

Edgar Filing: BIOENVISION INC - Form 424B5

BIOENVISION INC  
Form 424B5  
February 03, 2005

Filed pursuant to Rule 424(b) (5)  
Registration No. 333-119928

PROSPECTUS SUPPLEMENT

-----  
(TO PROSPECTUS DATED JANUARY 5, 2005)

7,500,000 SHARES

[Bioenvision Logo]

COMMON STOCK

Bioenvision, Inc. is offering all of the 7,500,000 shares of its common stock offered by this prospectus supplement.

Our common stock is included for quotation on the NASDAQ National Market under the symbol "BIVN." On February 2, 2005, the last reported sales price of shares of our common stock on the NASDAQ National Market was \$8.10 per share.

INVESTING IN OUR COMMON STOCK INVOLVES CERTAIN RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 3 OF THE ACCOMPANYING PROSPECTUS AND THOSE RISKS DISCUSSED BEGINNING ON PAGE S-8 OF THIS PROSPECTUS SUPPLEMENT.

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 SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	PER SHARE	TOTAL
	-----	-----
Public offering price .....	\$8.00	\$60,000,000
Underwriting discounts and commissions .....	\$0.48	\$ 3,600,000
Proceeds, before expenses, to us .....	\$7.52	\$56,400,000

The underwriters may also purchase up to an additional 1,125,000 shares of our common stock at the public offering price, less underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 30 days from the date of this prospectus supplement. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be \$4,140,000, and the total proceeds, before expenses, to us will be \$64,860,000.

The underwriters are offering our common stock as set forth under "Underwriting." Delivery of the shares will be made on or about February 8, 2005.

Edgar Filing: BIOENVISION INC - Form 424B5

JPMORGAN

UBS INVESTMENT BANK

CIBC WORLD MARKETS

FRIEDMAN BILLINGS RAMSEY

February 2, 2005

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT

	PAGE
	----
About this Prospectus Supplement .....	S-ii
Prospectus Supplement Summary .....	S-1
The Offering .....	S-6
Summary Financial Data .....	S-7
Risk Factors .....	S-8
Forward-Looking Statements .....	S-11
Use of Proceeds .....	S-12
Price Range of Common Stock and Dividend Policy .....	S-13
Capitalization .....	S-14
U.S. Federal Tax Considerations to Non-U.S. Holders .....	S-15
Underwriting .....	S-17
Legal Matters .....	S-20
Experts .....	S-20
Where You Can Find More Information .....	S-20
Incorporation by Reference .....	S-20
PROSPECTUS	
About this Prospectus .....	1
Bioenvision, Inc. ....	1
Risk Factors .....	3
Forward-Looking Statements .....	14
Use of Proceeds .....	15
Description of Capital Stock .....	15
Plan of Distribution .....	16
Legal Matters .....	18
Experts .....	19
Where You Can Find More Information .....	19
Incorporation by Reference .....	19
Disclosure of Commission Position on Indemnification for Securities Act Liabilities.....	20

S-i

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the

## Edgar Filing: BIOENVISION INC - Form 424B5

documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information, some of which may not apply to this offering of common stock. To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or any document incorporated by reference, the information in this prospectus supplement shall control.

In this prospectus supplement and the accompanying prospectus, references to "Bioenvision," "we," "us," "our" and "the Company" refer to Bioenvision, Inc. and Bioenvision Limited, our wholly-owned subsidiary.

"Modrenal," "Velostan" and "Virostat" are our proprietary marks. All other product names, trademarks and trade names referred to in this prospectus supplement and the accompanying prospectus are the property of their respective owners.

YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN, OR INCORPORATED BY REFERENCE INTO, THIS PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS. WE HAVE NOT, AND THE UNDERWRITERS HAVE NOT, AUTHORIZED ANYONE TO PROVIDE YOU WITH INFORMATION THAT IS DIFFERENT. THIS PROSPECTUS SUPPLEMENT IS NOT AN OFFER TO SELL OR SOLICITATION OF AN OFFER TO BUY THESE SHARES OF COMMON STOCK IN ANY CIRCUMSTANCES UNDER WHICH THE OFFER OR SOLICITATION IS UNLAWFUL. YOU SHOULD NOT ASSUME THAT THE INFORMATION WE HAVE INCLUDED IN THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE OF THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS OR THAT ANY INFORMATION WE HAVE INCORPORATED BY REFERENCE IS ACCURATE AS OF ANY DATE OTHER THAN THE DATE OF THE DOCUMENT INCORPORATED BY REFERENCE REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS SUPPLEMENT OR OF ANY SHARES OF OUR COMMON STOCK.

S-ii

### PROSPECTUS SUPPLEMENT SUMMARY

The following summary highlights selected information contained elsewhere or incorporated by reference into this prospectus supplement and the accompanying prospectus. This summary does not contain all the information that you should consider before investing in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the risk factors and financial statements included or incorporated by reference herein, before making an investment decision.

#### OUR COMPANY

We are a product-focused biopharmaceutical company with two approved cancer therapeutics. The FDA recently approved our lead cancer product, clofarabine, for the treatment of pediatric acute lymphoblastic leukemia, or ALL. We believe clofarabine is the first new medicine initially approved in the United States for children with leukemia in more than a decade. Clofarabine has received Orphan Drug designation in the U.S. and the European Union. Genzyme Corporation, our co-development partner, currently holds marketing rights in the U.S. and Canada for clofarabine for all cancer indications and controls U.S. development of clofarabine in these indications. Genzyme is marketing clofarabine under the brand name Clolar in the U.S. In Europe, we have filed for approval of clofarabine in pediatric ALL and acute myelogenous leukemia, or AML, with the European Medicines Evaluation Agency, or EMEA. If approved, we anticipate commencing sales in Europe during the second half of calendar 2005 through a dedicated European sales force.

## Edgar Filing: BIOENVISION INC - Form 424B5

We are selling our second product, Modrenal, in the United Kingdom, through our sales force of eight sales specialists. Modrenal is approved in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy, and we have initiated the filing process for mutual recognition in the E.U. on a country-by-country basis.

