |
| Merlin Nexus I (42)                             | 48,000    | *      | 48,000    |
| Millenium Partners LP (43)                      | 120,000   | *      | 120,000   |
| Jennison Health Sciences Fund (44)              | 288,000   | 1.02%  | 288,000   |
| BioPharmaceutical Portfolio (45)                | 30,240    | *      | 30,240    |
| MP BioPharmaceutical Partners, L.P. (46)        | 16,680    | *      | 16,680    |
| MP BioPharmaceutical Fund Ltd. (47)             | 68,880    | *      | 68,880    |
| MP BioPharm Market-Neutral, L.P. (48)           | 4,200     | *      | 4,200     |
| Silveroak Invenstments, Inc. (49)               | 48,000    | *      | 48,000    |
| SF Capital Partners Ltd. (50)                   | 288,000   | 1.02%  | 288,000   |
| Perceptive Lifesciences Master Fund, Ltd. (51)  | 216,000   | *      | 216,000   |
| Cranshire Capital, L.P. (52)                    | 48,000    | *      | 48,000    |

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|   |                |   |                |
|---|----------------|---|----------------|
| Quogue Capital LLC (53)                         | 84,000         | * | 84,000         |
| Meditor Master Curra Fund Limited (54)          | 192,000        | * | 192,000        |
| Atlas Equity I, Ltd. (55)                       | 120,000        | * | 120,000        |
| Steve Oliviera (56)                             | 24,000         | * | 24,000         |
| SRG Capital LLC (57)                            | 24,000         | * | 24,000         |
| StoneStreet LP (58)                             | 60,000         | * | 60,000         |
| DKR Soundshore Oasis Holding Company, Ltd. (59) | 48,000         | * | 48,000         |
| <br>Total                                       | <br>40,044,637 |   | <br>37,750,699 |

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

(1) Includes 3,000,000 shares of Series A Preferred Stock currently convertible into 6,000,000 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 3,000,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002. Also includes 375,044 common shares and a warrant to purchase 75,009 shares of common stock exercisable at \$7.50 for five years from May 13, 2004. Based upon information contained in its report on Schedule 13D filed with the Commission on May 20, 2002 and amended on January 8, 2003, Perseus-Soros BioPharmaceutical Fund, L.P. reported that Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners may be deemed to have sole power to direct the voting and disposition of the 9,000,000 shares of common stock. By virtue of the relationships between and among Perseus-Soros BioPharmaceutical Fund, L.P., Perseus-Soros Partners, LLC, Perseus BioTech Fund Partners, LLC, SFM Participation, L.P., SFM AH, LLC, Frank H. Pearl, George Soros, Soros Fund Management LLC, Perseus EC, LLC, Perseuspur, LLC, each of such Perseus entities, other than Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners, may be deemed to share the power to direct the voting and disposition of the

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9,000,000 shares of common stock. After the company's May 2002 financing, Perseus-Soros named two individuals to the company's board of directors.

(2) Includes 669,964 shares of Series A Preferred Stock currently convertible into 1,339,928 shares of common stock at a conversion price of \$1.50, a warrant to purchase 669,964 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, 83,765 common shares and a warrant to purchase 16,753 shares of common stock exercisable at \$7.50 for five years from May 13, 2004 all of which are held by Caduceus Private Investments, LP; 13,945 shares of Series A Preferred Stock currently convertible into 27,980 shares of common stock at a conversion price of \$1.50, a warrant to purchase 13,945 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, 1,744 common shares and a warrant to purchase 349 shares of common stock exercisable at \$7.50 for five years from May 13, 2004, all of which are held by OrbiMed Associates LLC; and 316,091 shares of Series A Preferred Stock currently convertible into 632,182 shares of common stock at a conversion price of \$1.50, a warrant to purchase 316,091 shares of common stock exercisable at \$2.00 per share for five years

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from May 16, 2002, 39,521 common shares and a warrant to purchase 7,904 shares of common stock exercisable at \$7.50 for five years from May 13, 2004, all of which are held by 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 shares of common stock.

- (3) Warrant to purchase 250,000 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (4) Includes 48,333 shares of Series A Preferred Stock currently convertible into 96,666 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 48,333 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (5) Includes 118,333 shares of Series A Preferred Stock currently convertible into 236,666 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 118,333 shares of common stock exercisable at \$3.00 per share for five years from May 8, 2002.
- (6) Includes 106,667 shares of Series A Preferred Stock currently convertible into 213,334 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 166,667 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (7) Includes 44,625 shares of Series A Preferred Stock currently convertible into 89,250 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 44,625 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (8) Includes 205,375 shares of Series A Preferred Stock currently convertible into 410,750 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 205,375 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002.
- (9) Includes 25,000 shares of Series A Preferred Stock currently convertible into 50,000 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 25,000 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002.
- (10) Includes 16,667 shares of Series A Preferred Stock currently convertible into 33,334 shares of common stock at a conversion price of \$1.50 and a warrant to purchase 16,667 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002.
- (11) Includes 333,334 shares of Series A Preferred Stock currently convertible into 666,668 shares of common stock at a conversion price of \$1.50; warrant to purchase 333,334 shares of common stock exercisable at \$2.00 per share for five years from March 22, 2002; 21,346 shares of common stock and a warrant to purchase 4,269 shares of common stock at \$7.50 per share for five years from March 22, 2004. Based upon information contained in its report on Schedule 13G filed with the Commission on June 28, 2002, Merlin BioMed Private Equity Fund, L.P. reported that it shares the power to direct the voting and disposition of its shares of common stock with Merlin BioMed Private Equity, LLC, its general partner and Dominique Semon, who is the sole managing member of the general partner.

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- (12) Includes 120,000 common shares; a warrant to purchase 166,666 shares of common stock exercisable at \$2.00 per share for five years from May 8, 2002; and a warrant to purchase 24,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (13) Includes 433,333 shares of Series A Preferred Stock currently convertible into 866,666 shares of common stock at a conversion price of \$1.50, a warrant to purchase 433,333 shares of common stock exercisable at \$2.00 per share for five years from May 14, 2002, 50,501 common shares and a warrant to purchase 10,100 shares of common stock exercisable at \$7.50 for five years from May 13, 2004. Deutsche Bank AG has sole voting and investment power with respect to these shares.
- (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. Also includes 7,809 common shares and a warrant to purchase 1,562 shares of common stock exercisable at \$7.50 for five years from May 13, 2004.
- (16) Under the terms of an amendment to a license agreement with Oklahoma Medical Research Foundation, we issued 200,000 shares of common stock, 100,000 of which were sold in October 2003, and a five-year warrant to purchase an additional 200,000 shares of common stock. Such warrant to purchase 200,000 shares of common stock is exercisable at \$2.33 per share for five years from May 14, 2002.
- (17) Dr. Wood is Chairman and Chief Executive Officer of the Company. Excludes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest, and 166,666 options which are exercisable at \$1.45 per share from December 31, 2003.
- (18) Includes options to acquire 500,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (19) Includes options to acquire 200,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001.
- (20) These shares are owned of record by Phoenix Ventures Limited, a Channel Islands (Jersey) corporation, which, to our knowledge, is wholly-owned by Kevin Leech. These shares include 500,000 options which are exercisable at \$1.25 per share for the benefit of Phoenix.
- (21) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors and includes options to acquire 500,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001. On October 8, 2003, certain options originally issued to Bioaccelerate, Inc. were transferred as follows:
- (i) NAB Holdings Ltd. received options to purchase 500,000 shares of common stock, 350,000 of which were transferred to Michelle Tidball on December 9, 2003;

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- (ii) Sterling Securities Ltd. received options to purchase 100,000 shares of common stock;
- (iii) Carpe DM, Inc. received options to purchase 80,000 shares of common stock;
- (iv) Michelle Tidball received options to purchase 100,000 shares of common stock;
- (v) Kingsley Securities Ltd. received options to purchase 124,544 shares of common stock; and
- (vi) Fontenelle LLC received options to purchase 50,000 shares of common stock, which it exercised in November 2003 for 50,000 shares of common stock.

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

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

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

- (22) Includes an option to purchase 250,000 shares of common stock exercisable at \$1.25 per share for five years from August 8, 2001.
- (23) Includes an option to purchase 100,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (24) Includes an option to purchase 50,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001.
- (25) Includes an option to purchase 450,000 shares of common stock exercisable at \$1.25 per share for five years from April 30, 2001. On December 16, 2003, NAB Holdings Ltd. exercised these options and received 328,247 shares of common stock pursuant to a cashless exercise.
- (26) Includes a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share issued to SCO Financial Group LLC for five years from November 16, 2001. Excludes a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 originally held by SCO Financial Group LLC but transferred to (i) Daniel DiPietro (50,000); (ii) Jeremy Kaplan (10,000); and (iii) Joshua Golumb (10,000). SCO Financial Group LLC serves as financial advisor to the company. SCO Capital Partners LLC extended a \$1 million secured credit line to the company in November

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2001. SCO Securities LLC, a related entity, served as placement agent in the company's May 2002 private placement of Series A Preferred Stock. SCO Securities LLC also acted as placement agent for the company's March 2004 private placement of common stock and received a warrant to purchase 204,452 shares of common stock exercisable at \$6.25 for five years from March 22, 2004 and a warrant to purchase 55,838 shares of common stock exercisable at \$6.25 for five years from May 13, 2004. After the Pathagon acquisition, SCO Financial Group named one individual to the company's board of directors.

- (27) Includes a warrant to purchase 250,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002. Mr. Davis is the President of SCO Financial Group LLC, an affiliate of SCO Capital Partners LLC. Mr. Davis disclaims beneficial ownership of all shares of common stock deemed beneficially owned by SCO Capital Partners LLC.
  - (28) Indicates the selling stockholder was a former stockholder of Pathagon.
  - (29) Mr. Kelly has executed a consulting agreement with us pursuant to which we issued to him 200,000 shares of common stock which vested over an eighteen month period.
  - (30) Indicates the selling stockholder is a current employee of SCO Financial Group LLC.
  - (31) Warrant to purchase 175,000 shares of common stock exercisable at \$2.00 per share for three years from April 2, 2003.
  - (32) Warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share for three years from February 23, 2004.
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- (33) Warrant to purchase 60,000 shares of common stock exercisable at \$2.00 per share for three years from February 23, 2004.
  - (34) Includes 133,168 shares of common stock and warrant to purchase 26,634 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
  - (35) Includes 50,000 shares of common stock and warrant to purchase 10,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
  - (36) Includes 1,200 shares of common stock and warrant to purchase 240 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
  - (37) Includes 13,200 shares of common stock and warrant to purchase 2,640 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
  - (38) Includes 25,600 shares of common stock and warrant to purchase 5,120 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
  - (39) Includes 96,000 shares of common stock and warrant to purchase 19,200 shares of common stock exercisable at \$7.50 per share for five years

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from March 22, 2004.

- (40) Includes 64,000 shares of common stock and warrant to purchase 12,800 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (41) Includes 80,000 shares of common stock and warrant to purchase 16,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (42) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (43) Includes 100,000 shares of common stock and warrant to purchase 20,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (44) Includes 240,000 shares of common stock and warrant to purchase 48,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (45) Includes 25,200 shares of common stock and warrant to purchase 5,040 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (46) Includes 13,900 shares of common stock and warrant to purchase 2,780 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (47) Includes 57,400 shares of common stock and warrant to purchase 11,480 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (48) Includes 3,500 shares of common stock and warrant to purchase 700 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (49) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (50) Includes 240,000 shares of common stock and warrant to purchase 48,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (51) Includes 180,000 shares of common stock and warrant to purchase 36,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (52) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.

- (53) Includes 70,000 shares of common stock and warrant to purchase 14,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.



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- (54) Includes 160,000 shares of common stock and warrant to purchase 32,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (55) Includes 100,000 shares of common stock and warrant to purchase 20,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (56) Includes 20,000 shares of common stock and warrant to purchase 4,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (57) Includes 20,000 shares of common stock and warrant to purchase 4,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (58) Includes 50,000 shares of common stock and warrant to purchase 10,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.
- (59) Includes 40,000 shares of common stock and warrant to purchase 8,000 shares of common stock exercisable at \$7.50 per share for five years from March 22, 2004.

### PLAN OF DISTRIBUTION

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

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

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

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- o an exchange distribution in accordance with the rules of an exchange; through agents;
- o through market sales, both long or short, to the extent permitted under the federal securities laws; or in any combination of these methods.

The sale price to the public may be:

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

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

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

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

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

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

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

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

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

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

The selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may also sell the shares directly to market makers acting as principals and/or broker-dealers acting as agents for themselves or their customers. These broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom these

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broker-dealers may act as agents or to whom they sell as principal or both, which compensation as to a particular broker-dealer might be in excess of customary commissions. Market makers and block purchasers purchasing the shares will do so for their own account and at their own risk. It is possible that the selling stockholders will attempt to sell shares of common stock in block transactions to market makers or other purchasers at a price per share which may be below the then market price. The selling stockholders cannot assure that all or any of the shares offered by this prospectus will be issued to, or sold by, the selling stockholders if they do not exercise or convert the common stock equivalents that they own. The selling stockholders and any brokers, dealers or agents, upon effecting the sale of any of the shares offered by this prospectus, may be deemed "underwriters" as that term is defined under the securities act or the exchange act, or the rules and regulations under those acts. In that event, any commissions received by the broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the securities act.

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

- o the number of shares being offered;
- o the terms of the offering, including the name of any selling stockholder, underwriter, broker, dealer or agent;

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

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

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

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

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

We have agreed to indemnify the selling stockholders, or their respective transferees or assignees, against certain liabilities, including liabilities under the securities act, or to contribute to payments that the

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selling stockholders or their respective pledgees, donees, transferees or other successors in interest, may be required to make in respect of those liabilities.

### LEGAL PROCEEDINGS

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleged a breach of contract by the Company and demanded judgment against the Company for \$112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary

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judgment and RLB filed its response on October 27, 2003. On November 12, 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. In March 2004, the complaint and two counterclaims asserted by the Company were dismissed with prejudice.

On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the "Tessman Defendants") in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously .

DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

The names, ages as of June 11, 2004 and existing positions with the Company, if any, are as follows:

| Name of Individual<br>-----  | Age<br>--- | Position with Bioenvision<br>-----                |
|------------------------------|------------|---|
| Christopher B. Wood, M.D.    | 58         | Chairman of the Board and Chief Executive Officer |
| Jeffrey B. Davis             | 41         | Director  |
| Thomas Scott Nelson, C.A.    | 65         | Director  |
| Steven A. Elms               | 40         | Director  |
| Andrew Schiff, M.D.          | 39         | Director  |
| Michael Kauffman M.D., Ph.D. | 40         | Director  |
| David P. Luci, C.P.A., Esq.  | 37         | Director of Finance, General Counsel and Corporat |
| Hugh S. Griffith             | 36         | Commercial Director (Europe) of Bioenvision, Ltd. |

The name, principal occupation for the last five years, selected biographical information and the period of service to the Company of each director and executive officer is set forth below.

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., a Delaware company. 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. 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, C.A. was named a director in May 1998. Mr. Nelson served as our Chief Financial Officer from May 1998 to September 2002. 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

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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.

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 HemaSure, Inc., 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' primary areas of focus were the genomics and drug discovery technology sectors.

Andrew Schiff, M.D. was named a director in May 2002. Dr. Schiff currently serves as a Managing Director of Perseus-Soros Biopharmaceutical Fund. Over the last 10 years, Schiff has practiced internal medicine 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 since September 1993.

Michael Kauffman M.D., Ph.D. was named a director in January 2004. Dr. Kauffman is currently the President and CEO of Predix Pharmaceuticals. Prior to that he was the Vice President, Medicine, and Proteasome Inhibitor (VELCADE(TM)) Program Leader at Millennium Pharmaceuticals Inc. Prior to that, Dr.

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Kauffman held senior positions at Millennium Predictive Medicine, Inc., as cofounder and Vice President of Medicine, and at Biogen Corporation. Dr. Kauffman received his M.D. and Ph.D. (molecular biology and biochemistry) at Johns Hopkins and his postdoctoral training at Harvard University. He is board certified in internal medicine, and comes with over 10 years of experience in drug discovery and development.

David P. Luci, C.P.A., Esq. has served as Director of Finance, General Counsel and Corporate Secretary since July 2002. From September 1994 to July 2002, Mr. Luci served as a corporate associate at Paul, Hastings, Janofsky & Walker LLP (New York office). Prior to that, Mr. Luci served as a senior auditor at Ernst & Young LLP (New York office). Mr. Luci is a certified public accountant. He 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.

Hugh S. Griffith has served as Commercial Director (Europe) of Bioenvision, Ltd., a wholly-owned sales and marketing subsidiary of the Company since October 2002. From January 2002 to October 2002, Mr. Griffith served as Executive

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Commercial Director of QuantaNova Ltd. From January 2000 to December 2001, Mr. Griffith served as Senior Business Unit Manager at Abbott Laboratories, Ltd. where he was responsible for strategic development, implementation and commercialization of a new neonatology business unit. This role encompassed the management of the sales force, marketing, PR, policy and healthcare liaison teams whilst also directing the clinical development programme for the neonatology portfolio. From April 1998 to January 2000, Mr. Griffith was the HIV Business Unit Manager at Abbott Laboratories Ltd where he was responsible for the profitability of the HIV franchise. Mr Griffith managed the Norvir capsule crisis including the fully comprehensive named patient programme. At Abbott Laboratories Ltd., Mr. Griffith also served as Business Development Manager (July 1997 to April 1998) and as Area Sales Manager (October 1995 to July 1997). Mr. Griffith holds a Masters of Business Administration from Cardiff Business School, a Diploma of Marketing and a Bachelor of Science in Honours Biology from University of Stirling.

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### 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 11, 2004, 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 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.

| NAME   | BENEFICIAL OWNERSHIP<br>OF STOCK | CURRENT PERCENTAGE OF<br>CLASS (1) |
|--|----------------------------------|------------------------------------|
| Perseus-Soros Biopharmaceutical<br>Fund, LP (2)<br>888 Seventh Avenue, 29th Floor<br>New York, New York 10106..... | 9,450,053                        | 26.94%                             |
| OrbiMed Advisors Inc. (3)<br>767 Third Avenue, 30th Floor<br>New York, New York 10017.....                         | 3,150,036                        | 10.81%                             |
| SCO Capital Partners LLC (4)<br>1285 Avenue of the Americas, 35th Floor<br>New York, New York 10019.....           | 7,370,236                        | 27.85%                             |

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|  |           |        |
|--|-----------|--------|
| Kevin Leech (5)<br>The Old Chapel<br>Sacre Couer<br>Rouge Boullion<br>St Helier<br>Jersey, Channel Islands.....          | 1,900,000 | 7.17%  |
| Bioaccelerate, Inc. (6)<br>PO Box 3175<br>Road Town<br>Tortolla<br>British Virgin Islands.....                           | 1,227,272 | 4.63%  |
| Christopher B. Wood, M.D. (7)<br>c/o Bioenvision, Inc.<br>509 Madison Avenue, Suite 404<br>New York, New York 10022..... | 3,805,258 | 14.00% |

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|   |         |       |
|---|---------|-------|
| David P. Luci (8)<br>c/o Bioenvision, Inc.<br>509 Madison Avenue, Suite 404<br>New York, New York 10022.....            | 280,000 | 1.07% |
| Hugh Griffith (9)<br>c/o Bioenvision, Inc.<br>509 Madison Avenue, Suite 404<br>New York, New York 10022.....            | 100,000 | *     |
| Thomas Scott Nelson (10)<br>c/o Bioenvision, Inc.<br>509 Madison Avenue, Suite 404<br>New York, New York 10022.....     | 287,523 | 1.09% |
| Jeffrey B. Davis (11)<br>1285 Avenue of the Americas, 35th Floor<br>New York, New York 10019.....                       | 749,243 | 2.85% |
| Steven A. Elms<br>888 Seventh Avenue, 29th Floor<br>New York, New York 10106.....                                       | 0       | *     |
| Andrew N. Schiff, M.D.<br>888 Seventh Avenue, 29th Floor<br>New York, New York 10106.....                               | 0       | *     |
| Michael Kauffman M.D., Ph.D.<br>c/o Bioenvision, Inc.<br>509 Madison Avenue, Suite 404<br>New York, New York 10022..... | 0       | *     |



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|   |           |        |
|---|-----------|--------|
| All Executive Officers and Directors as a group (eight persons) (12)..... | 5,222,024 | 18.16% |
|---|-----------|--------|

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 \* Represents holdings of less than one percent (1%).

- (1) Based on a total of 26,002,829 shares of common stock outstanding as of May 18, 2004.
  
- (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. Also includes 375,044 common shares and a warrant to purchase 75,009 shares of common stock exercisable at \$7.50 for five years from May 13, 2004. Based upon information contained in its report on Schedule 13D filed with the Commission on May 20, 2002, Perseus-Soros BioPharmaceutical Fund, L.P. reported that Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners may be deemed to have sole power to direct the voting and disposition of the 9,000,000 shares of common stock. By virtue of the relationships between and among Perseus-Soros BioPharmaceutical Fund, L.P., Perseus-Soros Partners, LLC, Perseus BioTech Fund Partners, LLC, SFM Participation, L.P., SFM AH, Inc., Frank H. Pearl, George Soros, Soros Fund Management LLC, Perseus EC, LLC, Perseuspur, LLC, each of such Perseus entities, other than Perseus-Soros BioPharmaceutical Fund, L.P. and Perseus-Soros Partners, may be deemed to share the power to direct the voting and disposition of the 9,000,000 shares of common stock.
  
- (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, a warrant to purchase 669,964 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, 83,765 common shares and a warrant to purchase 16,753 shares of common stock exercisable at \$7.50 for five years from May 13, 2004 all of which are held by Caduceus Private Investments, LP; 13,945 shares of Series A Preferred Stock currently convertible into 27,980 shares of common stock at a conversion price of \$1.50, a warrant to purchase 13,945 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, 1,744 common shares and a warrant to purchase 349 shares of common stock exercisable at \$7.50 for five years from May 13, 2004, all of which are held by OrbiMed Associates LLC; and 316,091 shares of Series A

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Preferred Stock currently convertible into 632,182 shares of common stock at a conversion price of \$1.50, a warrant to purchase 316,091 shares of common stock exercisable at \$2.00 per share for five years from May 16, 2002, 39,521 common shares and a warrant to purchase 7,904 shares of common stock exercisable at \$7.50 for five years from May 13, 2004, all of which are held by 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 shares of common stock.