If we receive additional European approvals for our products, we intend to expand our sales force by adding up to six to 10 sales specialists in each of five other key regions within the E.U. which include the countries of France, Germany, Italy, Spain, Portugal, Netherlands, Austria, Belgium, Denmark and Sweden. In addition to clofarabine and Modrenal, we are developing Velostan for bladder cancer and Virostat for Hepatitis C.

### PRODUCTS AND PIPELINE

CANDIDATE	INDICATION	STATUS	U.S./CANADA RIG
Clofarabine (Clolar)	Relapsed or Refractory Acute Lymphoblastic Leukemia	Marketed in U.S. (pediatric); Filed in E.U. (pediatric)	Genzyme
	Acute Myelogenous Leukemia	Filed in E.U. (pediatric); Phase II in E.U. (adult)	Genzyme
	Refractory Chronic Lymphocytic Leukemia	Phase II in U.S. (adult)	Genzyme
	Solid Tumors	Phase I in U.S. (Intravenous)	Genzyme
	Solid Tumors	Phase I in U.S. (Oral)	Genzyme
	Non-Cancer	Developmental	Bioenvision
Modrenal	Breast Cancer	Marketed in U.K.; Phase IV in U.K.; Phase II in E.U.	Bioenvision
	Prostate Cancer	Phase II in U.S.	Bioenvision
Velostan	Bladder Cancer	IRB approval pending (1)	Bioenvision
Virostat	Hepatitis C	Investigator Sponsored Phase II in Europe and Middle East (2)	Bioenvision

(1) An internationally recognized cancer center in the U.K. has agreed to conduct a Phase I/II trial of Velostan in cancer patients. Ethics Committee Independent Review Board (IRB) approval is pending.

(2) This trial is a pilot study and is not a pivotal regulatory study.

## Edgar Filing: BIOENVISION INC - Form 424B5

### OUR PRODUCTS

#### CLOFARABINE (CLOLAR)

On December 28, 2004, clofarabine was approved by the FDA after a "fast track" review for the treatment of pediatric patients, ages one to 21, with relapsed or refractory ALL after at least two prior regimens. Genzyme currently maintains rights to market the drug for all cancer indications in the U.S. and Canada and we will receive a royalty on these sales. Genzyme is marketing clofarabine under the brand name Clolar. We also submitted a Marketing Authorization Application, or MAA, the European equivalent of a U.S. new drug application, or NDA, with the EMEA in July 2004 for European approval of clofarabine in relapsed or refractory pediatric acute leukemia. We expect an opinion from the EMEA in mid-2005. Clofarabine received Orphan Drug designation in the U.S. and in Europe, which provides ten years of marketing exclusivity in Europe and seven years of marketing exclusivity in the U.S. Further, in July 2004, the FDA granted a six-month extension of the marketing exclusivity for clofarabine in pediatric ALL under the federal Best Pharmaceuticals for Children Act.

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

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

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

In Europe, we facilitated an investigator sponsored trial, or an IST, of clofarabine as first line therapy for older adult patients with AML who were unsuitable for intensive chemotherapy. The IST was closed to recruitment in August 2004 because a 67% overall response rate was achieved. This response rate was more than three times greater than the expected response rate under the current standard of care for this patient population and the investigator

## Edgar Filing: BIOENVISION INC - Form 424B5

determined that these positive results warranted accelerated initiation of the pivotal Phase II regulatory study of clofarabine as a first-line treatment for older adult patients newly diagnosed with AML. We expect to complete the Phase II trial in mid-2005 and anticipate that it will form the basis for an E.U. regulatory submission for approval in this indication.

On December 1, 2004 the FDA's Oncologic Drug Advisory Committee, or ODAC, convened to determine if clinical data from Phase II trials in relapsed and refractory pediatric ALL and AML

S-2

demonstrated a durable clinical response that would predicate a clinical benefit in future clinical administration. The panel voted in favor of the approval of clofarabine for pediatric ALL under its accelerated approval pathway and voted against immediate use in pediatric AML, requesting additional information. In connection with the approval that was granted by the FDA, Genzyme is required to conduct further control studies of clofarabine to verify and describe its clinical benefit.

Clofarabine is currently being evaluated in an IST Phase II clinical trial for refractory CLL in the U.S. In addition, in 2005 we intend to investigate clofarabine in European Phase II clinical trials for CLL and indolent lymphoma.

In pre-clinical studies, clofarabine has shown anti-tumor activity against several human cancers, including cancers of the lung, colon, kidney, breast, pancreas and prostate, as well as its action against leukemia cells. The initial data from the Phase I clinical trials indicate activity for clofarabine in certain solid tumor types. We believe this level of activity against solid tumors distinguishes clofarabine from other purine nucleoside analogs. We intend to develop clofarabine as a potential drug for the treatment of certain solid tumors, such as colon, pancreatic, lung, breast and prostate cancer. Currently, we anticipate the initial Phase I clinical trials for clofarabine, using both the oral and intravenous formulations, in solid tumors will be completed by end of the first calendar quarter of 2005.

Pursuant to the terms of our co-development agreement with Genzyme, the successor-in-interest to ILEX Oncology, Inc., both parties are required to share promptly all information, including clinical data, generated under the co-development program and Genzyme is obligated to pay all of the U.S. and Canadian research and development costs and 50% of all approved ex-U.S. and Canada research and development costs (except for Japan and Southeast Asia). If additional resources are required above the agreed upon costs, we may elect to pay these additional costs and certain of these payments will be credited against future royalty payments to Genzyme at the rate of \$1.50 for every \$1.00 of additional expenditures. Under the co-development agreement with Genzyme, we receive royalties on Genzyme's annual net sales on a sliding scale based on the level of annual net sales. Similarly, we pay a royalty to Genzyme and Southern Research Institute, the inventor of clofarabine, on our European annual net sales.

Pursuant to the terms of our co-development agreement with Southern Research Institute, we have the exclusive license to market and distribute clofarabine throughout the world for all human applications except for U.S. and Canadian cancer indications and except for any indications in Japan and Southeast Asia. Our exclusive license expires upon the last to expire of the patents used or useful in connection with the development and marketing of clofarabine, which we expect to expire in 2021. In addition, we hold an exclusive option from Southern Research Institute to market and distribute clofarabine in Japan and Southeast Asia for all human applications. We intend to convert the option to

## Edgar Filing: BIOENVISION INC - Form 424B5

a license upon sourcing an appropriate co-marketing partner to develop these rights in Japan and Southeast Asia.