- (4) Includes a warrant to purchase 100,000 shares of common stock exercisable at \$1.25 per share issued to SCO Financial Group LLC for five years from

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November 16, 2001. Excludes a warrant to purchase 70,000 shares of common stock exercisable at \$1.50 per share for five years from May 8, 2002 originally held by SCO Financial Group LLC but transferred to (i) Daniel DiPietro (50,000); (ii) Jeremy Kaplan (10,000); and (iii) Joshua Golumb (10,000). SCO Financial Group LLC serves as financial advisor to the company. SCO Capital Partners LLC extended a \$1 million secured credit line to the company in November 2001. SCO Securities LLC, a related entity, served as placement agent in the company's May 2002 private placement of Series A Preferred Stock. SCO Securities LLC also acted as placement agent for the company's March 2004 private placement of common stock and received a warrant to purchase 204,452 shares of common stock exercisable at \$6.25 for five years from March 22, 2004 and a warrant to purchase 55,838 shares of common stock exercisable at \$6.25 for five years from May 13, 2004. After the Pathagon acquisition, SCO Financial Group named one individual to the company's board of directors.

- (5) 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 Ventures Limited.
- (6) Bioaccelerate, Inc. is a BVI corporation, owned of record by several private investors and includes options to acquire 500,000 shares of the common stock which are exercisable at \$1.25 per share for five years from April 30, 2001. 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.
- (7) Dr. Wood is Chairman and Chief Executive Officer of the Company. Excludes 318,750 shares of common stock owned by Julie Wood, Dr. Wood's spouse, as to which Dr. Wood disclaims any beneficial interest. Includes 1,500,000 options which are exercisable at \$1.25 for five years from April 30, 2001 and 166,666 options which are exercisable at \$1.45 per share from December 31, 2003.
- (8) Includes options to acquire 170,000 shares of common stock which are exercisable at \$0.735 per share from March 31, 2003 and 110,000 options which are exercisable at \$0.74 per share from March 31, 2004.
- (9) Includes options to acquire 100,000 shares of the common stock which are exercisable at \$1.45 per share for five years from October 23, 2003.
- (10) 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.
- (11) 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.
- (12) Includes options to purchase 2,496,666 shares of common stock, and a warrant to purchase 250,000 shares of common stock.

### LEGAL MATTERS

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

EXPERTS

Our auditors are Grant Thornton LLP. Our consolidated financial statements as at and for the years ended June 30, 2003 and June 30, 2002 appearing in this registration statement have been audited by Grant Thornton LLP as set forth in their report dated September 22, 2003, appearing elsewhere in this Prospectus, and are included in reliance upon such report given upon the authority of this firm as experts in accounting and auditing.

WHERE YOU CAN GET MORE INFORMATION

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

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

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

DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT  
LIABILITIES

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

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

DESCRIPTION OF BUSINESS

Bioenvision is 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 lead products have the following competitive advantages over existing products at market:

Modrenal (R) (emerging endocrine resistance technology)

- o Novel mode of action on estrogen receptors
- o Increases estrogen binding to ER(beta) resulting in decreased cancer cell proliferation
- o 35% overall clinical benefit rate in multi-center clinical trial: meta-analysis of 714 patients with advanced progressive post-menopausal breast cancer
- o 55% clinical benefit rate in patients who have become resistant to tamoxifen therapy
- o Possible synergistic combination therapy with tamoxifen
- o Phase II clinical trial commencing in prostate cancer Q2 of calendar 2004

Clofarabine (purine nucleoside anti

- o Next generation, halogenated-pu to overcome the limitations and both fludarabine (Fludara(R)) a
- o Multiple Mechanisms of Action:
  - o Potent Inhibition of DNA Sy dividing cancer cells).
  - o Induces Apoptotic (cell dea cancer cells).
- o Potent ability to kill cancer o including leukemia, non-small o renal, prostate, and breast can
- o Significant clinical benefit de adult leukemias:
  - o Overall response rates in r leukemias of between 25% an
  - o Overall response rates in r myeloid leukaemia (AML) and blast crisis (CML-BP) of be
- o Solid tumor studies initiated w intravenous formulations of Clo

Anti-Cancer Product Portfolio

Our anti-cancer product portfolio includes three products, Modrenal (R), Clofarabine, Gossypol, used or which may be useful in eight indications and one technology, Gene Therapy, which may be useful in two indications.

Modrenal (R)

We have the exclusive right to market and distribute Modrenal (R) (trilostane) throughout the world for all human applications. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the marketing of Modrenal (R). Given that we have new patent applications filed which are subject to issuance, we expect the last to expire of our underlying patents will be 2020.

Modrenal (R) is currently at market in the United Kingdom for the treatment of women with advanced post menopausal breast cancer. We have a very small marketing team that markets Modrenal (R) in the United Kingdom, and we record revenues accordingly.

Modrenal is in Phase II clinical studies in prostate cancer trials, and in Q2-Q3 2004, we intend to commence a Phase IV study in postmenopausal breast cancer and a Phase II study in pre-menopausal breast cancer.

Clofarabine

We have the exclusive right to manufacture, market and distribute Clofarabine for all human applications in all areas of the world other than Japan and Southeast Asia. We sublicensed the right to manufacture, market and distribute Clofarabine in the U.S. and Canada to ILEX Oncology, Inc. solely with

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respect to human cancer applications. We maintain our exclusive rights until the last to expire of the patents used or useful in our development and sales efforts which we expect to occur in 2020.

Currently, Clofarabine is in pivotal Phase II Clinical Trials for the treatment of pediatric acute leukemias. The final part of a rolling NDA will be filed with the FDA by early Q2, 2004. The drug has a Fast Track Designation and therefore we expect an FDA ruling by Q3,2004. As indicated in the previous paragraph, ILEX has the rights to market Clofarabine in the U.S. and we would receive a royalty on U.S. annual net sales.

Clofarabine is also in Phase II Clinical Trials in a range of hematological cancers and Phase I clinical trials in solid tumors.

### Gossypol

We have the exclusive world-wide right to manufacture and market an optical isomer of gossypol for human and veterinary applications. Currently gossypol, to which we have ascribed the provisional trade name of Velostan, is completing the manufacturing process. We have developed a novel method of separating the enantiomers of gossypol and we are seeking patent protection for the process. We expect to initiate Phase I clinical trials with the drug in Q2, 2004. The primary indication we are targeting for the drug is in bladder cancer, although the drug may show efficacy in other tumor indications

### Gene Therapy

We have the exclusive world-wide right to develop products from a gene therapy platform technology. To date, we have incorporated three human genes into the proprietary technology and we have tested two of these in preliminary clinical trials, with the emphasis on the treatment of patients with end-stage liver disease. Management believes the technology may also have application in patients undergoing chemotherapy for cancer. We maintain our exclusive rights until the last to expire of the patents which we expect to occur in 2017.

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### Non-Cancer Product Portfolio

Our non-cancer product portfolio is as follows:

#### Oligon(R) and Methylene Blue

We have the exclusive world-wide right to manufacture and market an anti-infective technology for the use of thiazine dyes, including Methylene Blue, and for other anti-infective uses. With the acquisition of Pathagon in February 2002, we acquired the exclusive worldwide license to this technology and license this technology from Oklahoma Medical Research Foundation. We maintain our exclusive license until the last to expire of the underlying patents. Currently, there are six patents issued in the U.S. and additional patents have been filed in the U.S., Europe, Canada and Japan.

We have sub-licensed the right to market the technology in the U.S. to Edwards Lifesciences which is currently marketing the technology in its line of short-term vascular access catheters. Bioenvision earns a nominal royalty on annual net sales from Edwards Lifesciences.

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### Products and Technologies

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. These studies were conducted by MD Anderson Cancer Center on behalf of the Company, ILEX and several United States hospitals involved with ILEX clinical studies. 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, pursuant to which we granted Ilex an option on a sub-license to make, sell and distribute Clofarabine in the United States and Canada, subject to successful completion of certain milestones. Clofarabine has successfully completed Phase I/II clinical trials at M.D. Anderson Cancer Center, Houston, Texas. 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 M.D. Anderson Cancer Center and other leading cancer centers in the U.S. and Europe and the encouraging results from the Phase I, early Phase II studies and current Phase II studies lead us to be enthusiastic for the prospects of Clofarabine reaching the market, possibly as soon as the third quarter of calendar year 2004. The United States Food and Drug Administration recently indicated that it would review Clofarabine for the treatment of refractory or relapsed ALL in children more quickly than normal after having granted "fast track" status to Clofarabine. "Fast track" status means that the FDA will start reviewing clinical trial data even before the entire New Drug Application ("NDA") is complete. The FDA could complete its review within six months rather than the normal 12 month review period. We believe the set of clinical data from the current Phase II clinical trials could serve as the basis for a marketing application, which we believe could be filed as early as April 2004.

ILEX is obligated to pay us royalties on US and Canadian annual net sales of Clofarabine on a sliding scale from 5.25% to 11.25%. The minimum royalty of 5.25% applies to annual net sales of up to \$30 million per year and the maximum 11.25% royalty rate applies to annual net sales at or above \$500 million per year. SRI receives royalties on the same scale of US and Canadian annual net sales from 3.5% to 7.5% from each of Bioenvision and ILEX. We pay royalties to each of SRI and ILEX in the amount of 3.5% to 7.5% on the same scale as applies to the ILEX royalty payment obligations noted above. ILEX also is responsible for 50% of our research and development costs associated with Clofarabine development in the Territory (worldwide outside of Japan and Southeast Asia) other than the US and Canada.

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. The current projected expiration date of the license is March 2021. We currently are developing Clofarabine for the treatment of leukemia and lymphoma and we plan to study its potential role in treatment of solid tumors. In August 2003, SRI granted us an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

Pre-clinical and clinical testing of Clofarabine demonstrated that the drug has anti-tumor activity against a range of human and animal cancers, including hematological malignancies and several solid tumors. Approximately 360 people participated in this clinical testing. In addition, Clofarabine has been shown to have good oral bioavailability, and in conjunction with ILEX, we have developed and expect to complete an oral formulation for Clofarabine prior to December 2003. 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 M.D. Anderson Cancer Center, interim Phase II study results showed that 45% of adults with acute myelogenous leukemia (AML) achieved a complete remission (CR) rate, and acute lymphocytic leukemia (ALL) patients achieved a 20% CR rate when treated with Clofarabine as a single agent. Data from a separate Phase I dose-escalation study demonstrated a 25% 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 U.S. and are planned to commence in Europe later this calendar 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 four weeks. In this context, a response, or partial response, has largely the same meaning, except that the bone marrow may still contain more than five percent but less than 25% 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 manner 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, are exploring 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) because Fludarabine, like Clofarabine, is in the same class of compounds, known as

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purine nucleoside analogs, with similar mechanisms of action in that they both work by damaging DNA in a cancer cell. Public reports indicate that Fludarabine, used in combination with a cyclophosphamide agent, blocks enzymes which promote cancer cell growth. Because Clofarabine and Fludarabine are in the same class of cancer agents with similar modes of action, we believe use of Clofarabine in combination with DNA damaging agents may have the same effect as with Fludarabine.

**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

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have changed very little in the past 50 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 usually is required. We intend to develop Clofarabine, or a derivative of Clofarabine, as a potential drug for the treatment of advanced colon and prostate cancer.

### Selective Steroid Receptor Modulation Technology

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, has also been approved 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 Modrastane(R). We receive royalty payments from Dechra on sales of trilostane in the veterinary market in Europe.

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



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exists. 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. 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 been treated with trilostane. Of these 800 patients, 87 of them were given the drug in the United States as part of an FDA-approved trial. Its anti-tumor activity has been well documented and the drug has been shown to produce tumor response rates (i.e. arrest the growth of the tumor) of up to 55% 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% in this group of patients. This compares to a response rate of about 30-35% with currently marketed aromatase inhibitors and approximately 25% 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 good manufacturing practices. We have no plans to establish our own manufacturing facility for trilostane, but will continue to use third-party contractors.

We launched Modrenal(R) in May 2003 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 and hormone independent prostate cancers. 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

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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 11 clinical trials to date, with a total of 783 patients tested, in the United States, Europe and Australia 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. In the view of several clinicians and investigators familiar with Modrenal's mode of action, Modrenal(R) is most effective 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 manner 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 pricing strategy should result in cost benefits for physicians, patients and health-care systems.

Anti-Estrogen Prostate. We have received Institutional Review Board 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 and currently is intended to commence in October 2003.

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 also plan to 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 extend broadly 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.

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### OLIGON(R) Technology

With the acquisition of Pathagon in February 2002, we acquired patents, technology and technology patents 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 a third party, which is currently marketing the technology in its line of short-term vascular access catheters.

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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, \$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) devices will be marketed as next generation products into large existing markets. 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 surfaces of implanted devices over long periods of time. OLIGON(R) effectively addresses these requirements.

### Methylene Blue Technology

We have licensed from Oklahoma Medical Research Foundation the rights to use 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. Currently, we do not derive any revenues from its commercial use.

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

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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 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. Separately, in May 2003, we granted to Dechra Pharmaceuticals, PLC, an affiliate of Arnolds Ltd., the exclusive right to market the drug in the United States for \$5.5 million of total consideration (including milestone payments) and a royalty of 2%-4% of annual net sales.

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### 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. Also, we will rely upon trade secrets, know-how, continuing technological

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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 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.

As a result of the licenses described above, we are the exclusive licensee or sublicensee of three United States patents expiring in 2005, 2008 and 2014 relating to compounds, pharmaceutical compositions and methods of use encompassing clofarbine. We have also filed two United States patent applications relating to the use of clofarbine in autoimmune diseases. Although the basic patents to trilostane have expired, we are the exclusive licensee of several United States and foreign patent applications relating to the use of trilostane alone or in combination with anticancer agents.

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

We intend to establish strategic partnerships for the marketing, sales

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and distribution of our products in North America and certain countries in Europe. As of the date of this annual report on Form 10-KSB, we have one such arrangement in place with Ilex for the co-development and marketing of one of our initial lead products, Clofarabine, and another arrangement with Edwards Lifesciences for the marketing of short-term vascular access catheters using the OLIGON(R) technology. We have also engaged in our own marketing and sales efforts in connection with the marketing and sale of Modrenal(R) in the United Kingdom and upon regulatory authorities' granting mutual recognition with which we intend to apply during calendar 2004, throughout Europe. However, in order to market any of our products effectively, we would need to establish a

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much more integrated 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.

Our marketing policy will be to generate awareness of our products and target the two key audiences for our products - doctors and patients. Medical education will be a priority, with the use of peer-opinion leaders, clinical trials at major centers, satellite symposia and conferences, product advertising in specific scientific journals and trained sales personnel. Patient education is carefully controlled and is important to our marketing approach. Patient education is particularly important because Modrenal(R), our first product for which we have obtained regulatory approval (in the United Kingdom) for marketing for use in a type of cancer treatment, is effective for patients with post-menopausal breast cancer, one of the most common cancers in women. In particular, the drug is approved as follow-on treatment for patients who have previously responded to hormonal therapy.

If the trials of trilostane in prostate cancer prove successful, we will have a drug for treating a cancer found in approximately 180,000 men each year in the United States. We will work with patient help organizations, inform the lay public through consumer journals and television.

### 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 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.

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### 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 these products to be manufactured on a commercial scale; (iii) whether or not 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 scientists currently working on a full-time basis who are involved in research and development activities. We have spent approximately \$1,900,000 and \$1,700,000 on research and development activities in 2002 and 2003, respectively.

### Industry Overview

We believe the biopharmaceutical industry has evolved significantly since its commercial inception in the 1970s and is currently approaching a period of sustained growth. To be successful, we believe biopharmaceutical companies 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 engage in 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 National Cancer Institute 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. Treatment of breast, lung and prostate cancer account for over half the direct medical costs.

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

Forecast Global Cancer Treatment Market 2001 - 2007 (amounts in \$ billions)

| Drug Class        | 2001     | 2002     | 2003     | 2004     | 2005     | 2006     | 2007     |
|-------------------|----------|----------|----------|----------|----------|----------|----------|
| Adjunct therapies | \$11,321 | \$11,834 | \$12,347 | \$12,860 | \$13,373 | \$13,752 | \$14,132 |
| Cytotoxics        | 8,651    | 9,136    | 9,501    | 9,881    | 10,277   | 10,585   | 10,902   |
| Hormonals         | 5,720    | 5,841    | 5,950    | 5,952    | 5,856    | 5,688    | 5,464    |
| Innovative agents | 3,679    | 4,665    | 5,650    | 7,126    | 8,602    | 10,432   | 12,261   |

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|        |          |          |          |          |          |          |          |
|--------|----------|----------|----------|----------|----------|----------|----------|
| TOTALS | \$29,372 | \$31,476 | \$33,448 | \$35,820 | \$38,108 | \$40,457 | \$42,760 |
|        | =====    | =====    | =====    | =====    | =====    | =====    | =====    |

Source: Reuters, 2002

We believe that new cancer therapies increasingly will 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.

With respect to our products and technologies within the overall cancer market, Clofarabine and Gossypol constitute cytotoxic agents and Modrenal constitutes a hormonal agent, in each case, which we believe may have significant market potential both in the U.S. and other parts of the world. Although we have received orphan drug status for Clofarabine in the U.S. and Europe in pediatric and adult acute leukemias, we continue to develop the drug, in conjunction with our U.S. co-development partner, ILEX Oncology, Inc., in other indications with broader markets including solid tumors and combination studies. If Clofarabine demonstrates efficacy in all of these indications, we believe it has potential to be a leading drug in the U.S. and Europe in hematological cancers with widespread use in solid tumors. We believe efficacy data on the use of Gossypol in bladder cancers will be available as early as Q1 2005 upon completion of our initial clinical trial. Modrenal is an approved agent which we market for the treatment of post-menopausal women with advanced breast cancer in the United Kingdom and we anticipate receiving mutual recognition from other European Union member states in Q1 2005. Taken together, we believe this portion of our cancer drug portfolio could create a significant commercial advantage for our company and our stockholders.

### 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.

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



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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

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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, 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.

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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 distributed 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.

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We are 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.

One of Bioenvision's lead drugs, 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<br>(\$m) | 2000<br>(\$m) | 2001<br>(\$m) | Growth<br>2000-01<br>(%) |
|-----------|---------------------------|-------------------|--------------------------|---------------|---------------|---------------|--------------------------|
| BMS       | Taxol                     | Paclitaxel        | Other Cytotoxics         | 1,481         | 1,592         | 1,197         | -2                       |
| Aventis   | Taxotere                  | Docetaxel         | Other Cytotoxics         | 461           | 686           | 925           | 3                        |
| Lilly     | Gemzar                    | Gemcitabine       | Antimetabolite           | 453           | 559           | 723           | 2                        |
| BMS       | Paraplatin                | Carboplatin       | Other Cytotoxics         | 600           | 690           | 702           |                          |
| Pharmacia | Camptosar                 | irinotecan        | Other Cytotoxics         | 293           | 441           | 613           | 3                        |
| Taiho     | UFT                       | tegafur<br>uracil | Antimetabolite           | 460           | 440           | 420e          | -                        |
| Pharmacia | Pharmorubicin/<br>Ellence | cpirubein         | Cytotoxic<br>Antibiotics | 206           | 199           | 261           | 3                        |
| Ivax      | Paxene                    | paclitaxel        | Other Cytotoxics         | n/a           | 35            | 215           | 51                       |
| Roche     | Furtulon                  | doxifluridine     | Antimetabolite           | 166           | 201           | 201           |                          |
| Aventis   | Campro                    | irinotecan        | Other Cytotoxics         | 83            | 139           | 186           | 3                        |
| Sanofi    | Eloxatine                 | oxilaplatin       | Other Cytotoxics         | 72            | 130           | 181           | 3                        |
| SP        | Temodar                   | temozolomide      | Alkylating agents        | 36            | 121           | 180           | 4                        |
| Roche     | Xeloda                    | capecitabine      | Antimetabolite           | 53            | 89            | 155           | 7                        |
| GSK       | Hycarntin                 | topotecan         | Other Cytotoxics         | 141           | 144           | 131           | -                        |

| Company      | Brand        | Generic                   | Class                    | 1999<br>(\$m) | 2000<br>(\$m) | 2001<br>(\$m) | Growth<br>2000-01<br>(%) |
|--------------|--------------|---------------------------|--------------------------|---------------|---------------|---------------|--------------------------|
| Schering AG  | Fludara      | fludarabine               | Antimetabolite           | 79            | 102           | 120           | 1                        |
| BMS          | Ifex         | ifosfamide                | Alkylating agents        | 88            | 108           | 120e          | 1                        |
| Alza US      | Doxil/Caelyx | liposomal/<br>doxorubicin | Cytotoxic<br>Antibiotics | 66            | 82            | 100           | 2                        |
| Pierre Fabre | Navelbine    | vinorelbine               | Vae                      | 76            | 82            | 90e           |                          |
| Wyeth        | Novantrone   | mitoxantrone              | Cytotoxic<br>Antibiotics | 45            | 60            | 71            | 1                        |
| BMS          | VcPesid      | ctoposide                 | Vae                      | 77            | 70            | 65e           | -                        |
| GSK          | Navelbine    | vinorelbine               | Vae                      | 67            | 65            | 63e           | -                        |
| Pharmacia    | Adriamycin   | doxorubicin               | Cytotoxic<br>Antibiotics | 65            | 62            | 55e           | -1                       |
| BMS          | Hydrea       | hydroxyurea               | Alkylating agents        | 56            | 52            | 48e           | -                        |
| Others       |              |                           |                          | 1,824         | 1,776         | 1,829         |                          |
| TOTAL        |              |                           |                          | 6,948         | 7,925         | 8,651         |                          |

Source: Reuters, 2002

Another of Bioenvision's lead drugs, 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 previously have responded to hormonal therapy.