### MODRENAL

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

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

Modrenal has been extensively studied in clinical trials in the U.S., Europe and Australia, and an analysis, known as a meta-analysis, of a series of these clinical studies, that included 714 patients with post-

S-3

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

We began marketing Modrenal in May 2003 in the U.K. for the treatment of post-menopausal advanced breast cancer following relapse to initial hormone therapy. We also intend to seek regulatory approval for Modrenal in the U.S. as a therapy for hormone-sensitive breast cancers and hormone independent prostate cancers, but this strategy is dependent upon the results of the ongoing clinical trials and the resource capability of the Company. Our ongoing clinical trials in breast cancer target patients that have hormone-sensitive cancers and have become refractory to prior hormone treatments, such as tamoxifen or any of the aromatase inhibitors. In addition, there is an ongoing Phase II clinical trial of Modrenal in the U.S. that is focused on patients who have androgen independent prostate cancer and have a rising prostate specific antigen, or PSA, level.

In the first calendar quarter of 2005, we intend to commence in the U.K. a Phase IV study in post-menopausal advanced breast cancer, a Phase II study in pre-menopausal breast cancer and a Phase II study in neo-adjuvant, pre-operative breast cancer. In Europe, we have initiated the filing process for mutual recognition for approval of Modrenal on a country-by-country basis.

## Edgar Filing: BIOENVISION INC - Form 424B5

Each such approval, if granted, would be based upon Modrenal's approval in the U.K. for post-menopausal advanced breast cancer following relapse to initial hormone therapy. The Company anticipates such approvals would be granted, on a country-by-country basis, within nine to 12 months following each such filing, but grant of any such approval is entirely within the control of the individual regulatory authorities.

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

### OTHER PRODUCTS AND TECHNOLOGIES

#### VELOSTAN

Velostan is a cytostatic drug we are investigating in Europe for bladder cancer. Velostan is the first compound in a group of chemically related compounds that are believed to work by blocking cell division and reversing the malignant process in the cancer cell. We believe the optical isomer we have developed is more active and less toxic than its parent compound. We expect that our planned Phase I/II trial will commence in the first calendar quarter of 2005 and will be conducted with Velostan in patients with urological cancers.

#### VIROSTAT

Virostat is currently used in several European countries to inactivate pathogens, notably certain viruses, in fresh frozen plasma. Virostat, especially when irradiated by light, acts by preventing replication of nucleic acid (DNA and RNA) in pathogens. Investigator sponsored Phase II clinical trials have been initiated in Europe and the Middle East to study Virostat's use in treating Hepatitis C.

S-4

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. We licensed from Oklahoma Medical Research Foundation the rights to use a range of thiazine dyes, including Virostat, for their use in in vitro and in vivo inactivation of pathogens in biological fluids.

### CORPORATE INFORMATION

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

S-5



# Edgar Filing: BIOENVISION INC - Form 424B5

## THE OFFERING

COMMON STOCK WE ARE OFFERING . . . 7,500,000 shares

COMMON STOCK TO BE  
OUTSTANDING AFTER THIS OFFERING . . 40,419,673 shares

USE OF PROCEEDS . . . . . We intend to use the net proceeds from the sale of the shares of common stock in this offering for further development of our lead products and sales and marketing expenses related to the commercial launch of our products, for working capital and other general corporate purposes. See "Use of Proceeds."

NASDAQ NATIONAL MARKET SYMBOL . . . BIVN

The share amounts listed here are based on shares of common stock outstanding as of February 2, 2005 and exclude:

- o 4,500,000 shares of common stock issuable upon the conversion of 2,250,000 shares of outstanding Series A convertible preferred stock;
- o 7,195,809 shares of common stock issuable upon the conversion of outstanding warrants at a weighted average exercise price of \$2.33 per share;
- o 4,350,500 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$3.05 per share; and
- o 1,662,000 shares of common stock reserved for issuance under the Company's 2003 Stock Incentive Plan, as amended.

Unless otherwise indicated, the information in this prospectus supplement assumes that the underwriters' over-allotment option will not be exercised.

S-6

## SUMMARY FINANCIAL DATA

The following summary consolidated financial data as of and for the fiscal years ended June 30, 2002, 2003 and 2004 was derived from our audited consolidated financial statements included in our Annual Reports on Form 10-KSB for each of the years presented. The summary consolidated financial data as of September 30, 2004 and for the three months ended September 30, 2003 and 2004 were derived from our unaudited consolidated financial statements included in our Quarterly Reports on Form 10-QSB for each of the periods presented, and, in the opinion of management, have been prepared on the same basis as our audited consolidated financial statements and reflect all adjustments, consisting of normal accruals, necessary for a fair presentation of the data for such periods. Results for the three months ended September 30, 2003 and 2004 are not necessarily indicative of results that may be expected