Listed below are other hormonal therapies currently at market.

| Company     | Brand        | Generic      | Class                   | 1999<br>(\$m) | 2000<br>(\$m) | 2001<br>(\$m) | Growth<br>2000-01<br>(%) |
|-------------|--------------|--------------|-------------------------|---------------|---------------|---------------|--------------------------|
| TAP         | Lupron       | Leuprorelin  | LHRH agonsists          | 775           | 798           | 833           |                          |
| AstraZeneca | Zoladex      | Goserelin    | LHRH agonsists          | 686           | 734           | 728           | -                        |
| AstraZeneca | Nolvadex     | Tamoxifen    | Anti-estrogens          | 573           | 576           | 630           |                          |
| AstraZeneca | Casodex      | Bicalulamide | Anti-estrogens          | 340           | 433           | 569           | 3                        |
| Takeda      | Leuplin      | leuprorelin  | LHRH agonsists          | 485           | 515           | 530e          |                          |
| Barr        | Tamoxifen    | Tamoxifen    | Anti-estrogens          | 297           | 322           | 501           | 5                        |
| Pharmacia   | Depo-Provera | Medroxy      | Progestagens            | 252           | 272           | 283           |                          |
| AstraZeneca | Arimidex     | Anastrozole  | Aromatase<br>Inhibitors | 140           | 156           | 191           | 2                        |
| Abbott      | Lupron       | leuprorelin  | LHRH agonsists          | 140           | 153           | 163           |                          |

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|              |                        |               |                      |       |       |       |    |
|--------------|------------------------|---------------|----------------------|-------|-------|-------|----|
| BMS          | Megace                 | megestrol     | Progestagens         | 114   | 180   | 150e  | -1 |
| Novartis     | Femara                 | letrozole     | Aromatase Inhibitors | 57    | 74    | 125   | 6  |
| Ipsen        | Decapepryl             | triptorelin   | LHRH agonsists       | 100   | 105   | 110e  |    |
| Aventis      | Nilandron              | nilutamide    | Anti-androgens       | 72    | 87    | 93e   |    |
| Schering AG  | Androcur               | cyproterone   | Anti-androgens       | 91    | 95    | 92    | -  |
| Aventis      | Suprecur/<br>Suprefact | buserelin     | LHRH agonsists       | 83    | 84    | 85e   |    |
| SP           | Eulexin                | flutamide     | Anti-androgens       | 155   | 128   | 83    | -3 |
| Pharmacia    | Aromasin               | exemestane    | Aromatase Inhibitors | n/a   | 36    | 65e   | 8  |
| Nihun Kayaku | Odyne                  | flutamide     | Anti-androgens       | 71    | 65    | 62e   | -  |
| Teikoku      | Prostal                | chlormadinone | Progestagens         | 63    | 63    | 62e   | -  |
| Hormone      |                        |               |                      |       |       |       |    |
| Novartis     | Lentaron               | formestane    | Aromatase Inhibitors | 47    | 45    | 43e   | -  |
| Nihun Kayaku | Fareston               | toremifene    | Anti-estrogens       | 44    | 43    | 40e   | -  |
| Novartis     | Afema                  | tadrozole     | Aromatase Inhibitors | 22    | 25    | 23e   | -  |
| Mitsui       | Tasuomin               | Tamoxifen     | Anti-estrogens       | 10    | 9     | 9e    | -  |
| Others       |                        |               |                      | 237   | 240   | 250   |    |
| TOTAL        |                        |               |                      | 4,855 | 5,237 | 5,720 |    |

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.

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### Employees

As of June 11, 2004, we had seven full-time and three part-time employees. Of these, three are in management, three are in sales/marketing, three are in administration and three are in research and development. We believe our relationships with our employees are satisfactory.

### Corporate History

We were incorporated as Express Finance, Inc. under the laws of the State of Delaware on August 16, 1996, and changed our name to Ascott Group, Inc. in August 1998 and further to Bioenvision, Inc. in December 1998, at which time 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.

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 non-public 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 product portfolio.

### DESCRIPTION OF PROPERTY

#### Facilities

As of the date of this report we do not own any interest in real property. We currently lease 3,229 square feet of office space at our principal executive offices at 509 Madison Avenue, Suite 404, New York, New York 10022 for approximately \$13,000 per month. These facilities are the center for all of our administrative functions in the United States. We also rent 250 square feet of office space at 32 Haymarket, London SW1Y 4TP for approximately \$1,000 per month. This office space is used to perform certain marketing functions throughout Europe. Also, we rent on a month-to-month basis approximately 500 square feet of office space in Edinburgh, Scotland for approximately \$3,000 per month. 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 do not plan to conduct laboratory research in any of our facilities in the near future, rather, we will conduct research through collaborative arrangements with Southern Research Institute, M.D. Anderson and others.

#### Investment Policies

We do not currently have any investments in real estate or interests in real estate; investments or interests in real estate mortgages or 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 currently invest our surplus cash in interest-bearing deposit accounts and short-term certificates of deposit.

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### MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEAR ENDED JUNE 30, 2003

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 consolidated financial statements and notes included in this Registration Statement, for further details.

#### 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, 2002 included herein.

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** - Revenue under research contracts is recorded as earned under the contracts, as services are provided. In accordance with SEC Staff Accounting Bulletin No. 101, upfront nonrefundable fees associated with license and development agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the period of involvement. If the estimated service period is subsequently modified, the period over which the up-front fee is recognized would be modified accordingly on a prospective basis. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved.

**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.

**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

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statements.

### Overview

We are an emerging biopharmaceutical company that develops and markets drugs to treat cancer. Our two lead drugs are Clofarabine and Modrenal(R), although we have several other products and technologies under development. As of May 1, 2004, our internal staff consisted of nine employees based in New York, New York and Edinborough, Scotland.

Clofarabine is a purine nucleoside analogue, or a small molecule, which, based on our own clinical studies and studies conducted by others on our behalf, we believe is effective in the treatment of leukemia. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I/II clinical trials performed to date. In the United Kingdom, we are currently conducting clinical trials with Clofarabine for the treatment of pediatric and adult acute leukemias. In the U.S., Clofarabine

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is currently in Pivotal Phase II clinical trials for pediatric acute leukemias. In January, 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for Clofarabine. The drug has also been granted orphan drug status and "fast track" treatment by the United States Food and Drug Administration (the "FDA"). Further, in August 2003, we obtained the exclusive, irrevocable option to sell, market and distribute Clofarabine in Japan and Southeast Asia from the inventor of Clofarabine. These rights were not previously granted by Southern Research Institute and fall outside the scope of the Company's then current licensing and development contracts with respect to Clofarabine. We originally obtained an exclusive license from Southern Research Institute to sell, market and distribute Clofarabine throughout the world, except for Japan and Southeast Asia, for all human applications, pursuant to a co-development agreement, dated August 31, 1998, between the Company and Southern Research Institute. On March 12, 2001, we granted an exclusive option to sell, market and distribute Clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute Clofarabine in the U.S.

Modrenal(R) is a hormonal agent with a novel mode of action, that makes it an effective agent in patients with advanced breast cancer who have acquired resistance to other hormonal agents. We launched Modrenal(R) in May 2003 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. In the first half of 2004, we intend to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such territory. We anticipate receiving approval in each such territory in the first half of calendar year 2005. Further, we filed an IND for prostate cancer clinical trials in the US in February 2004 and intend to commence our first US clinical trial in the second quarter of calendar year 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.



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Our primary business strategy relates to our two lead drugs, Clofarabine and Modrenal(R). With Clofarabine, our strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory authorities to market and distribute Clofarabine for the treatment of pediatric and adult acute leukemias. We anticipate receiving approval early in 2005, subject to our obtaining approval of the regulatory authorities. We will continue clinical trials in other indications with the intention of seeking label extensions after Clofarabine's first approval. With Modrenal, our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to sell Modrenal(R) throughout Europe. We anticipate receiving mutual recognition from major European Community member states by mid-2005. Our secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from Clofarabine and Modrenal(R) will permit us to further develop our portfolio of ancillary products and technologies.

### Company Status

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this emerging stage. Our management believes 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 currently plan to have as many as twelve products at market by the end of 2006. We have commenced marketing one of our lead products, Modrenal(R), and we intend 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, an advanced biomaterial that has been approved for certain indications by the FDA in the U.S., and is being sold by a product co-development partner, and the use of thiazine dyes, such as methylene blue, which are used for in vitro and in vivos inactivation of pathogens (viruses, bacteria and fungus) in biological fluids. It is not the Company's strategy to sell devices or to expand into the anit-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. In May 2003, we entered into a Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed the marketing and development rights to modrestane, solely with respect to animal health applications, in the United States and Canada, to Dechra. We received \$1.25 million in cash, together with

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future milestone and royalty payments which are contingent upon the occurrence of certain events We intend to continue to try and exploit these types of opportunities as they arise.

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

Year Ended June 30, 2003 Compared to Year Ended June 30, 2002

We reported revenues of \$505,000 and \$803,000 for the years ended June 30, 2003 and 2002, respectively. Revenues reflect recognition of consideration received pursuant to our agreements with co-development and sub-licensing partners in connection with our platform of drugs and technologies. Of the revenues recorded for the year ended June 30, 2003, \$12,000 was recognized from Dechra, pursuant to the Sub-License Agreement, dated May 13, 2003.

Research and development costs for the years ended June 30, 2003 and 2002 were \$1,689,000 and \$1,912,000, respectively, representing a decrease of \$223,000.

Our research and development costs include costs associated with six projects of which the Company devotes significant time and resource. Clofarabine research and development costs for the year ended June 30, 2003 and 2002 were \$871,000 and \$596,000, respectively, representing an increase of \$275,000. The increase primarily reflects the costs associated with our having commenced clinical trials in Europe to develop Clofarabine. Modrenal research and development costs for the year ended June 30, 2003 and 2002 were \$913,000 and \$923,000, respectively, representing a decrease of \$10,000. Gossypol research and development costs were \$30,000 and \$90,000, respectively, representing a decrease of \$60,000. The decrease primarily reflects a decrease in the amount of resource devoted by the Company to this compound while the Company focused on

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developing its lead drugs. Gene Therapy research and development costs for the year ended June 30,

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2003 were \$(130,000) and \$303,000, respectively, representing a decrease of \$433,000. The decrease primarily reflects an accrued expense in the year ended 2002 of \$200,000 which was determined to be less than originally estimated by the Company in the year ended June 30, 2003. The clinical trials and development strategy for the Clorfarabine and Modrenal projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Estimated total costs to date for each of these four projects is as follows: (i) Clorfarabine research and development costs have been approximately \$3.0 million; (ii) Modrenal research and development costs have been approximately \$2.35 million; (iii) Gossypol research and development costs have been approximately \$150,000; and (iv) Gene Therapy research and development costs have been approximately \$450,000. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, Clorfarabine and Modrenal, over the next two years.

Administrative expenses for the year ended June 30, 2003 and 2002 were \$4,567,000 and \$2,128,000, respectively, representing an increase of \$2,439,000. Of this amount, \$1,600,000 of this increase was due to the expansion of the internal management team from one full time employee to eight full time employees; approximately \$150,000 of this increase was due to lease expenses and office supplies /equipment for the newly opened New York and Edinburgh, Scotland offices, both of which we opened during the year; approximately \$300,000 of the increase was due to an increase in investor and public relations expenses related to pre-marketing activities with Clorfarabine and marketing costs associated with Modrenal; approximately \$200,000 of the increase was related to increases in related travel expense to successfully manage our drug development activities; and approximately \$150,000 of the increase was due to increases in our consulting and legal expenses as the result of our recent growth.

We reported interest and finance charges of \$325,000 for the year ended June 30, 2003, representing a decrease of \$1,848,000 from the year ended June 30, 2002. This decrease reflects the retirement of our credit facility in May 2002 and the fact that we carried no long term debt during the year ended June 30, 2003.

Depreciation and amortization expense totaled \$1,345,000 for the year ended June 30, 2003, representing an increase of \$766,000 from the year ended June 30, 2002. The increase is primarily due to the amortization of certain intangible assets we acquired in the Pathagon transaction which we consummated in February 2002.

Year Ended June 30, 2002 Compared to Year Ended June 30, 2001

We reported revenues of \$803,000 and \$245,000 for the years ended June 30, 2002 and 2001, respectively. Revenues reflect our agreements with our

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co-development partners and/or licensees in connection with our platform of drugs and technologies.

Research and development costs for the years ended June 30, 2002 and 2001 were \$1,912,000 and \$1,566,000, respectively, representing an increase of approximately \$346,000. This increase primarily is attributable to a full year amortization of deferred royalties, which represent advance royalties paid to SRI that are being amortized over the same period that related revenue is being recognized.

Administrative expenses for the year ended June 30, 2002 and 2001 were \$2,128,000 and \$550,000, respectively, representing an increase of \$1,578,000. Of this amount, (i) approximately \$650,000 related to an increase in legal and other professional fees paid during the year, (ii) approximately \$750,000 related to an increase in printing, investor and public relations costs and (iii) approximately \$85,000 was due to an increase in travel expenses related to the Company's expansion of the internal management team.

We reported interest and finance charges of \$2,173,000 and \$229,000 for the years ended June 30, 2002 and 2001, respectively, representing an increase of \$1,944,000. This increase reflects charges related to the issuance of warrants in connection with the Company's various financings.

Depreciation and amortization expense totaled \$579,000 and \$23,000 for the years ended June 30, 2002 and 2001, respectively. This increase primarily is due to the amortization of certain intangible assets we acquired in the Pathagon transaction, which we consummated in February 2002.

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### 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. 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. 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 \$52,000 through June 30, 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

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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, at which time ILEX was originally scheduled to complete Phase II trials of Clofarabine and make another payment to us.

We received an initial payment from Dechra of \$1,250,000 on May 13, 2003 upon execution of our sub-license agreement with Dechra. This agreement expires upon expiration of the last patent related to modrenal or the completion of the last royalty obligation as set forth therein.

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 adjustment.

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 in full the Jano Holdings and SCO Capital obligations upon which such facilities were terminated as well as to repay fees amounting to \$1,610,000 related to the transaction.

On June 30, 2003, we have cash and cash equivalents of \$8,200,000 and working capital of \$6,108,000 which management believes will be sufficient to continue currently planned operations over the next 12 months. Although we do not currently intend to raise any additional funds for the next 12 months, we can not ensure additional funds will not be raised during such period because of the significant scale up of our operating activities, including clofarabine development and the launch of modrenal. Further, 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 any significant assets over the coming 12 month period, but if any such opportunity arises 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 anticipate that we may continue to incur significant operating losses for the foreseeable future. There can be no assurance as to whether or where we will generate material revenues or achieve profitable operations.

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The Company has the following commitments as of June 30, 2003:

| Payments Due in |       |       |       |
|-----------------|-------|-------|-------|
| Total           | 2004  | 2005  | 2006  |
| -----           | ----- | ----- | ----- |

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|                    |         |         |         |        |
|--------------------|---------|---------|---------|--------|
| Employee Contracts | 266,400 | 266,400 | -       | -      |
| Occupancy Lease    | 369,500 | 161,600 | 166,100 | 41,000 |
| Total              | 635,900 | 418,500 | 156,000 | 39,000 |

In management's opinion, cash flows from operations and borrowing capacity combined with cash on hand will provide adequate flexibility for funding the Company's working capital obligations for the next twelve months. However, there can be no assurance that suitable debt or equity financing will be available for the Company. The Company has a commitment under its operating lease with the New York office. The Company leases 3,299 square feet under a lease that expires on September 30, 2005. The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision, Ltd.

### Plan of Operation

We are an emerging biopharmaceutical company with a primary business focus on the acquisition, development and distribution of drugs to treat cancer. We have acquired development and marketing rights to a portfolio of six platform technologies developed over the past 15 years from which a range of products have been derived and additional products may be developed in the future. Although we have commenced marketing one of our lead products, Modrenal(R), and intend to continue to develop Clofarabine, and 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.

We plan to continue to use 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.

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.

With respect to our gene therapy technology, we have completed laboratory research which confirms proof of principal of our gene therapy technology and has added to the pre-clinical data which will be important for any subsequent regulatory submission. This laboratory research was required to allow the Company and the research departments of the relevant universities assisting with this technology to file patents for which the Company has licensing rights. We now plan to perform additional clinical trials with the two lead products related to this technology.

### Key Personnel, Consultants and Infrastructure

On July 22, 2002, David P. Luci commenced employment with the Company and serves as Director of Finance, General Counsel and Corporate Secretary of the Company, pursuant to terms which are memorialized in an Employment

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Agreement, dated March 31, 2003. See Part III, Item 9 "Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act - Employment Agreements" below.

On September 3, 2002, the Company and ILEX constituted the management team (the "Management Team") for the development of Clofarabine in the U.S., Canada and Europe. The Management Team meets regularly to plan and coordinate clofarabine drug development on an ongoing basis. The Management Team currently consists of Dr. Wood and Mr. Luci from the Company and Jeffrey Buchalter, President and Chief Executive Officer of Ilex.

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On September 17, 2002, the Company announced its establishment of principal executive offices at 509 Madison Avenue, Suite 404, New York, New York 10022.

On September 24, 2002, Mr. Thomas Scott Nelson resigned his position as Chief Financial Officer of the Company. Mr. Luci has taken responsibility as the Company's principal accounting officer. Mr. Nelson continues his role as director of the Company.

On September 30, 2002, Stuart Smith resigned from his position as Senior Vice President of the Company; his employment agreement was terminated. The Company issued shares of its common stock to Mr. Smith at the then current fair market value in satisfaction of all outstanding obligations of the Company to Mr. Smith pursuant to the employment agreement.

On October 6, 2002, Mr. Hugh Griffith commenced employment with Bioenvision Ltd., a wholly owned subsidiary of the Company. Mr. Griffith serves as Commercial Director (Europe) and is responsible for Bioenvision's marketing campaign for modrenal, which is approved in the United Kingdom for the treatment of advanced post-menopausal breast cancer, and for Bioenvision's sales and marketing initiatives for all other approved products throughout Europe which, initially, includes methylene blue and OLIGON.

On November 1, 2002, the Company entered into an agreement with Queen Mary Westfield College, University of London ("Queen Mary"), pursuant to which, in pertinent part, Queen Mary has agreed to perform certain research and development activities in connection with the development of modrenal(TM). The term of the agreement is five years, subject to certain rights of the parties to terminate prior thereto.

On December 1, 2002, the Company appointed Mr. Ian Abercrombie to serve as Sales Manager (Europe). Messrs. Abercrombie and Griffith, together, are creating a worldwide marketing strategy for the Company's products and marketing Modrenal (TM) in the United Kingdom. Further, Messrs. Abercrombie and Griffith are designing plans to expand the Company's marketing strategy throughout the European Community and to commence pre-registration marketing activities with Clofarabine worldwide, except for North America.

On December 31, 2002, the Company entered into a one-year employment agreement with Dr. Christopher B. Wood who serves as Chairman and Chief Executive Officer of the Company. See Part III, Item 9 "Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act - Employment Agreements" below.

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On December 31, 2002, the Company entered into a consulting agreement with Dr. Deidre Tessman to serve as a regulatory consultant to the Company in connection with the European development of Clofarabine.

In January 2003, we entered into an agreement with RRD International LLC ("RRD"), pursuant to which RRD serves as the global product development consultant to the Company in connection with the development of Clofarabine, Modrenal (TM) and OLIGON and assists with designing and managing our clinical development program for our products. On April 2, 2003, the Company and RRD further memorialized their agreement pursuant to a formal Master Services Agreement and Registration Rights Agreement and, in connection therewith, the Company issued a Warrant to RRD pursuant to which RRD has the right to acquire 175,000 shares of our common stock at an exercise price of \$2.00 per share, which warrant includes registration rights under certain circumstances.

In April 2003, we entered into an exclusive license agreement with CLL Pharma ("CLL"), pursuant to which CLL has agreed to develop a new formulation of modrenal using proprietary patented technology of CLL. The term of the agreement is for a period of 24 months following the first delivery of reformulated drug product.

In May 2003, we entered into a Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed the marketing and development rights to modrestane, solely with respect to animal health applications, in the United States and Canada, to Dechra. We received \$1.25 million in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events.

In May 2003, we entered into a Master Services Agreement with Penn Pharmaceutical Services Limited ("Penn"), pursuant to which Penn will assist the Company with labeling, packaging and distribution of Clofarabine and certain other services including regulatory and quality control, in each case, as requested by the

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Company on an ongoing basis. The term of the agreement is 12 months subject to automatic 12 month extensions unless earlier terminated by either party.

In June 2003, we entered into a supply agreement and a development agreement, in each case, with Ferro Phanstiehl Laboratories, ("Ferro"), pursuant to which Ferro will manufacture and exclusively supply to us our global supply of Clofarabine and perform a scale-up of this compound for commercial use. The term of the supply agreement is five-years from the first product regulatory approval for Clofarabine, subject to certain early termination rights.

### Scientific Advisory Board / Modrenal Launch

In December 2002, the Company's scientific advisory board convened at the Meeting of the American Society of Hematologists in Philadelphia, PA and reviewed the clinical trial results to date and planned future clinical trials for clofarabine.

In May 2003, the Company's scientific advisory board met to review and discuss the design and strategy for the forthcoming clinical trials for modrenal, globally, for patients with breast cancer.



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In May 2003, the Company launched the marketing of modrenal in the United Kingdom for breast cancer at the Royal College of Surgeons in London, England.

### Recent Accounting Pronouncements

In July 2002, the FASB Issued Statement 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Cost to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The principal difference between this Statement and Issue 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. Effective January 1, 2003, the Company adopted the provisions of SFAS 146 which did not have an impact on the results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45, "Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). FIN 45 requires that certain guarantees be initially recorded at fair value, which is different from the general current practice of recording a liability only when a loss is probable and reasonably estimable. FIN 45 also requires a guarantor to make significant new disclosures for virtually all guarantees. Effective January 1, 2003, the Company adopted the disclosure requirements under FIN 45 which did not have a material impact on the results of operations or financial position of the Company.

On December 31, 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation Transition and Disclosure" ("SFAS 148"). SFAS 148 amends FASB Statement No. 123, "Accounting for Stock Based Compensation," to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure provisions of SFAS 123 and APB Opinion No. 28, "Interim Financial Reporting," to require disclosure on the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. While SFAS 148 does not amend SFAS 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS 148 are applicable to all companies with stock-based employee compensation, regardless of whether they account for the compensation using the fair value method of SFAS 123 or the intrinsic value method of APB Opinion 25. The Company adopted the required disclosure provisions of SFAS 148 as described under accounting policy footnote, "Stock Based Compensation."

In January 2003, the FASB issued interpretation No. 46, "Consolidation of Variable Interest Entities--An Interpretation of ARB No. 51" ("FIN 46"), which addresses consolidation of variable interest entities. FIN 46 expands the criteria for consideration in determining whether a variable interest entity should be consolidated

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by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disburse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material impact on the results of operation or financial position of the Company.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (SFAS 150"). The objective of SFAS No. 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial statements entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. The adoption of SFAS 150 is not expected to have a material impact on the results of operations or financial position of the Company.

In May 2003, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations, but could affect the timing or pattern of revenue recognition for future collaborative research and/or license agreements.

### Subsequent Events

In August 2003, we entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, we succeeded to the U.K. marketing rights to modrenal.

In August 2003, we received notice that our application to list our shares of common stock had been approved by the American Stock Exchange under the symbol "BIV". Our shares of common stock commenced trading on the American Stock Exchange on September 8, 2003.

In August 2003, SRI granted us an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

In September 2003, we entered into a letter agreement with ILEX Oncology, Inc. pursuant to which we are working with ILEX to co-develop an oral formulation for clofarabine; the rights and related costs to which we agreed to split equally with ILEX.

### MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE QUARTER ENDED MARCH 31, 2004

The following discussion and analysis of significant factors affecting the

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Company's operating results, liquidity and capital resources and should be read in conjunction with the accompanying financial statements and related notes.

### Overview

We have several products and technologies under development, but our two lead drugs are Clofarabine and Modrenal(R).

Clofarabine is a purine nucleoside analogue, or a small molecule, which, based on our own clinical studies and studies conducted by others on our behalf, we believe is effective in the treatment of leukemia. Clofarabine may also be an effective agent to treat patients with solid tumor cancers, based on preclinical studies and Phase I/II clinical trials performed to date. In the United Kingdom, we are currently conducting clinical trials with Clofarabine for the treatment of pediatric and adult acute leukemias. In the U.S., Clofarabine

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is currently in Pivotal Phase II clinical trials for pediatric acute leukemias. In January, 2002, the European orphan drug application for use of Clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for Clofarabine. The drug has also been granted orphan drug status and "fast track" treatment by the United States Food and Drug Administration (the "FDA"). Further, in August 2003, we obtained the exclusive, irrevocable option to sell, market and distribute Clofarabine in Japan and Southeast Asia from the inventor of Clofarabine. These rights were not previously granted by Southern Research Institute and fall outside the scope of the Company's then current licensing and development contracts with respect to Clofarabine. We originally obtained an exclusive license from Southern Research Institute to sell, market and distribute Clofarabine throughout the world, except for Japan and Southeast Asia, for all human applications, pursuant to a co-development agreement, dated August 31, 1998, between the Company and Southern Research Institute. On March 12, 2001, we granted an exclusive option to sell, market and distribute Clofarabine in the U.S. and Canada to ILEX Oncology, Inc. We converted ILEX's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute Clofarabine in the U.S.

Modrenal(R) is a hormonal agent with a novel mode of action, that makes it an effective agent in patients with advanced breast cancer who have acquired resistance to other hormonal agents. We launched Modrenal(R) in May 2003 in the United Kingdom, where we have received regulatory approval for its use in the treatment of post-menopausal breast cancer. In the first half of 2004, we intend to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such territory. We anticipate receiving approval in each such territory in the first half of calendar year 2005. Further, we filed an IND for prostate cancer clinical trials in the US in February 2004 and intend to commence our first US clinical trial in the second quarter of calendar year 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals Ltd. to sell, market and distribute Modrenal(R) throughout the world, except for South Africa, for all human and animal health applications, pursuant to a co-development agreement dated July 15, 1998.

Our primary business strategy relates to our two lead drugs, Clofarabine

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and Modrenal(R). With Clofarabine, our strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory authorities to market and distribute Clofarabine for the treatment of pediatric and adult acute leukemias. We anticipate receiving approval early in 2005, subject to our obtaining approval of the regulatory authorities. We will continue clinical trials in other indications with the intention of seeking label extensions after Clofarabine's first approval. With Modrenal, our strategy is to expand sales in the United Kingdom and apply for mutual recognition to obtain the right to sell Modrenal(R) throughout Europe. We anticipate receiving mutual recognition from major European Community member states by mid-2005. Our secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from Clofarabine and Modrenal(R) will permit us to further develop our portfolio of ancillary products and technologies.

Although our primary business strategy is to develop and commercialize our two lead drugs, Clofarabine and Modrenal(R) for sale in the territories within which we have licensed the right to sell, market and distribute these drugs, our board of directors continues to evaluate other strategic alternatives for the Company and its products, including the potential disposition of all or a portion of our business, potential licensing and/or co-development arrangements with other pharmaceutical companies and certain financing strategies.

### Company Status

We have made significant progress in developing our product portfolio over the past twelve months, and have multiple products in clinical trials. We have incurred losses during this emerging stage. We anticipate that revenues derived from the two lead drugs will permit us to further develop our other products and potential products currently in our development portfolio. On March 29, 2004, ILEX Oncology, Inc. filed a New Drug Application with the FDA for approval of Clofarabine in the U.S. for the treatment of pediatric ALL and AML (the "NDA Filing"). The Company has taken the NDA filing and currently is in the process of converting the filing to a Common Technical Document (the "CTD") for filing with the EMEA as the basis potentially for European approval of Clofarabine for the treatment of pediatric ALL and AML. The Company expects to file the CTD with the EMEA in the third quarter of calendar year 2004. We have commenced marketing one of our lead products, Modrenal(R), and we intend 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 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, an advanced biomaterial that has been approved for certain indications by the FDA in the United States, and is being sold by a product co-development partner, and the use of thiazine dyes, such as methylene blue, which are used for in vitro and in vivos inactivation of pathogens (viruses, bacteria and fungus) in biological fluids. It is not the Company's strategy to sell devices or to expand into the anit-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

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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. In May 2003, we entered into a Sub-License Agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Bioenvision sub-licensed to Dechra the marketing and development rights to modrestane, solely with respect to animal health applications, in the United States and Canada. We received \$1.25 million in cash, together with future milestone and royalty payments which are contingent upon the occurrence of certain events. We intend to continue to try to exploit these types of opportunities as they arise.

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 are 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

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 (TM), 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 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.

The Company recorded revenues for the three months ended March 31, 2004 and 2003 of approximately \$846,000 and \$46,000, respectively, representing an increase of \$800,000. The Company recorded revenues for the nine months ended March 31, 2004 and 2003 of approximately \$1,758,000 and \$464,000, respectively, representing an increase of \$1,294,000. Approximately \$620,000 and \$1,390,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, relates to reimbursement for Clofarabine research and development costs incurred by the Company for European drug development (partially offset, for the for the nine months ended March 31, 2004, by an extension of the time period within which the Company recognizes Clofarabine milestone revenues, which has the effect of reducing revenue recognized for such milestones by approximately \$300,000 during the period). Revenues reflect our agreement with our co-development partners and/or licenses in connection with our platform of drugs and technologies and includes sales of Clofarabine in Europe pursuant to the Company's Named Patient Program.

Research and development costs for the three months ended March 31, 2004 and 2003 were \$994,000 and \$320,000, respectively, representing an increase of \$674,000.

Research and development costs for the nine months ended March 31, 2004 and 2003 were \$2,545,000 and \$1,162,000, respectively, representing a increase of \$1,383,000.

Our research and development costs include costs associated with six projects for which the Company devotes significant time and resource. Clofarabine research and development costs for the nine months ended March 31, 2004 and 2003 were \$1,612,000 and \$730,000, respectively, representing an increase of \$881,000. The increase primarily reflects the costs associated with our having commenced clinical trials in Europe to develop Clofarabine. Modrenal research and development costs for the nine months ended March 31, 2004 and 2003 were \$744,000 and \$561,000, respectively, representing a decrease of \$183,000. Gossypol research and development costs were \$152,000 and \$27,000, respectively, representing a increase of \$124,000. Gene Therapy research and development costs for the nine months ended March 31, 2004 and 2003 were 0 and \$(158,000), respectively, representing a decrease of \$158,000. The decrease primarily reflects an accrued expense in the year ended 2002 of \$200,000 which was determined to be less than originally estimated by the Company in the year ended June 30, 2003. The clinical trials and development strategy for the Clofarabine and Modrenal projects, in each case, is anticipated to cost several million dollars and will continue for several years based on the number of clinical indications within which we plan to develop these drugs. Currently, management cannot estimate the timing or costs associated with these projects because many of the variables, such as interaction with regulatory authorities and response rates in various clinical trials, are not predictable. Our other two research and development projects involve our two ancillary technologies; OLIGON and Methylene Blue. We do not currently devote any significant time or resources to these research and development projects, but we intend to do so if and to the extent we successfully commercialize our lead drugs, Clofarabine and Modrenal, over the next two years.

Selling, general and administrative expenses for the three months ended March 31, 2004 and 2003 were \$3,722,000 and \$1,050,000, respectively, representing an increase of \$2,672,000. Selling, general and administrative

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expenses for the nine months ended March 31, 2004 and 2003 were \$7,080,000 and \$2,743,000, respectively, representing an increase of \$4,337,000. Approximately \$1,943,000 and \$2,597,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, relates to stock based compensation recorded during the period resulting from the repricing of the options issued to an officer of the Company. Approximately \$57,000 and \$155,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, was due to the expansion of the internal management team from one full time employee to eight full time employees during the three and nine month periods then ended. Approximately \$98,000 and \$532,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, was due to an increase in investor and public relations expenses related to pre-marketing activities with Clofarabine and marketing costs associated with Modrenal. Approximately \$2,000 and \$107,000 of the increase for the three and nine month periods ended March 31, 2004, respectively, was related to increases in travel related expenses incurred in order to successfully manage our more active drug development activities during the three and nine month periods then ended. Approximately \$562,000 and \$817,000 of the increase in Selling, general and administrative expense for the three and nine month periods ended March 31, 2004, respectively, was due to increases in our consulting and legal expenses as the result of our recent growth internally and operationally during the three and nine month periods ended March 31, 2004, respectively.

Depreciation and amortization expense for the three months ended March 31, 2004 and 2003 were \$343,000 and \$339,000, respectively, representing an increase of \$5,000. Depreciation and amortization

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expense for the nine months ended March 31, 2004 and 2003 were \$1,023,000 and \$1,006,000, respectively, representing an increase of \$17,000. The increase is primarily due to the amortization of certain intangible assets we acquired.

### 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.

We consummated a private placement transaction on March 22, 2004, pursuant to which we raised \$12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of our common stock at a conversion price of \$7.50 per share. We consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional \$3.5 million in the second closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of \$7.50 per share.

We received an initial payment from Dechra of \$1,250,000 on May 13, 2003 upon execution of our sub-license agreement with Dechra. This agreement expires upon expiration of the last patent related to modrenal or the completion of the last royalty obligation as set forth therein.

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We received a milestone payment from ILEX of \$3.5 million on December 30, 2003, upon executing an amendment to the co-development agreement. This payment related to the achievement of a milestone; namely, completion of pivotal phase II trials. Pursuant to the Company's co-development agreement with SRI, the Company immediately paid \$1.75 million of such milestone payment to SRI.

On March 31, 2004, we had cash and cash equivalents of \$17,558,813 and working capital of \$17,197,041, which management believes will be sufficient to continue currently planned operations over the next twelve months. Although we do not currently intend to raise any additional funds for the next twelve months, we cannot ensure additional funds will not be raised during such period because of the significant scale-up of our operating activities, including Clofarabine development and the launch of Modrenal.

Further, a key element of our business strategy is to continue to 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 any significant assets over the coming twelve month period, but if any such opportunity arises 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.

Future commitments of the Company for the twelve-month period April 1st through March 31 are as follows:

|                    | Payments Due: |           |           |
|--------------------|---------------|-----------|-----------|
|                    | Total         | 2005      | 2006      |
| Employee Contracts | 2,436,186     | 1,218,093 | 1,218,093 |
| Occupancy Lease    | 248,605       | 164,972   | 83,633    |
| Total              | 2,684,791     | 1,383,065 | 1,301,726 |

In management's opinion, cash flows from operations and borrowing capacity combined with cash on hand will provide adequate flexibility for funding the Company's working capital obligations for the next twelve months. However, there can be no assurance that suitable debt or equity financing will be available for the Company. The Company has a commitment under its operating lease with the New York office. The Company leases 3,229 square feet under a lease that expires on September 30, 2005. The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision Limited.

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. In the event of a voluntary or involuntary liquidation or dissolution of the Company, before any distribution of assets shall be made to the holders of the Company's securities which are junior to the preferred stock (such as the common stock), holders of the preferred stock shall be paid out of the assets of the Company legally available for distribution to the

Company's stockholders an amount per share equal to the initial original issue price (\$3.00) subject to certain adjustments plus all accrued but unpaid dividends on such preferred stock.



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### Subsequent Events

In April 2004, ILEX paid the Company the \$2,000,000, which it agreed to pay upon the filing of the NDA. ILEX filed the NDA with FDA in March 2004.

In April 2004, the Company entered into a Clinical Development Agreement with Covance Inc. pursuant to which Covance has agreed to perform certain drug development activities in connection with the Company's BIV-121 sponsor lead clinical trial in Europe.

### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In August 2001 Bioenvision issued 208,333 shares at the rate of \$1.25 per share in lieu of salary and consulting fees as follows: Christopher B. 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 stockholders. This credit facility was terminated in May 2002.

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

On November 16, 2001, we entered into an engagement letter with SCO Financial Group, 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 adjustments. The warrants expire five years from the date of issuance. Pursuant to this engagement letter, among other things, SCO Financial Group performs investor relations services for the Company and earns a monthly fee of \$9,000 per month in connection therewith.

On November 16, 2001, in connection with securing a credit 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 credit facility with SCO Capital was terminated in May 2002.

On February 5, 2002, we completed the acquisition of Pathagon Inc. In connection therewith, on February 1, 2002 we issued 7,000,000 shares of common stock to the former stockholders of Pathagon Inc.

In May 2002, we completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock and in March and May of 2004 we completed a private placement pursuant to which we issued an aggregate of 2,602,898 shares of our common stock and warrants to purchase an aggregate of 780,870 shares of common stock. An affiliate of SCO Capital Partners LLC, one of our stockholders, served as financial advisor to the Company in connection with these financings and earned a placement fee of approximately \$1,200,000 in connection with the May 2002 private placement and warrants to purchase 260,291 shares of common stock for \$6.25 per share for the March and May 2004 financings. This affiliate of SCO Capital Partners LLC continues to serve as a financial advisor to the Company.

### MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

In August 2003, we received notice that our application to list our shares of common stock had been approved by the American Stock Exchange. Our

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shares of common stock commenced trading on the American Stock Exchange on September 8, 2003. The following represents the range of reported high and low bid quotations for our common stock on a quarterly basis since July 1, 2001 as reported on the OTC Bulletin Board through the first quarter of 2003 and as reported on AMEX for the second quarter of 2003 and all subsequent periods. Throughout this period and through September 5, 2003, our trading symbol was "BIOV" Our trading symbol was changed to "BIV" on September 8, 2003 upon commencement of listing our shares of common stock on the American Stock Exchange. The quotations also reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

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|                                  | High<br>---- | Low<br>--- |
|----------------------------------|--------------|------------|
| Fiscal Year Ended June 30, 2002  |              |            |
| First Quarter                    | \$2.50       | \$1.60     |
| Second Quarter                   | \$2.50       | \$1.15     |
| Third Quarter                    | \$3.00       | \$2.25     |
| Fourth Quarter                   | \$3.60       | \$1.75     |
| Fiscal Year Ended June 30, 2003  |              |            |
| First Quarter                    | \$2.55       | \$1.35     |
| Second Quarter                   | \$2.25       | \$1.10     |
| Third Quarter                    | \$1.55       | \$0.39     |
| Fourth Quarter                   | \$2.89       | \$0.77     |
| Nine Months Ended March 31, 2004 |              |            |
| First Quarter                    | \$4.90       | \$1.70     |
| Second Quarter                   | \$5.40       | \$3.13     |
| Third Quarter                    | \$10.25      | \$3.74     |

On June 11, 2004, we had 189 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. However, the Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. We have not paid dividends on our cumulative Series A Convertible Participating Preferred Stock since May 8, 2002 but have accrued the dividends since that time. 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 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.

### EXECUTIVE COMPENSATION

The following table sets forth information for each of the fiscal years ended June 30, 2003, 2002 and 2001 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

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executive officer) at the end of our fiscal year ended June 30, 2003 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, 2003:

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Summary Compensation Table

| Name &<br>Principal<br>Position<br>----- | Year<br>---- | Annual compensation   |                      |                      | Long term compensation                    |   |                                |
|--|--------------|-----------------------|----------------------|----------------------|---|---|--------------------------------|
|  |              | Salary<br>-----<br>\$ | Bonus<br>-----<br>\$ | Other<br>-----<br>\$ | Awards                                    |   | LTIP<br>payouts<br>-----<br>\$ |
|  |              |                       |                      |                      | Restricted<br>Stock Awards<br>-----<br>\$ | Securities<br>underlying<br>options/SARs<br>----- |                                |
| Christopher B.<br>Wood (1)               | 2003         | 225,000               | -                    |                      |   |   |                                |
|  | 2002         | 225,000               | -                    |                      | 500,000                                   |   |                                |
|  | 2001         | 180,000               | -                    |                      | 1,500,000                                 |   |                                |
| David P. Luci (2)                        | 2003         | 205,200               | 57,000 (3)           |                      | 500,000                                   |   |                                |
|  | 2002         | -                     | -                    |                      |   |   |                                |
|  | 2001         | -                     | -                    |                      |   |   |                                |
| Hugh Griffith (4)                        | 2003         | 180,000               | 20,000               |                      | 300,000                                   |   |                                |
|  | 2002         | -                     | -                    |                      |   |   |                                |
|  | 2001         | -                     | -                    |                      |   |   |                                |
| Stuart Smith (5)                         | 2003         | -                     | -                    |                      |   |   |                                |
|  | 2002         | 150,000               | -                    |                      |   | -   |                                |
|  | 2001         | 150,000               | -                    |                      | 500,000                                   |   |                                |

(1) On April 30, 2001, Dr. Wood was granted options to purchase 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. On December 31, 2002, Dr. Wood was granted options to purchase 500,000 shares of our common stock which vest and become exercisable in equal amounts on the first, second and third anniversaries of the December 31, 2002 grant date.

(2) On July 22, 2002, Mr. Luci was granted options to purchase 380,000 shares of our common stock. On March 31, 2003, in connection with the execution of an employment agreement between the Company and Mr. Luci, these options were cancelled and the Company issued options to purchase 500,000 shares of common stock at a then-current fair market value. Of these options, options to purchase 170,000 shares of our common stock are immediately exercisable and, subject to certain circumstances, options to purchase 110,000 shares of common stock vest and become exercisable on each of the first, second and third anniversaries of March 31, 2003, the grant date.

(3) This annual bonus was prorated for the portion of calendar year 2002

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- within which Mr. Luci was employed by the Company. The net amount of the bonus paid to Mr. Luci after such pro-ration was equal to \$25,000.
- (4) On October 23, 2002, Mr. Griffith was granted options to purchase 300,000 shares of our common stock at a then-current fair market value. Of these options, options to purchase 100,000 shares of our common stock vest and become exercisable, subject to certain circumstances, on each of the first, second and third anniversaries of October 23, 2002, the grant date.
  - (5) On April 30, 2001, Mr. Smith was granted options to purchase 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. On September 30, 2002, Stuart Smith resigned from his position as Senior Vice President of the Company and his employment agreement was terminated.

### Employment Agreements

We have entered into employment agreements with each of our principal executive officers. 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.

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On September 1, 1999, we entered into an employment agreement with Christopher B. Wood, M.D. under which he serves as our 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. On December 31, 2002, we entered into a new employment agreement with Dr. Wood, under which he continues to serve as our Chairman and Chief Executive Officer. Under this contract, the term is one year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. Dr. Wood's new employment agreement provides for an initial base salary of \$225,000, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to key employees of the Company. If Dr. Wood's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to his then current annual base salary and any and all unvested options will vest and immediately become exercisable.

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. On September 30, 2002, Mr. Smith resigned from his position as Senior Vice President of the Company; his employment agreement was terminated and the Company agreed to issue shares of its common stock to Mr. Smith at the then current fair market value in satisfaction of all outstanding obligations of the Company to Mr. Smith pursuant to the employment agreement.

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On March 31, 2003, we entered into an employment agreement with David P. Luci, pursuant to which he serves as our Director of Finance, General Counsel and Corporate Secretary. The initial term of Mr. Luci's employment agreement is one-year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. If Mr. Luci's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 1.5 multiplied by the sum of (i) his then current annual base salary plus (ii) his then average annual bonus for the preceding two years and any and all unvested options will vest and immediately become exercisable.

### Director Compensation

Our policy is that non-management directors are entitled to receive a director's fee of \$1,000 per meeting for attendance at meetings of the board of directors, and are reimbursed for actual expenses incurred in respect of such attendance. We do not separately compensate employees for serving as directors. We do not provide additional compensation for committee participation or special assignments of the board of directors.

### Stock Options

Our Board of Directors has adopted, and our stockholders have approved our 2003 Stock Incentive Plan. The plan was adopted to recognize the contributions made by our employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to our future success and to improve our ability to attract, retain and motivate individuals upon whom our growth and financial success depends.

The key provisions of the plan are as follows:

#### Eligibility and Administration.

The plan authorizes the Board of Directors or the compensation committee (the "Administrator"), to (i)select the participants who are to be granted options, restricted shares or performance units, (ii)determine the number of shares of Common Stock to be granted to each participant, (iii)designate options, to the extent the award consists of options, as incentive stock options or nonstatutory stock options, (iv)determine the vesting schedule and performance criteria, if any, for restricted shares and performance units and (v)determine to what extent the awards may be transferable. As of the date hereof, there are approximately 7 employees who are currently eligible to participate in the plan under the Company's policies. All directors and consultants are currently eligible to participate in the plan. The Administrator's interpretations and construction of the plan are final and binding on the Company.

#### Shares Available for Issuance Under the Plan

The stock subject to options granted under the plan are shares of the Company's authorized but unissued or reacquired shares of Common Stock. On March 23, 2004, the closing price of the common stock on the American Stock Exchange of the Common Stock was \$8.45 per share. There are 3,000,000 shares reserved for grants of options under the plan. On the same date, there were 22,934,616 shares of Common Stock outstanding.

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Grant, Exercise and other Terms of Awards.

Options issued under the plan are designated as either incentive stock options or nonstatutory stock options. Incentive stock options are options meeting the requirements of Section 422 of the Code, and nonstatutory options are options not intended to so qualify.

The exercise price of options granted under the plan may not be less than 100% of the fair market value of the Common Stock of the Company (as defined by the plan) on the date of the grant. With respect to any participant who owns stock representing more than 10% of the voting rights of the outstanding Common Stock of the Company, the exercise price of any incentive stock option granted must equal at least 110% of the fair market value of the Common Stock on the grant date, and the maximum term of any such incentive stock option must not exceed five years.

Options, restricted shares and performance units are evidenced by written award agreements in a form approved by the Administrator from time to time and no award is effective until the applicable award agreement has been executed by both parties thereto. Options granted under the plan may become exercisable in cumulative increments over a period of months or years, or otherwise, as determined by the Administrator. The purchase price of options shall be paid in cash; provided, however, that if the applicable award agreement so provides, or the Administrator, in its sole discretion otherwise approves thereof, the purchase price may be paid in shares of Common Stock having a fair market value on the exercise date equal to the exercise price or in any combination of cash and shares of Common Stock, as long as the sum of the cash so paid and the fair market value of the shares so surrendered equals the aggregate purchase price. In addition, the Administrator may permit deferred compensation elections by certain directors and executive officers. The award agreement evidencing the restricted shares and/or performance units shall set forth the terms upon which the Common Stock subject to any awards or the achievement of any cash bonus may be earned.

No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Administrator) from the date of the grant, and no incentive stock options granted under the Amended Award Plan to a participant who owns more than ten percent of the total combined voting power of all classes of outstanding stock of the Company shall be exercisable after the expiration of five years (or less, in the discretion of the Administrator) from the date of the grant. The aggregate fair market value (as of the respective date or dates of grant) of the shares of Common Stock underlying the incentive stock options that are exercisable for the first time by a participant during any calendar year under the plan and all other similar plans maintained by the Company may not exceed \$100,000. If a participant ceases to be an employee of the Company for any reason other than his or her death, Disability or Retirement (as such terms are defined in the plan), such participant shall have the right, subject to certain restrictions, to exercise that option at any time within ninety days (or less, in the discretion of the Administrator) after cessation of employment, but, except as otherwise provided in the applicable award agreement, only to the extent that, at the date of cessation of employment, the participant's right to exercise such option had vested and had not been previously exercised. The Administrator, in its sole discretion, may provide that the option shall cease to be exercisable on the date of such cessation if such cessation arises by reason of termination for Cause (as such term is defined in the Amended Award Plan) or if the participant becomes an employee, director or consultant of an entity that the Administrator determines is in direct competition with the Company.