Edgar Filing: BIOENVISION INC - Form 424B5

for the entire year. The summary financial data set forth below as of and for the fiscal years ended June 30, 2003 and 2004 and as of September 30, 2004 and for the three months ended September 30, 2003 and 2004 is qualified in its entirety by, and should be read in conjunction with, "Management's discussion and analysis or plan of operation" and the financial statements and notes thereto incorporated by reference in this prospectus supplement. The summary financial data set forth below as of and for the fiscal year ended June 30, 2002 is qualified in its entirety by, and should be read in conjunction with, "Management's discussion and analysis or plan of operation" and the financial statements and notes thereto included in our Annual Report on Form 10-KSB for the fiscal year ended June 30, 2002. The as adjusted balance sheet data give effect to the issuance and sale by us of 7,500,000 shares of our common stock in this offering at the public offering price of \$8.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	FISCAL YEARS ENDED JUNE 30,		
	2002	2003	2004
<b>CONSOLIDATED STATEMENT OF OPERATIONS:</b>			
<b>Revenues:</b>			
Licensing and royalty revenue.....	\$ 802,965	\$ 504,857	\$ 1,187,212
Research and development contract revenue.....	--	--	1,915,002
<b>Total revenues.....</b>	<b>802,965</b>	<b>504,857</b>	<b>3,102,214</b>
<b>Cost and expenses:</b>			
Research and development.....	1,912,258	1,689,278	4,882,574
Selling, general and administrative.....	2,127,664	4,567,413	9,082,420
Depreciation and amortization.....	579,342	1,344,969	1,348,064
<b>Total costs and expenses.....</b>	<b>4,619,264</b>	<b>7,601,660</b>	<b>15,313,058</b>
Loss from operations.....	(3,816,299)	(7,096,803)	(12,210,844)
Interest income (expense).....	(2,172,682)	(186,426)	99,763
Income tax benefit.....	253,000	536,903	536,903
<b>Net loss.....</b>	<b>(5,735,981)</b>	<b>(6,746,326)</b>	<b>(11,574,178)</b>
Preferred stock dividend.....	(131,328)	(877,818)	(856,776)
Beneficial conversion preferred stock dividend....	(9,351,339)	--	--
<b>Net loss available to common stockholders.....</b>	<b>\$ (15,218,648)</b>	<b>\$ (7,624,144)</b>	<b>\$ (12,430,954)</b>
<b>Basic and diluted net loss per share of common stock to common stock.....</b>	<b>\$ (1.25)</b>	<b>\$ (0.45)</b>	<b>\$ (0.61)</b>
<b>Weighted average shares used in computing basic and diluted net loss per common share.....</b>	<b>12,184,152</b>	<b>16,920,939</b>	<b>20,257,482</b>

Edgar Filing: BIOENVISION INC - Form 424B5

	JUNE 30,		
	2002	2003	2004
CONSOLIDATED BALANCE SHEET DATA:			
Cash and cash equivalents.....	\$ 12,882,521	\$ 7,929,686	\$ 18,875,675
Working capital.....	10,668,927	6,108,493	18,828,164
Total assets.....	34,743,091	28,535,675	44,533,387
Accumulated deficit.....	(21,027,299)	(28,651,443)	(41,082,397)
Total stockholders' equity.....	24,639,406	18,828,392	27,382,571

S-7

RISK FACTORS

An investment in our common stock involves various risks. You should carefully consider the risk factors beginning on page 3 of the accompanying prospectus and the following risk factors in conjunction with the other information contained and incorporated by reference into this prospectus supplement and the accompanying prospectus before purchasing our common stock. If any of the risks discussed in this prospectus supplement or the accompanying prospectus actually occur, our business, operating results, prospects and/or financial condition could be adversely impacted. This could cause the market price of our common stock to decline and could cause you to lose all or part of your investment.

WE MAY NEED TO IMPROVE OUR FINANCIAL CONTROL PROCEDURES.

We may need to add additional personnel in the area of financial management. In connection with its review of our consolidated financial statements as of and for the three and nine month periods ended March 31, 2004, Grant Thornton LLP, our registered independent public accounting firm, advised the Audit Committee and management of certain significant internal control deficiencies that they considered to be, in the aggregate, a material weakness, under standards established by the American Institute of Certified Public Accountants, including, inadequate staffing and supervision leading to the untimely identification and resolution of certain accounting matters, failure to perform timely reviews, substantiation and evaluation of certain general ledger account balances, lack of procedures or expertise needed to prepare all required disclosures and evidence that employees lack the qualifications and training to fulfill their assigned functions. A material weakness is a significant deficiency in one or more of the internal control components that alone or in the aggregate precludes the entity's internal control from reducing to an appropriately low level the risk that material misstatements in the financial statements will not be prevented or detected on a timely basis. In response to the observations made by Grant Thornton LLP, we undertook a re-evaluation of our internal controls and procedures relating to those observations and implemented such enhancements as the review suggested were appropriate. While we have taken measures designed to address the matters raised by Grant Thornton LLP, we may need to implement additional measures to further enhance our internal controls and procedures.

WE ARE EXPOSED TO POTENTIAL RISKS FROM RECENT LEGISLATION REQUIRING COMPANIES TO EVALUATE THEIR INTERNAL CONTROL OVER FINANCIAL REPORTING UNDER SECTION 404

## Edgar Filing: BIOENVISION INC - Form 424B5

OF THE SARBANES-OXLEY ACT OF 2002.

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

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

S-8

enforce protection for products that we develop under U.S. and foreign patent laws and other intellectual property laws, preserve the confidentiality of our trade secrets and operate without infringing the proprietary rights of third parties. Through our current license agreements, we have acquired the right to utilize the technology covered by issued patents and patent applications, as well as additional intellectual property and know-how that could be the subject of further patent applications in the future. Several of the original patents to Modrenal have expired in the U.S. and foreign countries. Thus, we and our licensors are pursuing patent applications to specific uses, combination therapy and dosages or formulations of Modrenal. We cannot guarantee that such applications will result in issued patents or that such patents if issued will provide adequate protection against competitors. Patents may not be issued from these applications and issued patents may not give us adequate protection or a competitive advantage. Issued patents may be challenged, invalidated, infringed or circumvented, and any rights granted thereunder may not provide us with competitive advantages. Parties not affiliated with us have obtained or may obtain U.S. or foreign patents or possess or may possess proprietary rights relating to products being developed or to be developed by us. Patents now in existence or hereafter issued to others may adversely affect the development or commercialization of products developed or to be developed by us. Our planned activities may infringe patents owned by others. Our patents to clofarabine are licensed from 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

## Edgar Filing: BIOENVISION INC - Form 424B5

Institute was the first to invent the subject matter of these patents. In addition, we are aware of a third party U.S. patent which is directed to the treatment of chronic myeloid leukemia, or CML, using specific doses of clofarabine. We believe that our development and marketing of clofarabine for treatment of acute leukemias will not infringe any of the claims of this U.S. patent. Further, we believe that our development and marketing of clofarabine for treatment of chronic lymphocytic leukemia will not infringe any of the claims of this U.S. patent. If this patent is asserted against us, even though we may be successful in defending against such an assertion, our defense would require substantial financial and human resources. In addition, we may need a license to this patent to use the claimed dose in the treatment of CML. However, we do not know if such a license is available at commercially reasonable terms, if at all.