In the event a participant dies before such participant has fully exercised his or her option, then the option may be exercised at any time within

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twelve months after the participant's death by the executor or administrator of his or her estate or by any person who has acquired the option directly from the participant by bequest or inheritance, but except as otherwise provided on the applicable award agreement, only to the extent that, at the date of death, the participant's right to exercise such option had vested pursuant to the terms of the applicable award agreement and had not been forfeited or previously exercised.

In the event a participant ceases to be an employee of the Company by reason of Disability, such

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participant shall have the right, subject to certain restrictions, to exercise the option at any time within twelve months (or such shorter period as the Administrator may determine) after such cessation of employment, but only to the extent that, at the date of cessation of employment, the participant's right to exercise such option had previously vested pursuant to the terms of the applicable award agreement and had not previously been exercised.

In the event a participant ceases to be an employee of the Company by reason of Retirement, such participant shall have the right, subject to certain restrictions, to exercise the option at any time within ninety days (or such longer or shorter period as the Administrator may determine) after cessation of employment, but only to the extent that, at the date of cessation of employment, the participant's right to exercise such option had vested pursuant to the terms of the applicable award agreement and had not previously been exercised.

Adjustment of Awards Upon Certain Events.

If the Company merges with another corporation and the Company is the surviving corporation in such merger and under the terms of such merger the shares of Common Stock outstanding immediately prior to the merger remain outstanding and unchanged, each outstanding award shall continue to apply to the shares subject thereto and will also pertain and apply to any additional securities and other property, if any, to which a holder of the number of shares subject to the option would have been entitled as a result of the merger.

In the event all or substantially all of the assets of the Company are sold, the Company engages in a merger where the Company does not survive or the Company is consolidated with another corporation, each participant shall receive immediately before the effective date of such sale, merger or consolidation restricted shares and the value of any performance units to which the participant is then entitled (regardless of any vesting condition) and each outstanding option will become exercisable (without regard to the vesting provisions thereof) for a period of at least 30 days ending five days prior to the effective date of the transaction. Notwithstanding the foregoing, the surviving corporation may, in its sole discretion, (i) (a) grant to participants with options, options to purchase shares of the surviving corporation upon substantially the same terms as the options granted under the plan, (b) tender to all participants with restricted shares, an award of restricted shares of the surviving or acquiring corporation, and (c) tender to all participants with performance units, an award of performance units of the surviving or acquiring corporation, or (ii) (a) permit participants with restricted shares to receive unrestricted shares immediately prior to the effective date of any transaction, (b) permit participants with performance units to receive cash with respect to the value of any performance units immediately before the effective date of the

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transaction and (c) provide participants with options the choice of exercising the option prior to the consummation of the transaction or receiving a replacement option.

Notwithstanding anything to the contrary and except as otherwise expressly provided in the applicable award agreement, the vesting or similar installment provisions relating to the exercisability of any award, option or replacement option tendered as described in the previous sentence shall be accelerated, and the participant with restricted shares or performance units shall become fully vested, and the participant with options shall have the right, for a period of at least 30 days, to exercise such options; provided that such accelerations of vesting and exercisability shall occur only in the event that the participant's employment with or services for the Company should terminate within two years following a Change of Control (as defined in the plan), unless such employment or services are terminated by the Company for Cause (as defined in the plan) or by the participant voluntarily without Good Reason (as defined in the plan), or such employment or services are terminated due to the death or Disability of the participant. Notwithstanding the foregoing, no incentive stock option shall become exercisable pursuant to the foregoing without the participant's consent, if the result would be to cause such option not to be treated as an incentive stock option.

The number of shares of Common Stock covered by the plan, the number of shares of Common Stock covered by each outstanding option, restricted share and performance unit and the exercise price of any options shall be proportionately adjusted for any increase or decrease in the number of issued shares of Common Stock resulting from a subdivision or consolidation of such shares or a stock split or the payment of a stock dividend (but only of Common Stock) or any other increase or decrease in the number of issued shares effected without receipt of consideration by the Company.

### Transfer of Awards.

Unless an award is designated transferable by the Administrator upon grant, during the lifetime of the participant who has been granted an award, the award shall be shall not be assignable or transferable. No

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incentive stock option may be designated as transferable. In the event of the participant's death, any nontransferable award shall be transferable by the participant's will or the laws of descent and distribution.

### Amendment and Termination.

The plan will continue in effect until terminated by the Board of Directors or until expiration of the plan on November 17, 2013. The Board may suspend or discontinue the plan or revise or amend it.

The following table sets forth information concerning option/SAR grants in our fiscal year ended June 30, 2003 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, 2003 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



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fiscal year ended June 30, 2003:

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 base price (\$/Share) | Expiration Date |
|------------------------|--|---|-----------------------------------|-----------------|
| Christopher B. Wood    | 500,000  | 35.84%  | \$1.45                            | 12/31/12        |
| David P. Luci          | 500,000  | 35.84%  | \$0.74                            | 3/31/13         |
| Hugh Griffith          | 300,000  | 21.51%  | \$1.45                            | 10/22/12        |
| All Executive Officers | 1,300,000  | 93.13%  | n/a                               | n/a             |

There were no options/SARs exercised in our fiscal year ended June 30, 2003 by the named executive officers.

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The following table shows the June 30, 2003 fiscal year-end value of the stock options held by the Named Executive Officers.

Year End 2003 Option/SAR Values

| Name                | Number of Securities Underlying Unexercised Options/SARs at Year End |               | Value of Unexercised In-the-Money Options/SARs at Year End (1) |               |
|---------------------|--|---------------|--|---------------|
|                     | Exercisable  | Unexercisable | Exercisable  | Unexercisable |
| Christopher B. Wood | 1,500,000  | 500,000       | \$1,455,000  | \$385,000     |
| David P. Luci       | 170,000  | 330,000       | \$251,600  | \$448,000     |
| Hugh Griffith       | 100,000  | 200,000       | \$77,000   | \$154,000     |

(1) Amounts shown reflect the excess of the market value of the underlying our common stock at year end based upon the \$2.22 per share closing price on June 30, 2003 over the exercise prices for the stock options. The actual value, if

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any, an executive may realize is dependent upon the amount by which the market price of our common stock exceeds the exercise price when the stock options are exercised.

### Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under the Company's equity compensation plans as of June 30, 2003:

| Plan category  | Number of securities<br>to be issued upon<br>exercise of outstanding<br>options, warrants<br>and rights<br>(a) | Weighted-average<br>exercise price of<br>outstanding options,<br>warrants and rights<br>(b) | Number of securities<br>remaining available<br>for future issuance under<br>equity compensation<br>plans (excluding<br>securities<br>reflected in column<br>(c) |
|--|--|---|---|
| Equity compensation plans approved by security holders (1) | --   | --  | --  |
| Equity compensation plans not approved by security holders | 6,378,333  | \$1.30  | --  |
| Total  | 6,378,333  | \$1.30  | --  |

(1) At June 30, 2003, the Company had no equity compensation plans approved by security holders.

### FINANCIAL STATEMENTS

The consolidated financial statements of Bioenvision, Inc. and its subsidiaries including the notes thereto and the report thereon, is presented beginning at page F-1.

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

None.

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## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

|   |      |
|---|------|
| Report of Independent Registered Public Accounting Firm   | F-1  |
| Consolidated Balance Sheets as of June 30, 2003 and 2002  | F-2  |
| Consolidated Statements of Operations for years ended June 30, 2003 and 2002                              | F-3  |
| Consolidated Statements of Stockholders' Equity (Deficit) for years ended June 30, 2003 and 2002          | F-4  |
| Consolidated Statements of Cash Flows for years ended June 30, 2003 and 2002                              | F-5  |
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| Consolidated Balance Sheets as of March 31, 2004  | F-24 |
| Consolidated Statements of Operations for the nine month period ended March 31, 2004 and 2003 (Unaudited) | F-25 |
| Consolidated Statements of Cash Flows for the nine month period ended March 31, 2004 and 2003 (Unaudited) | F-26 |
| Notes to Consolidated Financial Statements (Unaudited)  | F-27 |

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

### Board of Directors and Stockholders of Bioenvision, Inc. and Subsidiaries

We have audited the accompanying consolidated balance sheets of Bioenvision, Inc. and Subsidiaries as of June 30, 2003 and 2002 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Bioenvision, Inc. and Subsidiaries as of June 30, 2003 and 2002, and the consolidated results of their operations and cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

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/s/ Grant Thornton LLP

GRANT THORNTON LLP  
New York, New York  
September 22, 2003

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Bioenvision, Inc. and Subsidiaries

CONSOLIDATED BALANCE SHEETS

|                             | June 30<br>2003 |
|-----------------------------|-----------------|
|                             | -----           |
| Current assets              |                 |
| Cash and cash equivalents   | \$ 7,929        |
| Restricted cash             | 290             |
| Deferred costs - current    | 22              |
| Accounts receivable         | 25              |
| Other assets                | 105             |
|                             | -----           |
| Total current assets        | 8,373           |
| Property and equipment, net | 49              |
| Deferred costs - long term  | 224             |
| Intangible assets, net      | 15,779          |
| Goodwill                    | 3,902           |
| Security deposits           | 79              |
| Other Long term assets      | 126             |
|                             | -----           |
| Total assets                | \$ 28,535       |
|                             | =====           |

LIABILITIES AND STOCKHOLDERS' EQUITY

|                                      |        |
|--------------------------------------|--------|
| Current liabilities                  |        |
| Accounts payable                     | \$ 411 |
| Accrued expenses                     | 730    |
| Accrued dividends payable            | 1,009  |
| Deferred revenue - current           | 113    |
|                                      | -----  |
| Total current liabilities            | 2,264  |
| Deferred revenue - long term         | 1,124  |
| Deferred tax liability - non-current | 6,317  |
|                                      | -----  |
| Total liabilities                    | 9,707  |
|                                      | -----  |

COMMITMENTS AND CONTINGENCIES

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|   |           |
|---|-----------|
| Stockholders' equity  |           |
| Preferred stock - \$0.001 par value; 5,920,000 shares authorized<br>and 5,916,966 shares issued and outstanding at June 30,<br>2003 and June 30, 2002, respectively (liquidation preference \$17,750,898) | 5         |
| Common stock - \$0.001 par value; 50,000,000 shares authorized<br>and 17,122,739 and 16,887,786 shares issued and outstanding at June 30,<br>2003 and June 30, 2002, respectively                         | 17        |
| Additional paid-in capital  | 47,304    |
| Accumulated deficit   | (28,651)  |
| Accumulated other comprehensive income  | 152       |
|   | -----     |
| Stockholders' equity  | 18,828    |
|   | -----     |
| Total liabilities and stockholders' equity  | \$ 28,535 |
|   | =====     |

The accompanying notes are an integral part of these statements.

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Bioenvision, Inc. and Subsidiaries  
CONSOLIDATED STATEMENTS OF OPERATIONS

|                               | Year ended<br>June 30, |             |
|-------------------------------|------------------------|-------------|
|                               | 2003                   | 2002        |
|                               | -----                  | -----       |
| Revenue                       | \$ 504,857             | \$ 802,965  |
|                               | -----                  | -----       |
| Costs and expenses            |                        |             |
| Research and development      | 1,689,278              | 1,912,258   |
| General and administrative    | 4,567,413              | 2,127,664   |
| Depreciation and amortization | 1,344,969              | 579,342     |
|                               | -----                  | -----       |
| Total costs and expenses      | 7,601,660              | 4,619,264   |
|                               | -----                  | -----       |
| Loss from operations          | (7,096,803)            | (3,816,299) |
| Interest income (expense)     |                        |             |
| Interest and finance charges  | (325,000)              | (2,172,682) |
| Interest income               | 138,574                |             |
|                               | -----                  | -----       |

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|  |                |                 |
|--|----------------|-----------------|
|  | (186,426)      | (2,172,682)     |
| Net loss before income tax benefit   | (7,283,229)    | (5,988,981)     |
| Income tax benefit   | 536,903        | 253,000         |
|  | -----          | -----           |
| NET LOSS   | (6,746,326)    | (5,735,981)     |
| Cumulative preferred stock dividend  | (877,818)      | (131,328)       |
| Beneficial conversion preferred stock dividend                                 |                | (9,351,339)     |
|  | -----          | -----           |
| Net loss available to common stockholders                                      | \$ (7,624,144) | \$ (15,218,648) |
|  | =====          | =====           |
| Basic and diluted net loss per share of common stock                           | \$ (0.45)      | \$ (1.25)       |
|  | =====          | =====           |
| Weighted-average shares used in computing basic and diluted net loss per share | 16,920,939     | 12,184,152      |
|  | =====          | =====           |

The accompanying notes are an integral part of these statements.

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Bioenvision, Inc. and Subsidiaries

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

|   | Preferred |    | Common Stock |       | Additional | Accumulat |
|---|-----------|----|--------------|-------|------------|-----------|
|   | Stock     |    |              |       | Paid In    | Deficit   |
|   | Shares    | \$ | Shares       | \$    | Capital    |           |
|   | -----     | -  | -----        | -     |            |           |
| Balance at June 30, 2001                        |           |    | 8,248,919    | 8,249 | 3,165,540  | (5,808,   |
| Net loss for the year                           |           |    |              |       |            | (5,735,   |
| Shares issued to employees for accrued salaries |           |    | 1,048,352    | 1,048 | 1,269,864  |           |
| Shares issued to consultants                    |           |    |              |       |            |           |

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|   |           |         |            |           |              |                |
|---|-----------|---------|------------|-----------|--------------|----------------|
| for services  |           |         | 390,515    | 391       | 168,083      |                |
| Shares issued in connection with acquisition of Pathagon      |           |         | 7,000,000  | 7,000     | 12,484,926   |                |
| Shares issued in connection with licensing agreement - OMRF   |           |         | 200,000    | 200       | 619,800      |                |
| Warrants issued in connection with licensing agreement - OMRF |           |         |            |           | 425,600      |                |
| Gross proceeds from issuance of preferred stock               | 5,916,966 | 5,917   |            |           | 17,744,081   |                |
| Direct costs incurred to issue preferred stock                |           |         |            |           | (3,911,906)  |                |
| Cumulative preferred stock dividend                           |           |         |            |           |              | (131,000)      |
| Beneficial conversion preferred stock dividend                |           |         |            |           | 9,351,339    | (9,351,339)    |
| Warrants issued in connection with credit facility            |           |         |            |           | 1,872,000    |                |
| Warrants issued for services rendered                         |           |         |            |           | 2,302,228    |                |
| -----   |           |         |            |           |              |                |
| Balance at June 30, 2002                                      | 5,916,966 | 5,917   | 16,887,786 | 16,888    | 45,491,554   | (21,027,000)   |
| Net loss for the year   |           |         |            |           |              | (6,746,000)    |
| Cumulative preferred stock dividend                           |           |         |            |           |              | (877,000)      |
| Shares issued to consultants for services                     |           |         | 234,953    | 235       | 1,258,080    |                |
| Warrants issued in connection with services                   |           |         |            |           | 182,350      |                |
| Repricing of options  |           |         |            |           | 372,465      |                |
| -----   |           |         |            |           |              |                |
| Balance at June 30, 2003                                      | 5,916,966 | \$5,917 | 17,122,739 | \$ 17,123 | \$47,304,449 | \$(28,651,000) |
|   | =====     | =====   | =====      | =====     | =====        | =====          |

The accompanying notes are an integral part of this statement.

Bioenvision, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF CASH FLOWS

|  | -----<br>2003<br>----- |
|--|------------------------|
| Cash flows from operating activities                                       |                        |
| Net loss   | \$ (6,746)             |
| Adjustments to reconcile net loss to net cash used in operating activities |                        |
| Depreciation and amortization  | 1,344                  |
| Financing charges - noncash  |                        |
| Deferred tax benefit   | (536)                  |
| Compensation costs - shares and warrants issued to nonemployees            | 1,440                  |
| Compensation costs - re-pricing of options                                 | 372                    |
| Changes in assets and liabilities  |                        |
| Deferred costs   | (63)                   |
| Deferred revenue   | 870                    |
| Accounts payable   | (22)                   |
| Other current assets   | (105)                  |
| Other long term assets   | (126)                  |
| Accounts receivable  | 25                     |
| Security deposits  | (79)                   |
| Officer's salary for equity conversion                                     |                        |
| Other accrued expenses and liabilities                                     | (782)                  |
| Net cash used in operating activities                                      | (4,411)                |
| Cash flows from investing activities                                       |                        |
| Purchase of intangible assets  | (191)                  |
| Capital expenditures   | (59)                   |
| Restricted cash  | (290)                  |
| Net cash used in investing activities                                      | (541)                  |
| Cash flows from financing activities                                       |                        |
| Bank overdraft   |                        |
| Proceeds from loan financing   |                        |
| Repayment of loan financing  |                        |
| Proceeds from issuance of preferred stock                                  |                        |
| Costs incurred in connection with offering                                 |                        |



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|  |          |
|--|----------|
| Net cash provided by financing activities                              |          |
| Net (decrease) increase in cash and cash equivalents                   | (4,952)  |
| Cash and cash equivalents, beginning of year                           | 12,882   |
| Cash and cash equivalents, end of year                                 | \$ 7,929 |
| Supplemental disclosure of cash flow information:                      |          |
| Cash paid during the year for  |          |
| Interest   | \$       |
| Supplemental disclosure of noncash investing and financing activities: |          |
| Noncash conversion of officer's salary into common stock               | \$       |
| Noncash conversion of trade payables into common stock                 | \$       |
| Noncash issuance of warrants related to SCO financing agreement        | \$       |
| Noncash issuance of warrants in connection with preferred stock        | \$       |
| Noncash issuance of stock related to Pathagon acquisition              | \$       |
| Noncash issuance of warrants and shares related to OMRFA               | \$       |

The accompanying notes are an integral part of these statements.

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

#### Note 1 - Organization and significant accounting policies

##### Description of business

Bioenvision, Inc. ("Bioenvision" or the "Company") is an emerging biopharmaceutical company whose primary business focus is the acquisition, development and distribution of drugs to treat cancer. The Company has a broad range of products and technologies under development, but its two lead drugs are Clofarabine and Modrenal(R). Modrenal(R) is approved for marketing in the U.K. for advanced breast cancer. The Company's plan is to bring Modrenal(R) into the U.S. to perform further clinical trials and to access the U.S. market. Most of the Company's other drugs are now in clinical trials 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.

On February 1, 2002, the Company completed the acquisition of Pathagon Inc. ("Pathagon"), a privately held company focused on the development of novel anti-infective products and technologies. Pathagon's principal products are

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OLIGON(R) and methylene blue. Affiliates of SCO Financial Group, 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.

### Basis of presentation

Prior to the acquisition of Pathagon and the May 2002 private placement in which the Company raised gross proceeds of \$17.7 million (see note 6), the Company devoted most of its efforts to establishing a new business (raising capital, research and development, etc.) and had been a development stage enterprise. Management believes they now have the financial resources to market some of the Company's late-stage products which can lead to significant revenues from royalty payments and drug sales. Accordingly, effective June 30, 2002, the financial statements do not reflect the required disclosure for a Development Stage Enterprise.

### 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.

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## BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

### Note 1 - Organization and significant accounting policies - continued

#### Revenue Recognition

In accordance with SEC Staff Accounting Bulletin No. 101, upfront nonrefundable fees associated with research and development collaboration agreements where the Company has continuing involvement in the agreement, are recorded as deferred revenue and recognized over the estimated research and development period using the straight-line method. If the estimated period is subsequently modified, the period over which the up-front fee is recognized is modified accordingly on a prospective basis using the straight-line method. Revenues from the achievement of research and development milestones, which represent the achievement of a significant step in the research and development process, are recognized when and if the milestones are achieved. Continuation of certain contracts and grants are dependent upon the Company and/or its co-development partners' achieving specific contractual milestones; however, none of the payments received to date are refundable regardless of the outcome of the project.

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Upfront nonrefundable fees associated with licensing arrangements are recorded as deferred revenue and recognized over the licensing arrangement using the straight line method, which approximates the life of the patent.

### Research and development

Research and development costs are charged to expense as incurred.

### Stock based compensation

At June 30, 2003, the Company has stock based compensation plans which are described more fully in Note 9. As permitted by SFAS No. 123, "Accounting for Stock Based Compensation", the Company accounts for stock based compensation arrangements with employees in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees". Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. Under APB 25, no stock based employee compensation cost is reflected in reported net loss, when options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant. For year ended June 30, 2003, the Company recognized stock based employee compensation cost of \$372,465 as a result of the March 31, 2003 re-pricing of 380,000 options granted to an employee pursuant to the terms of his Employment Agreement (see Note 7).

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 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," as amended by EITF 00-27. 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. The Company expects to continue applying the provisions of APB 25 for equity issuances to employees.

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

Note 1 - Organization and significant accounting policies - continued

The following table illustrates the effect on net loss and loss per share as if the fair value based method had been applied to all outstanding and unvested awards in each period.

|  | Year Ended June 30, |                |
|--|---------------------|----------------|
|  | 2003                | 2002           |
| Net loss available to common stockholders, as reported                       | \$(7,624,144)       | \$(15,111,000) |
| Add: Stock based employee compensation expense included in reported net loss | 372,465             | 372,465        |

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|   |                |         |
|---|----------------|---------|
| Deduct: Total stock based employee compensation expense determined under fair value based method for all awards | (1,214,723)    |         |
| Pro forma net loss available to common stockholders   | \$ (8,466,402) | \$ (15) |
|   |                |         |
| Loss per share  |                |         |
| Basic and diluted - as reported   | \$ (0.45)      | \$ (1.  |
| Basic and diluted - pro forma   | \$ (0.50)      | \$ (1.  |

The fair value of options at the date of grant was established using the Black-Scholes model with the following assumptions:

|                         |       |
|-------------------------|-------|
|                         | 2003  |
|                         | ----  |
| Expected life (years)   | 4.00  |
| Risk free interest rate | 3.00% |
| Expected volatility     | 80%   |
| Expected dividend yield | 0.00  |

### 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. The Company records a valuation allowance for certain temporary differences for which it is more likely than not that it will not receive future tax benefits.

### 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 and warrants to purchase 15,749,543 and 13,604,543 shares of common stock have not been included in the calculation of net loss per share for the years ended June 30, 2003 and 2002,

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

Note 1 - Organization and significant accounting policies - continued  
respectively, as their effect would have been anti-dilutive.

### 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

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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.