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

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

We require our employees, consultants, 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.

S-9

ANTI-TAKEOVER LAWS, OUR SHAREHOLDER RIGHTS PLAN, AND PROVISIONS OF OUR CERTIFICATE OF INCORPORATION MAY DISCOURAGE, DELAY, OR PREVENT A MERGER OR ACQUISITION THAT OUR STOCKHOLDERS MAY CONSIDER FAVORABLE.

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

- o our Board of Directors approves of the transaction before the third party acquires 15% of our common stock;
- o the third party acquires at least 85% of our common stock at the time its

## Edgar Filing: BIOENVISION INC - Form 424B5

ownership goes past the 15% level; or

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

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

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

MANAGEMENT MAY INVEST OR SPEND THE PROCEEDS OF THIS OFFERING IN WAYS WITH WHICH STOCKHOLDERS MAY NOT AGREE AND IN WAYS THAT MAY NOT YIELD A RETURN TO OUR STOCKHOLDERS.

We will retain broad discretion over the use of proceeds from this offering. Stockholders may not deem such uses desirable, and our use of the proceeds may not yield a significant return or any return at all for our stockholders. We expect to use the net proceeds from this offering for further development of our lead products and sales and marketing expenses related to the commercial launch of our products, for working capital and other general corporate purposes. A number of variables will influence our actual use of the proceeds from this offering, and our actual uses of the proceeds of this offering may vary substantially from our currently planned uses. Pending the use of the net proceeds, we intend to invest the net proceeds from this offering in short-term marketable securities.

S-10

### FORWARD-LOOKING STATEMENTS

Our disclosure and analysis in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference herein and therein, contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements describe our current expectations, plans, objectives and forecasts of future events. Words such as "may," "will," "believe," "estimate," "anticipate," "plan," "expect," "may affect," and "intend," or statements concerning "potential" or "opportunity" and similar expressions or the negative thereof, are intended to identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements include, without limitation:

## Edgar Filing: BIOENVISION INC - Form 424B5

- o statements about our drug development and commercialization goals and expectations;
- o potential regulatory approvals;
- o our plans for and anticipated results of our clinical development activities;
- o the potential advantage of our drug candidates;
- o statements about our future capital requirements, the sufficiency of our capital resources to meet those requirements and the expected composition of our capital resources; and
- o other statements that are not historical facts.

Forward-looking statements are based on the judgment of management at the time the statements are made. Inaccurate assumptions and known and unknown risks and uncertainties can affect the accuracy of forward-looking statements. Our actual results could differ materially from those stated in or implied by forward-looking statements for a number of reasons, including the risks described in the sections of this prospectus supplement and the accompanying prospectus entitled "Risk Factors," in our other public filings, press releases and statements by our management. Other factors besides those described in this prospectus supplement, the accompanying prospectus supplement and in our other public filings, press releases and statements by our management could also affect actual results.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus supplement or the accompanying prospectus. We undertake no obligation to publicly update any forward-looking statement to reflect new information, events or circumstances, whether anticipated or unanticipated, or to conform the statement to actual results or changes in our expectations. You should, however, review the factors, risks and other information we provide in the reports we file from time to time with the SEC.

S-11

### USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$55.7 million based on the public offering price of \$8.00 per share, or approximately \$64.1 million if the underwriters exercise their over-allotment option in full, after deducting underwriting discounts and commissions and estimated expenses of this offering. We intend to use the net proceeds for further development of our lead products and sales and marketing expenses related to the commercial launch of our products, for working capital and other general corporate purposes.

Our management will have considerable discretion in the application of the net proceeds of this offering and may spend the net proceeds in a manner and at times other than as set forth above. As a result, you will not have the opportunity, as part of your investment decision, to assess how and when the net proceeds will be used.

Pending such uses, the net proceeds may be invested in short-term marketable securities.

S-12

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock is listed on the NASDAQ National Market under the symbol "BIVN." Prior to August 21, 2004, our common stock was traded on the American Stock Exchange and prior to September 8, 2003, our common stock was included for quotation on the over-the-counter bulletin board. The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock on the NASDAQ National Market.

	HIGH	LOW
	-----	-----
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
FISCAL YEAR ENDED JUNE 30, 2004		
First Quarter .....	\$ 5.20	\$1.70
Second Quarter .....	5.40	3.13
Third Quarter .....	10.25	3.74
Fourth Quarter .....	12.00	8.00
FISCAL YEAR ENDED JUNE 30, 2005		
First Quarter .....	\$ 9.24	\$5.90
Second Quarter .....	11.74	6.86
Third Quarter (through February 2, 2005) .....	9.18	7.35

On February 2, 2005, the last reported sale price on the NASDAQ National Market for our common stock was \$8.10. As of February 2, 2005, there were approximately 166 holders of record of our common stock.

We have never paid cash dividends on our common stock. We do not expect to declare cash dividends on our common stock in the future and expect to retain all earnings for business development. Holders of our 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.

S-13

CAPITALIZATION

The following table sets forth our cash and cash equivalents, stockholders' equity and total capitalization as of September 30, 2004, assuming that the underwriters do not exercise their over-allotment option to purchase additional shares of common stock:

o on an actual basis; and



Edgar Filing: BIOENVISION INC - Form 424B5

o as adjusted to give effect to the issuance and sale by us of 7,500,000 shares of our common stock in this offering at the public offering price of \$8.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	SEPTEMBER 30, 2004	
	----- ACTUAL -----	AS ADJUSTED -----
	(UNAUDITED)	
CASH AND CASH EQUIVALENTS .....	\$ 17,662,989	\$ 73,312,989
	=====	=====
STOCKHOLDERS' EQUITY:		
Preferred stock -- \$0.001 par value, 20,000,000 shares authorized; 3,341,666 shares issued and outstanding (liquidation preference \$10,024,998) .....	\$ 3,342	\$ 3,342
Common stock -- par value \$0.001; 70,000,000 shares authorized; 28,597,172 shares issued and outstanding -- actual; 36,097,172 shares issued and outstanding -- as adjusted (1) .....	28,597	36,097
Deferred compensation .....	(201,927)	(201,927)
Additional paid-in capital .....	69,066,456	124,708,956
Accumulated deficit .....	(44,169,063)	(44,169,063)
Accumulated other comprehensive income .....	139,304	139,304
	-----	-----
Total stockholders' equity .....	24,866,709	80,516,709
	-----	-----
TOTAL CAPITALIZATION .....	\$ 24,866,709	\$ 80,516,709
	=====	=====

-----

(1) The number of shares of common stock issued and outstanding does not include: (a) 4,441,000 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of \$1.86 per share; (b) 8,542,534 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$2.36 per share; (c) 885,000 shares of common stock available for future issuance under our 2003 Stock Incentive Plan; and (d) 6,683,332 shares of common stock issuable upon conversion of 3,341,666 shares of our Series A convertible preferred stock.