### 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. The Company invests all its funds with a single financial institution which provides for FDIC insurance of \$100,000.

### Advertising costs

Costs related to advertising and other promotional expenditures are expensed as incurred. Advertising costs totaled \$144,300 and \$4,850, respectively, for the years ended June 30, 2003 and 2002, respectively.

### Deferred costs

Deferred costs represents royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology advance royalties. These costs have been presented together with research and development costs on the statement of operations for the years ended June 30, 2003 and 2002.

### Property and equipment

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

### Goodwill and Other Intangible Assets

Goodwill represents the excess of costs over the fair value of identifiable net assets of Pathagon. Intangible assets include patents and licensing rights acquired in connection with the acquisition of Pathagon. The Company accounts for these assets in accordance with Statement of Financial Accounting Standards ("SFAS") No. 142, Goodwill and Other Intangible Assets. Goodwill and intangible assets acquired in a purchase business combination and determined to have an indefinite useful life are not amortized, but instead tested for impairment at least annually in accordance with the provisions of SFAS No. 142. SFAS No. 142 also requires that intangible assets with estimable useful lives be amortized over their respective estimated useful lives to their estimated residual values, and reviewed for impairment in accordance with SFAS No. 144, Accounting for Impairment or Disposal of Long-Lived Assets ("SFAS No. 144"). The Company does not have any intangible assets with an indefinite useful life.

### Long-Lived Assets

The Company adopted the provisions of SFAS No. 144 on July 1, 2003. In accordance with SFAS No. 144, long-lived assets, such as property and equipment and intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

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JUNE 30, 2003 AND 2002

Note 1 - Organization and significant accounting policies - continued

Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Prior to the adoption of SFAS No. 144, the Company accounted for long-lived assets in accordance with SFAS No. 121, Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed Of.

Impact of recently issued accounting pronouncements

In July 2002, the FASB Issued Statement 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS 146"). This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force (EITF) Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Cost to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The principal difference between this Statement and Issue 94-3 relates to its requirements for recognition of a liability for a cost associated with an exit or disposal activity. This Statement requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. The provisions of this Statement are effective for exit or disposal activities that are initiated after December 31, 2002. Effective January 1, 2003, the Company adopted the provisions of SFAS 146 which did not have an impact on the results of operations or financial position.

In November 2002, the FASB issued Interpretation No. 45, "Guarantors Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ("FIN 45"). FIN 45 requires that certain guarantees be initially recorded at fair value, which is different from the general current practice of recording a liability only when a loss is probable and reasonably estimable. FIN 45 also requires a guarantor to make significant new disclosures for virtually all guarantees. Effective January 1, 2003, the Company adopted the disclosure requirements under FIN 45 which did not have a material impact on the results of operations or financial position of the Company.

On December 31, 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation Transition and Disclosure" ("SFAS 148"). SFAS 148 amends FASB Statement No. 123, "Accounting for Stock Based Compensation," to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure provisions of SFAS 123 and APB Opinion No. 28, "Interim Financial Reporting," to require disclosure on the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. While SFAS 148 does not amend SFAS 123 to require companies to account for employee stock options using the fair value method, the disclosure provisions of SFAS 148 are applicable to all companies with stock-based employee compensation, regardless of whether they account for the compensation using the fair value method of SFAS 123 or the intrinsic value method of APB Opinion 25. The Company adopted the required disclosure provisions of SFAS 148 as described under accounting policy footnote "Stock based compensation".

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## BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

### Note 1 - Organization and significant accounting policies - continued

In January 2003, the FASB issued interpretation No. 46, "Consolidation of Variable Interest Entities--An Interpretation of ARB No. 51" ("FIN 46"), which addresses consolidation of variable interest entities. FIN 46 expands the criteria for consideration in determining whether a variable interest entity should be consolidated by a business entity, and requires existing unconsolidated variable interest entities (which include, but are not limited to, Special Purpose Entities, or SPE's) to be consolidated by their primary beneficiaries if the entities do not effectively disburse risks among parties involved. This interpretation applies immediately to variable interest entities created after January 31, 2003 and variable interest entities in which an enterprise obtains and interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN 46 is not expected to have a material impact on the results of operation or financial position of the Company.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (SFAS 150"). The objective of SFAS No. 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. The adoption of SFAS 150 is not expected to have a material impact on the results of operations or financial position of the Company.

In May 2003, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations, but could affect the timing or pattern of revenue recognition for future collaborative research and/or license agreements.

### NOTE 2 - Acquisition of Pathagon

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) surrounding November 22, 2001, the day of the Company's announcement of the agreed upon acquisition. The acquired patents and licensing rights of OLIGON(R) and methylene blue (collectively referred to as "Purchased Technologies"), were recorded at their fair market value which was approximately \$17,576,000. The patent and licensing rights acquired are being amortized over 13 years, which is the estimated remaining contractual life of

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these assets. Since the estimated fair value of the Purchased Technologies was at least equal to the amount paid, the purchase price, net of assumed liabilities, was allocated to Purchased Technologies. The transaction qualified as a tax-free merger which resulted in a difference between the tax basis value of the assets acquired and the fair market value of the patents and licensing rights. As a result, a deferred tax liability was recorded for approximately \$7,909,000. The purchase price exceeded the fair market value of the net assets acquired resulting in the recording of Goodwill of \$4,704,100. The Company recorded a charge to goodwill of \$801,395 for fiscal year ended June 30, 2003 as a result of a change in tax rates used to compute the deferred tax liability arising as a result of this acquisition. Pathagon had no operations other than holding the patents and licenses acquired. As Pathagon had no operations, its pro-forma financials would not be meaningful and thus are not presented.

The Company now has the worldwide rights to the use of thiazine dyes, including methylene blue, for in vitro and in vivos 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

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

#### Note 2 - Acquisition of Pathagon - continued

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.

The OLIGON(R) technology is a patented anti-microbial 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 that destroy bacteria, fungi and other pathogens. The Company intends to commercialize the technology in partnership with leading medical devices manufacturers.

On May 6, 1997, Baxter Healthcare Corporation acting through its Edwards Clinical-Care Division ("Edwards") entered into an Exclusive License Agreement with Implemed, Inc. ("Implemed"), a predecessor in interest to the Pathagon and, by virtue of the acquisition of Pathagon, a predecessor in interest to the Company. Pursuant to the terms of the License Agreement, among other things, Edwards licensed certain intellectual property technology relating to the manufacture of anti-microbial polymers from Implemed.

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. Pursuant to the amendment, the Company paid OMRF \$100,000 and issued 200,000 shares of the Company's common stock and a five-year warrant to purchase an additional 200,000 shares of common stock. The exercise price of the warrant is \$2.33 per share,



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subject to adjustment. The Company capitalized the costs of approximately \$1,145,600 related to this amendment as an intangible asset and will amortize this asset over the remaining life of the methylene blue license agreement.

### NOTE 3 - Intangible Assets

| Intangible assets consist of the following: | June 30, 2003 | June 30, 2002 |
|---|---------------|---------------|
| Patents and licensing rights                | \$17,644,521  | \$17,487,548  |
| Less: accumulated amortization              | 1,865,122     | 565,756       |
|   | -----         | -----         |
|   | \$15,779,399  | \$16,921,792  |
|   | =====         | =====         |

Amortization of patents and licensing rights amounted to \$1,334,241 and \$561,832 for the years ended June 30, 2003 and June 30, 2002, respectively. Amortization for each of the next five fiscal years will amount to approximately \$1,342,000 annually.

### NOTE 4 - License and Co-Development Agreements

#### Clofarabine

We have a license from Southern Research Institute ("SRI"), 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. Under the terms of the agreement with SRI, 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

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## BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

### Note 4 - License and Co-Development Agreements - continued

information related to the technology to obtain patent and other proprietary rights to products developed by us and by SRI from the technology. We plan to develop Clofarabine initially for the treatment of leukemia and lymphoma and to study its potential role in treatment of solid tumors.

In August 2003, SRI granted us an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. We intend to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

To facilitate the development of Clofarabine, we entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX") in March 2001. 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

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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. Under the co-development agreement, ILEX will have certain rights if it performs its development obligations in accordance with that agreement. The Company would be required to pay ILEX a royalty on sales outside the U.S., Canada, Japan and Southeast Asia. In turn, ILEX, which would have U.S. and Canadian distribution rights, would 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 per share 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 Research Institute based on certain milestones. The Company is obligated to milestones and royalties to Southern Research Institute in respect to Clofarabine.

The Company received a nonrefundable, upfront payment of \$1.35 million when they entered into the agreement with ILEX and is entitled to receive milestone payments of \$2.5 million upon completion of management designed pivotal Phase II clinical trials of Clofarabine and \$5.0 million after submission of a new drug application with the FDA. The upfront payment was deferred and recognized as revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company recognized revenues of approximately \$490,000 and \$800,000 in connection with the up-front payment of ILEX agreement for the years ended June 30, 2003 and 2002, respectively.

Deferred costs represents royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology. The Company also defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with Ilex agreement. Research and Development includes approximately \$207,000 and \$368,000 for the years ended June 30, 2003 and 2002, respectively, related to such charges.

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

Note 4 - License and Co-Development Agreements - continued

#### Modrenal (R)

The Company holds an exclusive license, until the expiration of existing and new patents related to Modrenal(R), to market Modrenal in major international territories, and an agreement with a United Kingdom company to co-develop Modrenal(R) for other therapeutic indications. Management believes that Modrenal(R) currently is manufactured by third-party contractors in accordance with good manufacturing practices. The Company has no plans to establish its own manufacturing facility for Modrenal(R), but will continue to use third-party contractors.

Anti-Estrogen Prostate. We have received Institutional Review Board approval

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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 and currently is intended to commence in May 2004.

### Operational Developments

In June 2003, we entered into a supply agreement with Ferro-Pfanstiehl Laboratories ("Ferro"), pursuant to which Ferro has agreed to manufacture and supply 100% of Bioenvisions global requirements for Clofarabine-API. Subject to certain circumstances, this agreement will expire on the fifth anniversary date of the first regulatory approval of Clofarabine drug product.

In June 2003, the Company entered into a development agreement with Ferro, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply CTM and GMP supplier qualifications of the API-Clofarabine. Subject to certain circumstances, this agreement expires upon the completion of the development program. The development agreement is milestone based and payments are to be paid upon completion of each milestone. If Ferro has not completed the development agreement by December 2007, the development agreement will automatically terminate without further action by either party. Through June 30, 2003, the Company paid and capitalized \$50,000 related to development costs.

In May 2003, we entered into a sub-license agreement with Dechra, pursuant to which Dechra has been granted a sub-license for all of Bioenvision's rights and entitlements to market and distribute Modrenal in the United States and Canada solely in connection with animal health applications. Subject to certain circumstances, this agreement expires upon expiration of the last patent related to Modrenal or the completion of the last royalty set forth in the agreement. Through June 30, 2003, we have recognized deferred revenue and deferred costs related to this agreement as described below in this Note 4. The Company received an upfront non-refundable payment of \$1.25 million upon execution of this agreement and may receive up to an additional \$3.75 million upon the achievement by Dechra of certain milestones set forth in the agreement.

In May 2003, we entered into a master services agreement with Penn-Pharmaceutical Services Limited ("Penn"), pursuant to which Penn has agreed to label, package and distribute Clofarabine on behalf of and at our request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three month prior written notice.

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

NOTE 4 - License and Co-Development Agreements - continued

In April 2003, we entered into an exclusive license agreement with CLL-Pharma ("CLL"), pursuant to which CLL has agreed to perform certain development works and studies to create a new formulation of Modrenal in the form of a soft gel capsule. CLL intends to use its proprietary MIDDs.-patented technology to perform this service on behalf of the Company. This new formulation, once in

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hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell Modrenal throughout Europe. Through June 30, 2003, the Company paid an advance of \$175,000 related to development services to be provided by CLL over an eighteen month period, which advance was recorded as a prepaid development cost by the Company.

### Note 5 - Income taxes

The components of the income tax benefit are as follows:

|               | June 30,     |              |
|---------------|--------------|--------------|
|               | 2003         | 2002         |
| Current:      |              |              |
| Federal       | \$       --  | \$       --  |
| State         | --           | --           |
| Deferred:     |              |              |
| Federal       | (404,000)    | (160,000)    |
| State         | (133,000)    | (93,000)     |
|               | (537,000)    | (253,000)    |
| Total benefit | \$ (537,000) | \$ (253,000) |

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

### Note 5 - Income taxes - continued

Significant components of the company's deferred tax assets and liability at June 30 are as follows:

|   | June 30,       |                |
|---|----------------|----------------|
|   | 2003           | 2002           |
| Deferred tax liability                      |                |                |
| Acquired intangibles                        | \$ (6,318,000) | \$ (7,656,000) |
| Deferred tax assets                         |                |                |
| Net operating loss                          | 5,512,000      | 3,256,000      |
| Depreciation                                | 11,000         | 13,000         |
| Net deferred revenue                        | 401,000        | --             |
| Other                                       | 66,000         | 1,000          |
| Total deferred tax assets                   | 5,990,000      | 3,270,000      |
| Valuation allowance for deferred tax assets | (5,990,000)    | (3,270,000)    |

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|                            |                               |                               |
|----------------------------|-------------------------------|-------------------------------|
| Net deferred tax asset     | -----<br>--                   | -----<br>--                   |
| Net deferred tax liability | -----<br>(6,318,000)<br>===== | -----<br>(7,656,000)<br>===== |

At June 30, 2003, the Company had approximately \$13,609,000 of net operating loss carryforwards for U.S. Federal and state income tax purposes that expire fiscal year ending 2019, with a tax value of \$5,512,000. A full valuation allowance has been established for the deferred tax assets due to the uncertainty of the utilization of such deferred tax asset.

The Tax Reform Act of 1986 enacted a complex set of rules (Internal Revenue Code Section 382) limiting the utilization of NOLs to offset future taxable income following a corporate "ownership change." Generally, this occurs when there is a greater than 50 percentage point change in ownership. Accordingly, such change could limit the amount of NOLs available in a given year, which could ultimately cause NOLs to expire prior to utilization.

The income tax benefit as recognized differs from the benefit that would be recognized at the Federal statutory rate on the pre-dividend net loss primarily due to the valuation allowance established against the net operating loss deferred tax assets.

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

NOTE 6 - Stockholders' transactions

Common Stock and Securities Convertible into Common Stock

In April 2001, in accordance with the terms of the Company's stock option plan, the Company issued the following options at an exercise price of \$1.25 per share, which immediately vested:

- o a total of 2,200,000 options to employees (Christopher Wood - 1,500,000 options; Stuart Smith - 500,000 options; and Thomas Scott Nelson - 200,000 options);
- o a total of 2,654,544 options to certain consultants to the Company; and
- o a total of 500,000 options to Phoenix Ventures, which were issued in connection with a credit facility made available to the Company by Glen Investments Limited, a Jersey (Channel Islands) corporation wholly owned by Kevin R. Leech, a U.K. citizen and one of the Company's stockholders, which facility was terminated in August 2001.

Originally, the terms of the options were that each option could be exercised after April 30, 2001 for a period of three years, whereby the options would no longer be able to be exercised after April 30, 2004 unless otherwise agreed to with the Company. In July 2002, the Company changed the three-year term to a five-year term. The extension of the foregoing options to a five-year term required the Company to record additional compensation, interest and finance

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charges and consulting fees and expenses of \$422,500 in the quarter ended September 30, 2002.

In August 2001, the Board of Directors approved the issuance of 208,333 shares of common stock to its officers and directors in exchange for accrued compensation at a rate of \$1.25 per share. In October 2001, the Board of Directors approved the issuance of 134,055 shares of common stock to its officers and directors in exchange for accrued compensation of approximately \$206,000.

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 financing costs of \$1,872,000, which were amortized over the term of the Facility. The warrants expire five years from the date of issuance. The credit facility with SCO Capital was terminated in May 2002 at which time the Company received a payoff letter evidencing such termination.

In December 2001, the Company granted 200,000 shares of common stock to a consultant to the Company, these shares vesting over an eighteen month period. Compensation expense of \$212,108 and \$80,456 were recorded as consulting fees for the years ended June 30, 2003 and 2002, respectively.

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, pursuant to which the Company is required to register the offer and resale of the shares of common stock issued in the acquisition. Affiliates of SCO Capital owned 82% of Pathagon prior to the acquisition.

On May 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 Series A Convertible Preferred Stock. The shareholder action became effective, and the amendment was filed and became effective, on April 30, 2002.

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

#### Note 6 - Stockholders' transactions - continued

In March 2002, the Company issued 705,984 shares of common stock to its officers and directors as payment for salaries accrued through June 30, 2001 of \$910,000

In June 2002, the Company granted options to an officer of the Company to purchase 380,000 shares of common stock at an exercise price of \$1.95 per share, which equaled the stock price on the date of the grant. Of this amount, 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003 the Company entered into an Employment Agreement with such officer of the Company, pursuant

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to which, among other things, the exercise price for all 380,000 options were changed to \$0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of \$0.735 per share which vested immediately. As a result of the re-pricing of 380,000 options, the Company will re-measure the intrinsic value of these options at the end of each reporting period and will adjust compensation expense based on changes in the stock price. Compensation expense recognized as a result of this re-pricing amounted to \$372,465 for the year ended June 30, 2003.

On October 23, 2002, the Company granted options to purchase 300,000 shares of common stock at an exercise price of \$1.45 per share to the Commercial Director (Europe) of the Company. Of these options, options to purchase 100,000 shares of common stock vest and become exercisable on each of the first, second and third anniversary of October 23, 2002, the grant date.

On October 23, 2002, the Company granted options to purchase 50,000 shares of common stock at an exercise price of \$1.45 per share to another employee of the Company. Of these options, options to purchase 50,000 shares of common stock vest and become exercisable on each of the first and second anniversary of October 23, 2002, the grant date.

On December 31, 2002 the Company issued options to purchase 500,000 shares of common stock at an exercise price equal to \$1.45 per share (average of the high and low bid price on the grant date), to its Chairman and Chief Executive Officer, Dr. Christopher B. Wood. Of these options, subject to certain circumstances, options to purchase 166,666 shares of common stock vest on each of the first, second and third anniversary of the grant date.

On December 31, 2002 the Company issues options to purchase 200,000 shares of common stock at an exercise price of \$2.00 per share to a consultant to the Company who performs European regulatory services for the Company. Of these options, options to purchase 66,666 shares of common stock vest on each of the first, second and third anniversary of the grant date. Compensation expense of \$24,333 was recorded as consulting fees for the year ended June 30, 2003.

On January 9, 2003 the Company issued to an employee of the Company, options to purchase 20,000 shares of common stock at an exercise price of \$1.42 per share, which equaled the stock price on the date of grant. Of these options, subject to certain circumstances, options to purchase 10,000 shares of common stock vest and become exercisable on the first anniversary of the grant date and the remaining options to purchase 10,000 shares of common stock vest and become exercisable on the second anniversary of the grant date.

In January 2003, we entered into an agreement with RRD International LLC ("RRD"), pursuant to which RRD serves as the global product development consultant to the Company in connection with the development of Clofarabine, Modrenal (TM) and OLIGON and assists with designing and managing our clinical development program for our products. On April 2, 2003, the Company and RRD further memorialized their agreement pursuant to a

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

NOTE 6 - Stockholders' transactions - continued

formal Master Services Agreement and Registration Rights Agreement and, in

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connection therewith, the Company issued a Warrant to RRD pursuant to which RRD has the right to acquire 175,000 shares of our common stock at an exercise price of \$2.00 per share, which warrant includes registration rights under certain circumstances. Compensation expense of \$182,350 was recorded as consulting fees for the year ended June 30, 2003.

### Preferred Stock

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 two 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. In May 2002, the Company consummated a Private Placement of Series A Preferred Stock and received gross proceeds of \$17.7 million (see Note 8). 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 registration rights. The preferred stock generally carries rights to vote with the holders of common stock as one class on a two-for-one basis. The preferred stock is convertible into the Company's common stock on a two-for-one basis subject to certain adjustments at the earlier to occur of (i) at the election of each holder from and after the issuance date, or (ii) the date at any time after the one year anniversary of the issuance date upon which both (x) the average of the market price for a share of common stock for thirty consecutive trading days exceeds \$10.00 per share, subject to certain adjustments, and (y) the average of the trading volume for the Company's common stock during such period exceeds 150,000, subject to certain adjustments.

The Company is required to accrue for and pay a dividend of 5%, subject to certain adjustments, on its cumulative Series A Convertible Participating Preferred Stock. In the event of a voluntary or involuntary liquidation or dissolution of the Company, before any distribution of assets shall be made to the holders of the Company's securities which are junior to the preferred stock (such as the common stock), holders of the preferred stock shall be paid out of the assets of the Company legally available for distribution to the Company's stockholders an amount per share equal to the initial original issue price (\$3.00) subject to certain adjustments plus all accrued but unpaid dividends on such preferred stock.

### NOTE 7 - Related party transactions

On November 16, 2001, we entered into an engagement letter with SCO Financial Group, 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 adjustments. The warrants expire five years from the date of issuance. The issuance of these shares was capitalized as deferred financing costs and was amortized over a twelve-month period.

In connection with securing a credit 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 credit facility with SCO Capital was terminated in May 2002 at which time the Company received a payoff letter evidencing such termination.

On February 5, 2002, we completed the acquisition of Pathagon Inc. Affiliates of SCO Capital owned 82% of Pathagon prior to the acquisition. In connection therewith, on February 1, 2002 we issued 7,000,000 shares of common stock to the



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former stockholders of Pathagon Inc.

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

#### NOTE 8 - Stock options

The Company adopted its 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 5 years from the date of grant.

In June 2002, the Company granted options to an officer of the Company to purchase 380,000 shares of common stock at an exercise price of \$1.95 per share, which equaled the stock price on the date of the grant. Of this amount, 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003 the Company entered into an Employment Agreement with such officer of the Company, pursuant to which, among other things, the exercise price for all 380,000 options were changed to \$0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of \$0.735 per share which vested immediately. As a result of the re-pricing of 380,000 options, the Company will re-measure the intrinsic value of these options at the end of each reporting period and will record a charge for compensation expense to the extent the vested portions are in the money. Compensation expense recognized as a result of this re-pricing amounted to \$372,467 for the year ended June 30, 2003.

On October 23, 2002, the Company granted options to purchase 300,000 shares of common stock at an exercise price of \$1.45 per share to the Commercial Director (Europe) of the Company. Of these options, options to purchase 100,000 shares of common stock vest and become exercisable on each of the first, second and third anniversary of October 23, 2002, the grant date.

On October 23, 2002, the Company granted options to purchase 50,000 shares of common stock at an exercise price of \$1.45 per share to another employee of the Company. Of these options, options to purchase 50,000 shares of common stock vest and become exercisable on each of the first and second anniversary of October 23, 2002, the grant date.