At our annual stockholders meeting on December 17, 2004, our stockholders approved, among other things, an amendment to our 2003 Stock Incentive Plan to increase the number of shares that may be granted under the plan from 3,000,000 to 4,500,000.

S-14

U.S. FEDERAL TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a summary of the material U.S. federal income tax considerations with respect to the ownership and disposition of our common stock by a non-U.S. holder (as defined below) as of the date hereof. This

## Edgar Filing: BIOENVISION INC - Form 424B5

summary deals only with non-U.S. holders that hold our common stock as a capital asset.

For purposes of this summary, a "non-U.S. holder" means a beneficial owner of our common stock that is not treated as a partnership for U.S. federal income tax purposes and is not any of the following for U.S. federal income tax purposes: (i) a citizen or resident of the U.S., (ii) a corporation, including any entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the U.S., any state thereof, or the District of Columbia, (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (iv) a trust if (1) its administration is subject to the primary supervision of a court within the U.S. and one or more U.S. persons have the authority to control all of its substantial decisions, or (2) it has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This summary is based upon provisions of the Internal Revenue Code of 1986, as amended, and regulations, rulings and judicial decisions as of the date hereof. Those authorities may be changed, perhaps retroactively, or be subject to differing interpretations, so as to result in U.S. federal tax considerations different from those summarized below. This summary does not represent a detailed description of the U.S. federal tax considerations to you in light of your particular circumstances. In addition, it does not represent a description of the U.S. federal tax considerations to you if you are subject to special treatment under the U.S. federal tax laws (including if you are a U.S. expatriate, "controlled foreign corporation" or "passive foreign investment company"), and it generally does not address any U.S. taxes other than the federal income tax. We cannot assure you that a change in law will not alter significantly the tax considerations that we describe in this summary.

If an entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. If you are a partnership holding our common stock, or a partner in such a partnership, you should consult your tax advisors.

IF YOU ARE CONSIDERING THE PURCHASE OF OUR COMMON STOCK, YOU SHOULD CONSULT YOUR OWN TAX ADVISORS CONCERNING THE PARTICULAR U.S. FEDERAL TAX CONSEQUENCES TO YOU OF THE OWNERSHIP AND DISPOSITION OF THE COMMON STOCK, AS WELL AS THE CONSEQUENCES TO YOU ARISING UNDER THE LAWS OF ANY OTHER TAXING JURISDICTION, INCLUDING ANY STATE, LOCAL OR FOREIGN TAX CONSEQUENCES.

### DIVIDENDS

We have never declared or paid any cash dividends on our common stock and do not currently anticipate paying any cash dividends on our common stock. If we were to pay dividends in the future on our common stock, they would be subject to U.S. federal income tax in the manner described below.

Dividends paid to a non-U.S. holder of our common stock generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. However, dividends that are effectively connected with the conduct of a trade or business by a non-U.S. holder within the U.S. and, where an income tax treaty applies, are attributable to a U.S. permanent establishment of the non-U.S. holder, are not subject to this withholding tax, but instead are subject to U.S. federal income tax on a net income basis at applicable individual or corporate rates. Certain certification and disclosure requirements must be complied with in order for effectively connected dividends to be exempt from this withholding tax. Any such effectively connected dividends received by a

## Edgar Filing: BIOENVISION INC - Form 424B5

foreign corporation may be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

S-15

A non-U.S. holder of our common stock who is entitled to and wishes to claim the benefits of an applicable treaty rate (and avoid backup withholding as discussed below) for dividends, will be required to (i) complete Internal Revenue Service, or IRS, Form W-8BEN (or successor form) and make certain certifications, under penalty of perjury, to establish its status as a non-U.S. person and its entitlement to treaty benefits (which may also require, in certain circumstances, the provision of a U.S. taxpayer identification number) or (ii) if the common stock is held through certain foreign intermediaries, satisfy the relevant certification requirements of applicable U.S. Treasury regulations. Special certification and other requirements apply to certain non-U.S. holders that are entities rather than individuals.

A non-U.S. holder of our common stock eligible for a reduced rate of U.S. federal withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

### GAIN ON DISPOSITION OF COMMON STOCK

A non-U.S. holder generally will not be subject to U.S. federal income tax with respect to gain recognized on a sale or other disposition of our common stock unless (i) the gain is effectively connected with a trade or business of the non-U.S. holder in the U.S. and, where a tax treaty applies, is attributable to a U.S. permanent establishment of the non-U.S. holder (in which case, for a non-U.S. holder that is a foreign corporation, the branch profits tax described above may also apply), (ii) in the case of a non-U.S. holder who is an individual, such holder is present in the U.S. for 183 or more days in the taxable year of the sale or other disposition and certain other conditions are met, or (iii) we are or have been a "U.S. real property holding corporation" for U.S. federal income tax purposes.

We believe we have not been and currently are not, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

### FEDERAL ESTATE TAX

Common stock held by an individual non-U.S. holder at the time of death will be included in such holder's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise.

### INFORMATION REPORTING AND BACKUP WITHHOLDING

We must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to such holder and the tax withheld (if any) with respect to such dividends, regardless of whether withholding was required. Copies of the information returns reporting such dividends and any withholding may also be made available to the tax authorities in the country in which the non-U.S. holder resides under the provisions of an applicable income tax treaty. In addition, dividends paid to a non-U.S. holder generally will be subject to backup withholding unless applicable certification requirements are met.

Payment of the proceeds of a sale of our common stock within the U.S. or conducted through certain U.S.-related financial intermediaries is subject to

## Edgar Filing: BIOENVISION INC - Form 424B5

information reporting and, depending on the circumstances, backup withholding unless the beneficial owner certifies under penalties of perjury that it is not a U.S. person (and the payor does not have actual knowledge or reason to know that the beneficial owner is a U.S. person) or the holder otherwise establishes an exemption.

Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against such holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

S-16

### UNDERWRITING

We are offering the shares of common stock described in this prospectus supplement and the accompanying prospectus through the underwriters named below. J.P. Morgan Securities Inc. and UBS Securities LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus supplement, the number of shares of common stock listed next to its name in the following table:

NAME ----	NUMBER OF SHARES -----
J.P. Morgan Securities Inc. ....	2,625,000
UBS Securities LLC .....	2,625,000
CIBC World Markets Corp. ....	1,312,500
Friedman, Billings, Ramsey & Co., Inc. ....	937,500
	-----
Total .....	7,500,000 =====

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus supplement and to certain dealers at that price less a concession not in excess of \$0.2880 per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to \$0.1000 per share from the public offering price. After the public offering of the shares, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the U.S. may be made by affiliates of the underwriters.

**Edgar Filing: BIOENVISION INC - Form 424B5**

The underwriters have an option to buy up to 1,125,000 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus supplement to exercise this over-allotment option. If any shares are purchased with this over-allotment option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of common stock.

	WITHOUT OVER-ALLOTMENT EXERCISE -----	WITH FULL OVER-ALLOTMENT EXERCISE -----
Per Share .....	\$ 0.48	\$ 0.48
Total.....	\$3,600,000	\$4,140,000

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately \$750,000.

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses electronically. A prospectus supplement accompanied by a prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if

S-17

any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, without the prior written consent of J.P. Morgan Securities Inc. and UBS Securities LLC for a period of 90 days after the date of this prospectus supplement, other than any shares of our common stock issued upon the exercise of options granted under existing employee stock option plans.

Our directors and executive officers, and certain of our significant

## Edgar Filing: BIOENVISION INC - Form 424B5

stockholders have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of these persons or entities, with limited exceptions, for periods ranging from 45 to 90 days after the date of this prospectus supplement, may not, without the prior written consent of J.P. Morgan Securities Inc. and UBS Securities LLC, (1) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock (including, without limitation, common stock which may be deemed to be beneficially owned by such directors, executive officers and stockholders in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common stock or such other securities, in cash or otherwise. All of our directors and executive officers are subject to 90 day lock-up agreements, with the exception of two of our directors who are subject to 45 day lock-up agreements. In addition, approximately 14.3 million shares of common stock beneficially owned by certain of our significant stockholders (including shares of common stock which may be issued upon exercise of stock options and warrants and shares of common stock which may be issued upon conversion of our preferred stock) are subject to 45 day lock-up agreements.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock is quoted on the NASDAQ National Market under the symbol "BIVN."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' over-allotment option referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that

S-18

there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that

## Edgar Filing: BIOENVISION INC - Form 424B5

stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the NASDAQ National Market, in the over-the-counter market or otherwise.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

S-19

### LEGAL MATTERS

The validity of the shares of common stock offered hereby and certain other matters relating to this offering will be passed on by Paul, Hastings, Janofsky & Walker LLP, New York, New York. Certain legal matters related to this offering will be passed upon for the underwriters by Morgan, Lewis & Bockius LLP, New York, New York.

### EXPERTS

Our auditors are Grant Thornton LLP. Our consolidated financial statements as of and for the years ended June 30, 2004 and June 30, 2003 included in our annual report on Form 10-KSB for the year ended June 30, 2004 and incorporated by reference herein, have been incorporated by reference herein in reliance upon the report of Grant Thornton LLP, independent registered public accountants, given on the authority of said firm as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

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

## Edgar Filing: BIOENVISION INC - Form 424B5

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

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

We have filed with the SEC a registration statement on Form S-3 under the Securities Act to register the common stock being offered in this prospectus supplement. This prospectus supplement and the accompanying prospectus, which form part of the registration statement, do not contain all of the information set forth in the registration statement or the exhibits and schedules to the registration statement. For further information regarding Bioenvision and the common stock offered in this prospectus supplement and the accompanying prospectus, please refer to the registration statement and the documents filed or incorporated by reference as exhibits to the registration statement. You may obtain the registration statement and its exhibits from the SEC as indicated above or from us. Statements contained in this prospectus supplement or the accompanying prospectus as to the contents of any contract or other document that is filed or incorporated by reference as an exhibit to the registration statement are not necessarily complete and we refer you to the full text of the contract or other document filed or incorporated by reference as an exhibit to the registration statement.

### INCORPORATION BY REFERENCE

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

The following documents, which have been filed with the SEC (File No. 001-31787), are hereby incorporated by reference:

S-20

- o our definitive proxy statement dated October 28, 2004, relating to our December 2004 annual meeting of stockholders, filed on October 28, 2004;
- o our annual report on Form 10-KSB for the year ended June 30, 2004, filed on September 24, 2004;
- o our quarterly report on Form 10-QSB for the quarter ended September 30, 2004, filed on November 15, 2004; and
- o our current report on Form 8-K, filed on November 18, 2004.

All other reports and documents subsequently filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act after the date of this prospectus supplement and prior to the termination of this offering are deemed incorporated by reference into this prospectus supplement and a part hereof from the date of filing of those documents. Any statement contained in the accompanying prospectus or any document incorporated by reference herein shall be deemed to be amended, modified or superseded for the purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement, any additional prospectus supplement or a later document that is or is considered to be incorporated by reference herein amends, modifies or supersedes such statement. Any statements



Edgar Filing: BIOENVISION INC - Form 424B5

so amended, modified or superseded shall not be deemed to constitute a part of this prospectus supplement, except as so amended, modified or superseded.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus supplement is delivered, upon written or oral request of such person, a copy of any or all of the documents referred to above which have been or may be incorporated by reference into this prospectus supplement (other than the exhibits to such documents). Requests for such documents should be directed to Bioenvision Inc., 345 Park Avenue, 41st floor, New York, New York 10154, Attention: David P. Luci (telephone: (212) 750-6700).