On December 31, 2002 the Company issued options to purchase 500,000 shares of common stock at an exercise price equal to \$1.45 per share (average of the high and low bid price on the grant date), to its Chairman and Chief Executive Officer, Dr. Christopher B. Wood. Of these options, subject to certain circumstances, options to purchase 166,666 shares of common stock vest on each of the first, second and third anniversary of the grant date.

On December 31, 2002 the Company issues options to purchase 200,000 shares of common stock at an exercise price of \$2.00 per share to a consultant to the Company who performs European regulatory services for the Company. Of these options, options to purchase 66,666 shares of common stock vest on each of the first, second and third anniversary of the grant date. Compensation expense of \$24,333 was recorded as consulting fees for the year ended June 30, 2003.

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On January 9, 2003 the Company issued to an employee of the Company, options to purchase 20,000 shares of common stock at an exercise price of \$1.42 per share, which equaled the stock price on the date of grant. Of these options, subject to certain circumstances, options to purchase 10,000 shares of common stock vest and become exercisable on the first anniversary of the grant date and the remaining options to purchase 10,000 shares of common stock vest and become exercisable on the second anniversary of the grant date.

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

NOTE 8 - Stock options - continued

A summary of the Company's stock option activity for options issued to employees and related information follows:

|                         | No. of Shares<br>----- | Weighted Avg.<br>Exercise Price<br>----- |
|-------------------------|------------------------|--|
| Balance - July 1, 2001  | 2,200,000              | \$ 1.25                                  |
| Granted during 2002     | -                      | -  |
| Exercised during 2002   | -                      | -  |
| Forfeiture during 2002  | -                      | -  |
|                         | -----                  |  |
| Balance - June 30, 2002 | 2,200,000              | 1.25                                     |
| Granted during 2003     | 1,370,000              | 1.19                                     |
| Exercised during 2003   | -                      | -  |
| Forfeiture during 2003  | -                      | -  |
|                         | -----                  |  |
| Balance - June 30, 2003 | 3,570,000              | \$ 1.23                                  |
|                         | =====                  |  |

| Stock Options Outstanding |                                    |                      |                |
|---------------------------|------------------------------------|----------------------|----------------|
| Exercise Price Range      | Weighted Average<br>Exercise price | Number of<br>Options | We<br>Re<br>Co |
| \$0.74                    | \$ 0.74                            | 500,000              | 9.             |
| \$1.25 - \$1.45           | \$ 1.29                            | 3,070,000            | 8.             |

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
JUNE 30, 2003 AND 2002

NOTE 9 - Commitments and Contingencies

Leases

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The Company leases 3,229 square feet of office space for its New York headquarters under a non-cancellable operating lease expiring on September 30, 2005. Rent expense in 2003, excluding real estate taxes, insurance and repair costs, was approximately \$110,000. At June 30, 2003, total minimum rentals under operating leases with initial or remaining non-cancellable lease terms of more than one year were:

| Year ended June 30, |           |
|---------------------|-----------|
| 2004                | \$193,317 |
| 2005                | 197,873   |
| 2006                | 63,439    |
| 2007                | 10,185    |
| 2008                | _____     |
|                     | \$464,814 |
|                     | =====     |

The Company is a party to an additional month-to-month lease agreement for its subsidiary, Bioenvision Ltd. in Edinburgh, Scotland.

Employment Agreements

-----

On September 1, 1999, we entered into an employment agreement with Christopher B. Wood, M.D. under which he serves as our 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. On December 31, 2002, we entered into a new employment agreement with Dr. Wood, under which he continues to serve as our Chairman and Chief Executive Officer. Under this contract, the term is one year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. Dr. Wood's new employment agreement provides for an initial base salary of \$225,000, a bonus as determined by the Board of Directors, health insurance and other benefits currently or in the future provided to key employees of the Company. If Dr. Wood's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to his then current annual base

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salary and any and all unvested options will vest and immediately become exercisable.

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. On September 30, 2002, Mr. Smith resigned from his position as Senior Vice President of the Company; his employment agreement was terminated and the Company agreed to issue shares of its common stock to Mr. Smith at the then current fair market value in satisfaction of all outstanding obligations of the Company to Mr. Smith pursuant to the employment agreement.

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### BIOENVISION, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS JUNE 30, 2003 AND 2002

#### Note 9 - Commitments and Contingencies - continued

On March 31, 2003, we entered into an employment agreement with David P. Luci, pursuant to which he serves as our Director of Finance, General Counsel and Corporate Secretary. The initial term of Mr. Luci's employment agreement is one-year, with automatic one-year extensions thereafter unless either party provides written notice to the contrary. If Mr. Luci's employment is terminated other than for cause or if he resigns for good reason or if a change of control occurs, he will receive a lump sum payment in an amount equal to 1.5 multiplied by the sum of (i) his then current annual base salary plus (ii) his then average annual bonus for the preceding two years and any and all unvested options will vest and immediately become exercisable.

#### Litigation

-----

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleges a breach of contract by the Company and demands judgment against the Company for \$112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. The Company believes that the grounds for the complaint are meritless and intends to defend this matter vigorously. If the Company is not able to successfully defend this complaint, management does not believe that any resulting judgment or settlement would have a material adverse effect on the Company, its financial position or results of operations.

#### NOTE 10 - Subsequent Events

In August 2003, we entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, we succeeded to the U.K. marketing rights to Modrenal. In August 2003, SRI granted us an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. We intend to convert

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the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

In September 2003, we entered into a letter agreement with ILEX Oncology, Inc. pursuant to which we are working with ILEX to co-develop an oral formulation for Clofarabine; the rights and related costs to which we agreed to split equally with ILEX.

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### BIOENVISION, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

|   | March<br>2004<br>-----<br>(unaudi |
|---|-----------------------------------|
| <b>ASSETS</b>                               |                                   |
| Current assets                              |                                   |
| Cash and cash equivalents                   | \$17,558,                         |
| Restricted cash                             | 290,                              |
| Deferred costs                              | 178,                              |
| Accounts receivable                         | 2,640,                            |
| Other assets                                | 187,                              |
|   | -----                             |
| Total current assets                        | 20,854,                           |
| Property and equipment, net                 | 37,                               |
| Intangible assets, net                      | 14,801,                           |
| Goodwill                                    | 3,902,                            |
| Security deposits                           | 79,                               |
| Other long term assets                      | 30,                               |
| Deferred costs-long term                    | 2,776,                            |
|   | -----                             |
| Total assets                                | \$42,481,<br>=====                |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b> |                                   |
| Current liabilities                         |                                   |
| Accounts payable                            | \$1,133,                          |
| Accrued expenses                            | 493,                              |
| Accrued dividends payable                   | 1,597,                            |
| Deferred revenue                            | 434,                              |
|   | -----                             |
| Total current liabilities                   | 3,657,                            |
| Deferred revenue-long term                  | 6,166,                            |
| Deferred tax liability                      | 5,914,                            |
|   | -----                             |
| Total liabilities                           | 15,738,                           |

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|  |           |
|--|-----------|
| Stockholders' equity   |           |
| Preferred stock - \$0.001 par value; 20,000,000 shares authorized;<br>4,698,333 and 5,916,966 shares issued and outstanding at March 31, 2004<br>and June 30, 2003, respectively (liquidation preference \$14,094,999 and<br>17,750,898 at March 31, 2004 and June 30, 2003, respectively) | 4,        |
| Common stock - par value \$0.001; 70,000,000 shares authorized;<br>23,017,950 and 17,122,739 shares issued and outstanding at March 31,<br>2004 and June 30, 2003, respectively  | 23,       |
| Additional paid-in capital   | 64,240,   |
| Accumulated deficit  | (37,676,  |
| Accumulated other comprehensive income   | 152,      |
|  | -----     |
| Stockholders' equity   | 26,743,   |
|  | -----     |
| Total liabilities and stockholders' equity   | \$42,481, |
|  | =====     |

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

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Bioenvision, Inc. and Subsidiaries  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

|  | Nine months ended<br>March 31, |             |
|--|--------------------------------|-------------|
|  | 2004                           | 2003        |
|  | -----                          | -----       |
|  | (unaudited)                    | (unaudited) |
| Licensing and royalty revenue  | \$361,308                      | \$463,935   |
| Research and development contract revenue  | 1,396,722                      | -           |
|  | -----                          | -----       |
| Total revenue  | 1,758,030                      | 463,935     |
| Costs and expenses   |                                |             |
| Research and development   | 2,545,128                      | 1,162,108   |
| Selling, general and administrative<br>(includes stock based compensation<br>expense of \$2,526,943 and \$256,056 for<br>the three months ended March 31, 2004 and<br>2003, respectively, and \$3,625,535 and<br>\$678,556 for the nine months ended March<br>31, 2004 and 2003, respectively) | 7,079,367                      | 2,743,160   |
| Depreciation and amortization  | 1,023,325                      | 1,005,709   |
|  | -----                          | -----       |
| Total costs and expenses   | 10,647,818                     | 4,910,977   |
|  | -----                          | -----       |
| Loss from operations   | (8,889,789)                    | (4,447,042) |

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|   |                |                |
|---|----------------|----------------|
| Interest income (expense)   |                |                |
| Interest and finance charges  | -              | (325,000)      |
| Interest income   | 49,465         | 117,054        |
|   | -----          | -----          |
| Net loss before income tax benefit  | (8,840,325)    | (4,654,988)    |
| Income tax benefit  | 402,928        | 456,300        |
|   | -----          | -----          |
| Net loss  | (8,437,397)    | (4,198,688)    |
| Cumulative preferred stock dividend   | (587,971)      | (658,972)      |
|   | -----          | -----          |
| Net loss available to common stockholders   | \$ (9,025,369) | \$ (4,857,660) |
|   | =====          | =====          |
| <br>  |                |                |
| Basic and diluted net loss per share of<br>common stock                           | \$ (0.50)      | \$ (0.29)      |
|   | =====          | =====          |
| <br>  |                |                |
| Weighted average shares used in computing<br>basic and diluted net loss per share | 18,122,445     | 16,887,786     |
|   | =====          | =====          |

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

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Bioenvision, Inc. and Subsidiaries  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

|   | Nine months ended<br>March 31,        |                                       |
|---|---------------------------------------|---------------------------------------|
|   | -----<br>2004<br>-----<br>(unaudited) | -----<br>2003<br>-----<br>(unaudited) |
| Cash flows from operating activities  |                                       |                                       |
| Net loss  | \$ (8,437,397)                        | \$ (4,198,688)                        |
| Adjustments to reconcile net loss to net<br>cash used in operating activities |                                       |                                       |
| Depreciation and amortization   | 1,023,325                             | 1,005,710                             |
| Deferred tax benefit  | (402,928)                             | (456,300)                             |
| Compensation costs - shares and warrants issued<br>to nonemployees            | 1,009,290                             | 678,556                               |
| Compensation costs - re-pricing of options                                    | 2,597,796                             | -                                     |
| Compensation costs-options issued to employees                                | 18,449                                | -                                     |

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|  |              |             |
|--|--------------|-------------|
| Changes in assets and liabilities  |              |             |
| Deferred costs   | (2,706,549)  | 184,091     |
| Deferred revenue   | 5,362,012    | (368,182)   |
| Accounts payable   | 721,608      | (109,623)   |
| Other current assets   | (81,628)     | (45,529)    |
| Other long term assets   | 96,868       | 4,247       |
| Accounts receivable  | (2,615,263)  | (79,111)    |
| Other accrued expenses and liabilities                                       | (237,353)    | (772,834)   |
|  | -----        | -----       |
| Net cash used in operating activities  | (3,651,771)  | (4,157,663) |
|  | -----        | -----       |
| Cash flows from investing activities   |              |             |
| Purchase of intangible assets  | (30,772)     | (161,183)   |
| Capital expenditures   | (3,116)      | (59,405)    |
| Restricted cash  | -            | (290,000)   |
|  | -----        | -----       |
| Net cash used in investing activities  | (33,888)     | (510,588)   |
|  | -----        | -----       |
| Cash flows from financing activities   |              |             |
| Proceeds from issuance of common stock                                       | 12,157,240   | -           |
| Proceeds from exercise of options, warrants and other convertible securities | 1,157,546    | -           |
|  | -----        | -----       |
| Net cash provided by financing activities                                    | 13,314,786   | -           |
|  | -----        | -----       |
| Net increase (decrease) in cash and cash equivalents                         | 9,629,127    | (4,668,251) |
| Cash and cash equivalents, beginning of period                               | 7,929,686    | 12,882,521  |
|  | -----        | -----       |
| Cash and cash equivalents, end of period                                     | \$17,558,813 | \$8,214,270 |
|  | =====        | =====       |

The accompanying notes are an integral part of these financial statements

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BIOENVISION, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2004

(Unaudited)

NOTE A - Description of Business



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Bioenvision, Inc. ("Bioenvision" or the "Company") is an emerging biopharmaceutical company whose primary business focus is the development and distribution of drugs to treat cancer. The Company has a broad range of products and technologies under development, but its two lead drugs are Clofarabine and Modrenal(R). Modrenal(R) is approved for marketing in the U.K. for advanced post-menopausal breast cancer. The Company' has filed an IND in the United States to test Modrenal(R) in a Phase II clinical trial for the treatment of androgen independent prostate cancer which clinical trial is expected to commence in Q2 of calendar 2004. The Company's future plans within the U.S. include development of Modrenal(R) in the U.S. for the treatment of advanced post-menopausal breast cancer. Most of the Company's other drugs are now in clinical trials in various stages of development including Clofarabine, a drug which we believe to be effective for the treatment of pediatric and adult acute leukemia, and potentially solid tumors and chronic leukemia.

### NOTE B - Interim Financial Statements

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all the adjustments (consisting only of normal recurring accruals) necessary to present fairly the consolidated financial position as of March 31, 2004 and the consolidated results of operations for the three months and nine months ended March 31, 2004 and 2003, and cash flows for the nine months ended March 31, 2004 and 2003.

The condensed consolidated balance sheet at June 30, 2003 has been derived from the audited financial statements at that date, but does not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. For further information, refer to the audited consolidated financial statements and footnotes thereto included in the Form 10-KSB filed by the Company for the year ended June 30, 2003.

The condensed consolidated results of operations for the three months and nine months ended March 31, 2004 and 2003 are not necessarily indicative of the results to be expected for any other interim period or for the full year.

### NOTE C - Stock Based Compensation

At March 31, 2004, the Company has stock based compensation plans which are described more fully in the Company's annual report on Form 10-KSB for the year ended June 30, 2003. As permitted by SFAS No. 123, "Accounting for Stock Based Compensation," the Company accounts for stock based compensation arrangements in accordance with provisions of Accounting Principles Board ("APB") Opinion No. 25 "Accounting for Stock Issued to Employees." Compensation expense for stock options issued to employees is based on the difference on the date of grant, between the fair value of the Company's stock and the exercise price of the option. Under APB 25, no stock based employee compensation cost is reflected in reported net loss, when options granted to employees have an exercise price equal to the market value of the underlying common stock at the date of grant. For the three months and nine months ended March 31, 2004, the Company recognized stock based employee compensation expense of \$1,943,888 and \$2,597,796, respectively, as a result of the March 31, 2003 re-pricing of 380,000 options granted to an employee pursuant to the terms of his employment contract. For each of the three months and nine months ended March 31, 2004, the Company recorded compensation expense of \$18,499, as a result of the 288,600 options granted to certain employees on January 20, 2004.

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The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force ("EITF") No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services," as amended by EITF No. 00-27. 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. The Company expects to continue applying the provisions of APB Opinion No. 25 for equity issuances to employees.

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The following table illustrates the effect on net loss and loss per share as if the fair value based method had been applied to all outstanding and unvested awards in each period.

|  | Three months ended<br>March 31, |                | Nine months<br>March 31, |                |
|--|---------------------------------|----------------|--------------------------|----------------|
|  | 2004                            | 2003           | 2004                     | 2003           |
| Net loss available to common stockholders,<br>as reported  | \$ (4,239,982)                  | \$ (1,699,307) | \$ (9,025,369)           | \$ (1,851,349) |
| Add: Stock based employee compensation<br>expense included in reported net income,<br>net of tax effects   | \$ 18,499                       | -              | \$ 18,499                | -              |
| Deduct: Total stock based employee<br>compensation expense determined under fair<br>value based method for all awards; net of<br>related tax effects | \$ (159,528)                    | \$ (152,042)   | \$ (284,959)             | \$ (152,042)   |
| Pro forma net loss   | \$ (4,381,011)                  | \$ (1,851,349) | \$ (9,291,829)           | \$ (1,851,349) |
| Loss per share   |                                 |                |                          |                |
| Basic and diluted - as reported  | \$ (0.21)                       | \$ (0.10)      | \$ (0.50)                | \$ (0.10)      |
| Basic and diluted - pro forma  | \$ (0.22)                       | \$ (0.11)      | \$ (0.51)                | \$ (0.11)      |

The fair value of options at the date of grant was established using the Black-Scholes model with the following assumptions:

|  | Three months ended<br>March 31, |      | Nine months ended<br>March 31, |      |
|--|---------------------------------|------|--------------------------------|------|
|  | 2004                            | 2003 | 2004                           | 2003 |

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|                         |        |        |        |        |
|-------------------------|--------|--------|--------|--------|
| Expected life (years)   | 4      | 4      | 4      | 4      |
| Risk free interest rate | 3.00%  | 3.00%  | 3.00%  | 3.00%  |
| Expected volatility     | 80.00% | 80.00% | 80.00% | 80.00% |
| Expected dividend yield | 0.00   | 0.00   | 0.00   | 0.00   |

### NOTE D - 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 and warrants to purchase 13,145,020 and 6,054,544 shares of common stock have not been included in the calculation of net loss per share for the nine months ended March 31, 2004 and 2003, respectively, as their effect would have been anti-dilutive.

### NOTE E - License And Co-Development Agreements

#### Clofarabine

The Company has a license from Southern Research Institute ("SRI"), 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. The Company is developing Clofarabine initially for the treatment of pediatric and adult leukemias, lymphomas and solid tumors.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from the technology in Japan and Southeast Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

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To facilitate the development of Clofarabine, the Company entered into a co-development agreement with ILEX Oncology, Inc. ("ILEX") in March 2001. Under the terms of the co-development agreement, the Company granted ILEX an option to market Clofarabine in the United States and Canada. ILEX is required to pay all development costs in the United States and Canada, and 50% of approved development costs worldwide outside the United States and Canada (excluding Japan and Southeast Asia). 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 around the date of exercise. Under the co-development agreement, ILEX also pays royalties to Southern Research Institute based on certain milestones. Also, the Company is obligated to pay milestones and royalties to Southern Research Institute in respect to Clofarabine sales outside the United State and Canada. On September

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12, 2003, ILEX paid the Company approximately \$775,000 in respect of Research and Development costs incurred by the Company for European drug development through August 31, 2003. The Company recognized additional revenue of \$622,000 from ILEX for Research and Development costs incurred by the Company during the three months ended March 31, 2004.

The Company received a nonrefundable, upfront payment of \$1.35 million when they entered into the agreement with ILEX and is entitled to receive milestone payments of \$2.5 million upon completion of management designed pivotal Phase II clinical trials of Clofarabine and \$5.0 million after submission of a new drug application with the FDA. The upfront payment was deferred and recognized as revenues ratably, on a straight-line basis over the related service period, through December 2002. The Company recognized revenues of \$0 for the three and nine months ended March 31, 2004 and \$0 and approximately \$368,000 for the three and nine months ended March 31, 2003, in connection with the up-front payment under the ILEX agreement.

Deferred costs represents royalty payments that became due and payable to SRI upon the Company's execution of the co-development agreement with Ilex Oncology. The Company also defers all royalty payments made to SRI and recognizes these costs ratably, on a straight-line basis concurrent with revenue that is recognized in connection with Ilex agreement.

### Modrenal (R)

The Company holds an exclusive license, until the expiration of existing and new patents related to Modrenal(R), to market Modrenal in major international territories, and an agreement with a United Kingdom company to co-develop Modrenal(R) for other therapeutic indications. Management believes that Modrenal(R) currently is manufactured by third-party contractors in accordance with good manufacturing practices. The Company has no plans to establish its own manufacturing facility for Modrenal(R), but will continue to use third-party contractors.

Anti-Estrogen Prostate. The Company has received Institutional Review Board approval from the Massachusetts General Hospital for a Phase II study of Modrenal(R) for the treatment of androgen independent prostate cancer. The study will be conducted by The Dana Faber Cancer Institute and currently is intended to commence in May 2004.

### Operational Developments

On April 27, 2004, the Company entered into a Clinical Development Agreement with Covance Inc., pursuant to which Covance has agreed to perform certain clinical investigatory services for the development of Clofarabine in Europe including, without limitation, performing CRO activities in connection with the Company's ongoing Phase II clinical trial of Clofarabine for the treatment of adults with Acute Myeloid Leukemia for which chemotherapy is not considered suitable ("BIV 121"). The Company's management acknowledges that BIV 121 could possibly be the basis for a regulatory submission in the adult AML indication; although several factors beyond management's control may affect the development of Clofarabine in this indication.

On March 31, 2004, ILEX Oncology, Inc., our U.S. co-development partner for the development of Clofarabine, filed a New Drug Application ("NDA") with FDA for approval of Clofarabine in the U.S. for the treatment of pediatric ALL and AML (the "NDA Filing"). The Company has taken the NDA filing and currently is in the process of converting the filing to a Common Technical Document (the "CTD") for filing with the EMEA as the basis potentially for European approval of

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Clofarabine for the treatment of pediatric ALL and AML. The Company expects to file the CTD with the EMEA in the third quarter of calendar year 2004.

On December 30, 2003, the Company converted ILEX's option to a sublicense and ILEX paid the Company \$3.5

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million constituting an acceleration of milestone payments required pursuant to the co-development agreement. Further, ILEX agreed to pay an additional \$2 million upon filing an NDA and a further \$2 million six months thereafter. Pursuant to the original co-development agreement, ILEX was obligated to pay the Company \$2.5 million upon completion of the pivotal phase II clinical trials; an additional \$500,000 on filing an NDA for acute leukemias; and an additional \$4.5 million within twelve months thereafter. These non-refundable fees that were received pursuant to license and other collaborative agreements where the Company has continuing involvement are recorded as deferred revenue and recognized over the estimated service period through March 2021. The related costs paid to SRI were also deferred and are being amortized over the same service period. ILEX filed the NDA with FDA in March 2004 and in April 2004, ILEX paid the Company \$2 million, representing the payment due to be paid upon filing of the NDA. The Company expects to receive the final \$2 million payment from ILEX Oncology in Q3 of calendar year 2004.

In September 2003, the Company and ILEX entered into an amendment to the co-development agreement, pursuant to which the Company collaborated with ILEX to co-develop an oral formulation for Clofarabine; the rights and related costs of which will be shared equally.

In August 2003, the Company entered into an amendment to the co-development agreement with Stegram Pharmaceuticals plc ("Stegram"), pursuant to which, in pertinent part, the Company succeeded to Stegram the United Kingdom marketing rights to Modrenal.

In August 2003, SRI granted the Company an irrevocable, exclusive option to make, use and sell products derived from Clofarabine in Japan and Southeast Asia. The Company intends to convert the option to a license upon sourcing an appropriate co-marketing partner to develop these rights in such territory.

In June 2003, the Company entered into a supply agreement with Ferro-Pfanstiehl Laboratories ("Ferro"), pursuant to which Ferro has agreed to manufacture and supply 100% of Bioenvision's global requirements for Clofarabine-API. Subject to certain circumstances, this agreement will expire on the fifth anniversary date of the first regulatory approval of Clofarabine drug product.

In June 2003, the Company entered into a development agreement with Ferro, pursuant to which Ferro agreed to perform certain development activities to scale up, develop, finalize, and supply CTM and GMP supplier qualifications of the API-Clofarabine. Subject to certain circumstances, this agreement expires upon the completion of the development program. The development agreement is milestone based and payments are to be paid upon completion of each milestone. If Ferro has not completed the development agreement by December 2007, the development agreement will automatically terminate without further action by either party. The Company paid and capitalized \$50,000 related to development costs.

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In May 2003, the Company entered into a sub-license agreement with Dechra Pharmaceuticals, plc ("Dechra"), pursuant to which Dechra has been granted a sub-license for all of Bioenvision's rights and entitlements to market and distribute Modrenal in the United States and Canada solely in connection with animal health applications. Subject to certain circumstances, this agreement expires upon expiration of the last patent related to Modrenal or the completion of the last royalty set forth in the agreement. The Company received an upfront non-refundable payment of \$1.25 million upon execution of this agreement and may receive up to an additional \$3.75 million upon the achievement by Dechra of certain milestones set forth in the agreement. The upfront payment received from Dechra has been deferred and will be recognized as revenues on a straight-line basis over the term of the license agreement through May 2014. The Company recognized revenues of \$29,000 and \$87,000 for the three and nine months ended March 31, 2004 in connection with this sublicense agreement with Dechra. As of March 31, 2004, deferred revenues include approximately \$1,153,000 related to this agreement.

In May 2003, the Company entered into a master services agreement with Penn-Pharmaceutical Services Limited ("Penn"), pursuant to which Penn has agreed to label, package and distribute Clofarabine on behalf of and at the Company's request. The services to be performed by Penn also include regulatory support and the manufacture, quality control, packaging and distribution of proprietary medicinal products including clinical trials supplies and samples. Subject to certain circumstances, the term of this agreement is twelve months and renews for subsequent twelve month periods unless either party tenders notice of termination upon no less than three months prior written notice.

In April 2003, we entered into an exclusive license agreement with CLL-Pharma ("CLL"), pursuant to which CLL has agreed to perform certain development works and studies to create a new formulation of Modrenal in the form of a soft gel capsule. CLL intends to use its proprietary MIDDS.-patented technology to perform this service on

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behalf of the Company. This new formulation, once in hand, will allow the Company to apply for necessary authorization, as required by applicable European health authorities, to sell Modrenal throughout Europe. Through June 30, 2003, the Company paid an advance of \$175,000 related to development services to be provided by CLL over an eighteen month period, which advance was recorded as a prepaid development cost by the Company.

### NOTE F - Equity Transactions

In June 2002, the Company granted options to an officer of the Company to purchase 380,000 shares of common stock at an exercise price of \$1.95 per share, which equaled the stock price on the date of grant. Of this amount 50,000 options vested on June 28, 2002 and the remaining 330,000 options vest ratably over a three-year period on each anniversary date. On March 31, 2003, the Company entered into an Employment Agreement with such officer of the Company, pursuant to which, among other things, the exercise price for all of the 380,000 options were changed to \$0.735 per share, which equaled the stock price on that date. In addition, the Company issued an additional 120,000 options at an exercise price of \$.735 per share which vest immediately. As a result of the repricing of all of the 380,000 options, the Company will remeasure the intrinsic value of these options at the end of each reporting period and will record a charge for compensation expense to the extent the vested portion of the

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options are in the money. For the three months and nine months ended March 31, 2004, the Company recognized stock based compensation expense of \$1,943,888 and \$2,597,796, respectively.

During the three months ended March 31, 2003, the Company also issued 20,000 options to another employee to purchase 20,000 shares of common stock at an exercise price of \$1.42 per share. Of this amount, 10,000 options vest on January 9, 2004 and the remaining 10,000 options will vest on January 9, 2005.

On April 2, 2003, the Company granted RRD International, a regulatory consultant to the Company, a warrant to acquire 175,000 shares of the Company's common stock at an exercise price of \$2.00 per share, which warrant vests ratably upon satisfaction of five milestones included in the warrant and includes registration rights under certain circumstances. In connection therewith, for the three months and nine month periods ended March 31, 2004, the Company recognized consulting expense of approximately \$485,000 and \$611,000, respectively.

During the three months ended December 31, 2003, the Company issued options to another employee to purchase 25,000 shares of common stock at an exercise price of \$3.53 per share. Of this amount, 12,500 options vest on November 11, 2004 and the remaining 12,500 will vest on November 11, 2005.

During the three and nine months ended March 31, 2004, certain holders of 760,000 shares of the Company's preferred stock converted such shares into 1,520,000 shares of the Company's common stock. In addition, during the three and nine months ended March 31, 2004, certain warrant holders of the Company exercised their warrants to acquire 433,000 and 608,000 shares of the Company's common stock, respectively. The Company received proceeds of approximately \$867,000 and \$1,129,000 during the three and nine months ended March 31, 2004, respectively from the exercise of these warrants.

During the three and nine month periods ended March 31, 2004, certain holders of options to purchase an aggregate of 1,025,000 and 2,113,000 shares, respectively of the Company's common stock were exercised pursuant to the cashless exercise feature available to such option holders and the Company issued approximately 847,000 and 1,738,000 shares of its common stock in connection therewith.

On January 3, 2004, the Company issued 14,510 restricted shares of its common stock to a consultant to the Company for certain executive placement services rendered to the Company. The Company recorded compensation expense of approximately \$60,637 for the three months ended March 31, 2004 in connection with such issuance.

On January 20, 2004, the Company granted 20,000 options to Dr. Michael Kauffman, for serving as a member of the Board of Directors, at an exercise price of \$4.55 per share which vest ratably on the first and second anniversaries of the grant date.

On January 20, 2004 the Company recorded a compensation expense of \$18,499 as a result of the 288,600 options granted to certain employees.

On February 4, 2004, the Company issued 20,000 shares of its common stock to an employee of the Company in connection with the exercise of options issued prior to that date.

On March 22, 2004, the Company consummated a private placement transaction, pursuant to which we raised \$12.8 million and issued 2,044,514 shares of our common stock and warrants to purchase an additional 408,903 shares of

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our common stock at a conversion price of \$7.50 per share. The Company recorded proceeds of \$12,151,240 net of all legal, professional and financing fees incurred in connection with the offering. The Company consummated a second closing for this financing on May 13, 2004 in order to comply with certain contractual obligations of the Company to its holders of Series A Preferred Stock which hold preemptive rights for equity offerings of the Company. The Company raised an additional \$3.5 million from the second closing and issued an additional 558,384 shares of our common stock and warrants to purchase 111,677 shares of our common stock at a conversion price of \$7.50 per share.

NOTE G - Related Party Transactions

In May 2002, we completed a private placement pursuant to which we issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock and in March of 2004 we consummated a private placement pursuant to which we raised \$12.8 million with a second closing in May 2004 in which we raised an additional \$3.5 million (See "Note F-Equity Transactions" above). An affiliate of SCO Capital Partners LLC, one of our stockholders, served as financial advisor to the Company in connection with these financings and earned a placement fee of approximately \$1.2 million in connection with May 2002 private placement and a placement fee of \$1.1 million and warrants to purchase 260,291 shares of common stock for \$6.25 per share for the March and May 2004 financings. This affiliate of SCO Capital Partners LLC continues to serve as a financial advisor to the Company.

NOTE H - New Accounting Pronouncements

In January 2003, the FASB issued Financial Interpretation No. 46, "Consolidation of Variable Interest Entities" ("FIN 46"), which addresses consolidation by business enterprises of variable interest entities (VIEs). The accounting provisions and disclosure requirements of FIN 46 are effective immediately for VIEs created after January 31, 2003, and are effective for the Company's fiscal period ending March 31, 2004, for VIEs created prior to February 1, 2003. In December 2003, the FASB published a revision to FIN 46 ("FIN 46R") to clarify some of the provisions of the interpretation and to defer the effective date of implementation for certain entities. Under the guidance of FIN 46R, public companies that have interests in VIE's that are commonly referred to as special purpose entities are required to apply the provisions of FIN 46R for periods ending after December 15, 2003. A public company that does not have any interests in special purpose entities but does have a variable interest in a VIE created before February 1, 2003, must apply the provisions of FIN 46R by the end of the first interim or annual reporting period ending after March 14, 2004. During the quarter ended March 31, 2004 the Company adopted the provisions of FIN 46R. Adoption of FIN46R did not have a material effect on the Company's financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" ("SFAS 150"). The objective of SFAS 150 is to establish standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and for existing financial instruments after July 1, 2003. Adoption of SFAS 150 did not have a material impact on the results of operations or financial position of the Company.



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In May 2003, the Emerging Issues Task Force ("EITF") reached a consensus on EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21"). EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in quarters beginning after June 15, 2003. The adoption of EITF 00-21 did not impact the Company's consolidated financial position or results of operations, but could affect the timing or pattern of revenue recognition for future collaborative research and/or license agreements.

### NOTE I - Litigation

On April 1, 2003, RLB Capital, Inc. filed a complaint against the Company in the Supreme Court of the State of New York (Index No. 601058/03). The Complaint alleged a breach of contract by the Company and demanded judgment against the Company for \$112,500 and warrants to acquire 75,000 shares of the Company's common stock. The Company submitted its Verified Answer on June 25, 2003 and, in pertinent part, denied RLB's allegations and asserted counterclaims based on negligence. In September 2003, the Company filed a motion for summary judgment and RLB filed its response on October 27, 2003. In December 2003, the Supreme Court granted the motion for summary judgment and the complaint was dismissed. In March 2004, the complaint and two counterclaims asserted by the Company were dismissed with prejudice.

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On December 19, 2003, the Company filed a complaint against Dr. Deidre Tessman and Tessman Technology Ltd. (the "Tessman Defendants") in the Supreme Court of the State of New York, County of New York (Index No. 03-603984). An amended complaint alleges, among other things, breach of contract and negligence by Tessman and Tessman Technology and demands judgment against Tessman and Tessman Technology in an amount to be determined by the Court. The Tessman Defendants removed the case to federal court, then remanded it to state court and served an answer with several purported counterclaims. The Company denies the allegations in the counterclaims and intends to pursue its claims against the Tessman Defendants vigorously.

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### 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

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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 not parties to such action, suit or proceeding, even though less than a quorum, or (2) by a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) by the stockholders. The statute authorizes the corporation to pay expenses incurred by an officer or director in advance of the final disposition of a proceeding upon receipt of an undertaking by or on behalf of the person to whom the advance will be made, to repay the advances if it shall ultimately be determined that he was not entitled to indemnification. DGCL Section 145 also provides that indemnification and advancement of expenses permitted thereunder are not to be exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any By-law, agreement, vote of stockholders or disinterested directors, or otherwise. DGCL Section 145 also authorizes the corporation to purchase and maintain liability insurance on behalf of its directors, officers, employees and agents regardless of whether the corporation

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would have the statutory power to indemnify such persons against the liabilities insures.

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 Registration cannot indemnify its officers and directors.

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

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

### OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

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

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

\* Estimated.

### RECENT SALES OF UNREGISTERED SECURITIES

In March and May 2004, we issued an aggregate of 2,602,898 shares of our common stock and warrants to purchase 780,871 shares of common stock to 35

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seventeen accredited investors, as defined under Regulation D of the Securities Act. The issuance of these shares and warrants was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In June 2003, in connection with that certain employment agreement, dated January 1, 2000, by and between the Company and Mr. Stuart Smith (the "Smith Employment Agreement"), we issued 19,728 shares of our common stock at fair market value to Mr. Smith in settlement of any and all obligations owing to Mr. Smith under the Smith Employment Agreement. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In May 2003, in connection with that certain consulting agreement, dated November 19, 2001 (the "Sterling Consulting Agreement"), we issued 15,225 shares of our common stock at fair market value to Mr. Sterling in settlement of all outstanding obligations under the Sterling Consulting Agreement. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In February 2003, in connection with that certain consulting agreement, dated March 1, 2002, by and between the Company and Mr. Edward W. Kelly (the "Kelly Consulting Agreement"), we issued 200,000 shares of our common stock at fair market value to Mr. Kelly in settlement of all of our outstanding obligations under the Kelly Consulting Agreement. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In January 2003, in connection with our employment of our office manager at the principal executive office, we issued options to purchase 20,000 shares of our common stock at an exercise price of \$1.42 per share which approximated the fair market value of the common stock on the date of the grant. Of such options, subject to certain terms and conditions, options to purchase 10,000 shares of our common stock vested immediately and options to purchase 10,000 shares of our common stock vest on the one-year anniversary of January 9, 2003, the grant date.

On December 31, 2002 the Company issued options to purchase 500,000 shares of common stock at an exercise price equal to \$1.45 per share, which approximated the fair market value of the common stock on the date of the grant, to its Chairman and Chief Executive Officer, Dr. Christopher B. Wood. Of these options, subject to certain circumstances, options to purchase 166,666 shares of common stock vest on each of the first, second and third anniversary of the grant date.

On December 31, 2002 the Company issued options to purchase 200,000 shares of common stock at an exercise price of \$2.00 per share, which approximated the fair market value of the common stock on the date of the grant, to a consultant to the Company who performs European regulatory services for the Company. Of these options, options to purchase 66,666 shares of common stock vest on each of the first, second and third anniversary of the grant date. Compensation expense of \$24,333 was recorded as consulting fees for the year ended June 30, 2003.

In October 2002, in connection with our employment of Ian Abercrombie as our Sales Manager (Europe), we issued options to purchase 50,000 shares of our common stock at an exercise price of \$1.45 per share, which approximated the fair market value of the common stock on the date of the grant. Of these

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options, subject to certain terms and conditions, options to purchase 25,000 shares of common stock vest on each of the first and second anniversaries of October 23, 2002, the grant date.

In October 2002, in connection with our employment of Hugh Griffith as our Commercial Director (Europe), we issued options to purchase 300,000 shares of our common stock at an exercise price of \$1.45 per share, which approximated the fair market value of the common stock on the date of the grant. Of these options, subject to certain terms and conditions, options to purchase 100,000 shares of common stock vest on each of the first, second and third anniversaries of October 23, 2002, the grant date.

In July 2002, in connection with our employment of David P. Luci as our Director of Finance and General Counsel, we issued options to purchase 380,000 shares of our common stock at an exercise price of \$1.95 per share, which approximated the fair market value of the common stock on the date of the grant. In connection with our entering into an employment agreement with Mr. Luci, dated March 31, 2003, we cancelled these options and issued options to purchase 500,000 shares of common stock, which are exercisable at \$0.735 per share, which approximated the fair market value of the common stock on the date of the grant. Of these options, subject to certain terms and conditions, options to purchase 170,000 shares of common stock vested on March 31, 2003 (the grant date), and options to purchase 110,000 shares of common stock vest on each of the first, second and third anniversaries of March 31, 2003.

In May 2002, Bioenvision issued an aggregate of 5,916,666 shares of Series A convertible participating preferred stock for \$3.00 per share and warrants to purchase an aggregate of 5,916,666 shares of common stock to

seventeen accredited investors, as defined under Regulation D of the Securities Act. The issuance of these shares and warrants was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

On February 1, 2002, Bioenvision issued 7,000,000 shares of common stock to the former stockholders of Pathagon in connection with the consummation of the Pathagon transaction. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

On November 16, 2001, we entered into an engagement letter with SCO Financial Group, pursuant to which SCO Financial Group 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 adjustments. In connection with securing a credit 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 shares and warrants were exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In October 2001, we issued 134,035 shares of common stock to three officers as payment for salaries accrued to September 30, 2001, each of which were accredited investors, as defined under the Securities Act of 1933. The issuance of these shares was exempt from registration under Regulation D under

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the Securities Act or Section 4(2) of the Securities Act.

In August 2001 in connection with outstanding deferred salaries, 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. The issuance of these shares was exempt from registration under Regulation D under the Securities Act or Section 4(2) of the Securities Act.

In addition, in August 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. The options expire in August 2004 and are immediately vested. Those issuances of options were exempt from registration under Regulation S promulgated under the Securities Act or Section 4(2) of the Securities Act. In August 2001, we cancelled these options and replaced them with 150,000 shares.

### EXHIBITS

Exhibit  
Number  
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Description  
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|        |  |
|--------|--|
| 2.1    | Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1) |
| 2.2    | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)                                    |
| 3.1    | Certificate of Incorporation of Registrant. (2)  |
| 3.1(a) | Amendment to Certificate of Incorporation filed January 29, 1999. (3)  |
| 3.1(b) | Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)  |
| 3.1(c) | Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)   |
| 3.2    | Amended and Restated By-Laws of the Registrant. (13)   |
| 3.2(a) | Amendment to Bylaws, effective April 30, 2002 (6)  |
| 4.1    | Certificate of Designation (6)   |
| 4.2    | Form of Warrant (6)  |
| 4.3    | Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)   |
| 4.4    | Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of RRD International, LLC (14)  |

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- 5.1 Opinion of Paul, Hastings, Janofsky & Walker, LLP
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, b and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories Inc. (15)
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision Inc. (15)
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. An Bioenvision, Inc. dated July 15, 1998. (3)
- 10.5 Co-Development Agreement between Southern Research Institute an Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by an between Bioenvision, Inc. and Dechra Pharmaceuticals, plc (15)
  
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B Wood, M.D., dated December 31, 2002 (3)
- 10.8 Employment Agreement between Bioenvision, Inc. and David P. Lucid dated March 31, 2003. (14)
- 10.9 Securities Purchase Agreement with Bioaccelerate Inc dated March 24 2000. (4)
- 10.10 Engagement Letter Agreement, dated as of November 16, 2001, by an between Bioenvision, Inc. and SCO Securities LLC. (7)
- 10.11 Security Agreement, dated as of November 16, 2001, by Bioenvision Inc. in favor of SCO Capital Partners LLC. (7)
- 10.12 Commitment Letter, dated November 16, 2001, by and between SC Capital Partners LLC and Bioenvision, Inc. (7)
- 10.13 Senior Secured Grid Note, dated November 16, 2001, by Bioenvision Inc. in favor of SCO Capital Partners LLC. (7)
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- 10.16 Form of Securities Purchase Agreement by and among Bioenvision, Inc. and certain purchasers, dated as of May 7, 2002. (6)
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- 23.1 Consent of Grant Thornton LLP



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### UNDERTAKINGS

(a) The undersigned registrant hereby undertakes:

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

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

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

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

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

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

(4) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities

offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(5) Insofar as indemnification for liabilities arising under the

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Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against such public policy as expressed in the Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense if any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

In accordance with 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 21st day of June, 2004.

BIOENVISION, INC.

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

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

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

| Signature<br>-----  | Title<br>-----   | Date<br>----  |
|---|--|---------------|
| /s/ Christopher B. Wood, M.D.<br>-----<br>Christopher B. Wood, M.D. | Chairman and Chief Executive<br>Officer and Director<br>(Principal Executive Officer)                              | June 21, 2004 |
| _____*_____<br>David P. Luci  | Director of Finance, General<br>Counsel and Corporate Secretary<br>(Principal Financial and<br>Accounting Officer) | June 21, 2004 |
| _____*_____<br>Thomas S. Nelson, C.A.                               | Director   | June 21, 2004 |
| _____*_____<br>Michael Kauffman                                     | Director   | June 21, 2004 |
| _____*_____<br>_____  | Director   | June 21, 2004 |

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Jeffrey B. Davis

\_\_\_\_\_\*\_\_\_\_\_  
 Andrew N. Schiff Director June 21, 2004

\_\_\_\_\_\*\_\_\_\_\_  
 Steven A. Elms Director June 21, 2004

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

EXHIBIT INDEX

Exhibit  
 Number

Description

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|        |  |
|--------|--|
| 2.1    | Acquisition Agreement between Registrant and Bioenvision, Inc. dated December 21, 1998 for the acquisition of 7,013,897 shares of Registrant's Common Stock by the stockholders of Bioenvision, Inc. (1) |
| 2.2    | Amended and Restated Agreement and Plan of Merger, dated as of February 1, 2002, by and among Bioenvision, Inc., Bioenvision Acquisition Corp. and Pathagon, Inc. (5)                                    |
| 3.1    | Certificate of Incorporation of Registrant. (2)  |
| 3.1(a) | Amendment to Certificate of Incorporation filed January 29, 1999. (3)  |
| 3.1(b) | Certificate of Correction to the Certificate of Incorporation, filed March 15, 2002 (6)  |
| 3.1(c) | Certificate of Amendment to the Certificate of Incorporation, filed April 30, 2002 (6)   |
| 3.2    | Amended and Restated By-Laws of the Registrant. (13)   |
| 3.2(a) | Amendment to Bylaws, effective April 30, 2002 (6)  |
| 4.1    | Certificate of Designation (6)   |
| 4.2    | Form of Warrant (6)  |
| 4.3    | Registration Rights Agreement, dated April 2, 2003, by and between Bioenvision, Inc. and RRD International, LLC (14)   |
| 4.4    | Warrant, dated April 2, 2003, made by Bioenvision, Inc. in favor of  |

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- RRD International, LLC (14)
- 5.1 Opinion of Paul, Hastings, Janofsky & Walker, LLP
- 10.1 Pharmaceutical Development Agreement, dated as of June 10, 2003, b and between Bioenvision, Inc. and Ferro Pfanstiehl Laboratories Inc. (15)
- 10.2 Co-Development Agreement between Bioheal, Ltd. and Christopher Wood dated May 19, 1998. (3)
- 10.3 Master Services Agreement, dated May 14, 2003, by and between PennDevelopment Pharmaceutical Services Limited and Bioenvision Inc. (15)
- 10.4 Co-Development Agreement between Stegram Pharmaceuticals, Ltd. An Bioenvision, Inc. dated July 15, 1998. (3)
- 10.5 Co-Development Agreement between Southern Research Institute an Eurobiotech Group, Inc. dated August 31, 1998. (3)
- 10.5(a) Agreement to Grant License from Southern Research Institute to Eurobiotech Group, Inc. dated September 1, 1998. (3)
- 10.6 License and Sub-License Agreement, dated as of May 13, 2003, by an between Bioenvision, Inc. and Dechra Pharmaceuticals, plc (15)
- 10.7 Employment Agreement between Bioenvision, Inc. and Christopher B Wood, M.D., dated December 31, 2002 (3)
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