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus supplement. You should not rely on any unauthorized information. This prospectus supplement does not offer to sell or solicit an offer to buy any shares in any jurisdiction in which it is unlawful. The information in this prospectus supplement is current as of the date on the cover.

S-21

PROSPECTUS

[Bioenvision Logo]

BIOENVISION, INC.

\$90,000,000

COMMON STOCK

From time to time, we may sell our common stock, par value \$.001 per share (the "Common Stock"), in one or more offerings. The specific terms and number of shares of Common Stock so offered will be fully described in supplements to this prospectus. Please read any prospectus supplements and this prospectus carefully before you invest. This prospectus may not be used to sell shares of Common Stock unless accompanied by a prospectus supplement.

Our Common Stock is included for quotation on the Nasdaq National Market under the symbol "BIVN". The last reported sales price of shares of our common stock on December 31, 2004 was \$8.96 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 OUR COMMON STOCK 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 shares of Common Stock may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. See "Plan of Distribution". If any underwriters are involved in the sale of

## Edgar Filing: BIOENVISION INC - Form 424B5

any shares of Common Stock in respect of which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale also will be set forth in a prospectus supplement.

THE DATE OF THIS PROSPECTUS IS JANUARY 5, 2005.

### TABLE OF CONTENTS

	PAGE
	----
ABOUT THIS PROSPECTUS .....	1
BIOENVISION, INC. ....	1
RISK FACTORS .....	3
FORWARD-LOOKING STATEMENTS .....	14
USE OF PROCEEDS .....	15
DESCRIPTION OF CAPITAL STOCK .....	15
PLAN OF DISTRIBUTION .....	16
LEGAL MATTERS .....	18
EXPERTS .....	19
WHERE YOU CAN FIND MORE INFORMATION .....	19
INCORPORATION BY REFERENCE .....	19
DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES.....	20

### ABOUT THIS PROSPECTUS

This prospectus is part of a Registration Statement on Form S-3 that we filed with the Securities and Exchange Commission utilizing a "shelf" registration process. Under this shelf process, we may from time to time offer Common Stock described in this prospectus in one or more offerings up to a total dollar amount of \$90,000,000. Each time we use this prospectus to offer shares of Common Stock, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described below under the heading "Where You Can Find More Information".

In this prospectus, "Bioenvision", "we", "us, and "our" and "the Company" refer to Bioenvision, Inc.

### BIOENVISION, INC.

You should read the following summary together with the more detailed information, including the consolidated financial statements and the notes thereto and other information, included, or incorporated by reference, in this

## Edgar Filing: BIOENVISION INC - Form 424B5

prospectus.

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 December 31, 2004, our internal staff consisted of 21 employees based in New York, New York and Edinburgh, Scotland.

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

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 second quarter of 2005, we intend to apply for mutual recognition in another four large European territories in an effort to gain approval for Modrenal(R) in each such territory. We anticipate receiving approval in each such territory during calendar 2005, but such approval is subject to the appropriate regulatory decisions.

Our primary business strategy relates to our two lead drugs, clofarabine and Modrenal(R). With clofarabine, our strategy is to complete drug development in Europe and obtain marketing authorization from the European regulatory authorities to market and distribute clofarabine in Europe for the treatment of pediatric and adult acute leukemias (ALL and AML). We anticipate launching clofarabine in Europe in mid-2005, subject to our obtaining from the European regulatory authorities the first approval for clofarabine which is expected to be for pediatric acute leukemias. We intend to continue clinical trials in other indications with the intention of aggressively seeking label extensions after clofarabine's first approval, including our Pivotal Phase II trial of clofarabine in adults with Acute Myeloid Leukemia (AML) which commenced in August 2004 and is ongoing. Following this strategy, throughout the world, approximately two-thirds of the cancer patients dosed with clofarabine to date fall outside of the pediatric acute leukemias.

In July 2004, we filed for approval of clofarabine in Europe to treat children with pediatric acute leukemia (ALL and AML). Further, we are conducting a Pivotal Phase II clinical trial of clofarabine, as first line therapy for the treatment of adults with Acute Myeloid Leukemia (AML). Also in Europe, at our direction, an Investigator Sponsored Trial of clofarabine as first-line therapy for adults with AML was completed ahead of schedule and an interim analysis indicates a 64% complete response rate observed in this patient population. In January, 2002, the European orphan drug application for use of clofarabine to treat acute leukemia in adults was approved. Orphan Drug Designation provides the Company with ten years of market exclusivity in Europe for clofarabine, upon grant of marketing authorization. The drug has also been

-1-

granted orphan drug status and "fast track" treatment by the FDA. Further, in July 2004, the FDA granted six months of extended market exclusivity to clofarabine under the Best Pharmaceuticals for Children Act.

In the U.S., ILEX Oncology, Inc., which was our sub-licensor of U.S. and Canadian cancer marketing rights until it was acquired by Genzyme Corporation

## Edgar Filing: BIOENVISION INC - Form 424B5

on December 21, 2004, filed a New Drug Application ("NDA") in March 2004 for approval of clofarabine to treat children with acute leukemias (ALL or AML). The NDA was based upon results of two Pivotal Phase II clinical trials completed by ILEX prior to the NDA filing. In connection with the NDA, the United States Food and Drug Administration (the "FDA") has set a Prescription Drug User Fee Act ("PDUFA") response date at December 30, 2004. A PDUFA date is the date by which the FDA is expected to review and act upon an NDA submission. Clofarabine will be reviewed by the FDA Oncologic Drug Advisory Committee ("ODAC") on December 1, 2004.

In 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 our 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, which was acquired by Genzyme Corporation on December 21, 2004. We converted Genzyme's option to an exclusive sublicense on December 30, 2003. Accordingly, we do not possess the rights to sell, market and distribute clofarabine for cancer indications in the U.S.

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

In the U.S., we filed an IND to conduct Modrenal(R) clinical trials for prostate cancer in February 2004 and commenced enrolling patients in this clinical trial in July 2004. Further, we intend to seek regulatory approval for Modrenal(R) in the United States as salvage therapy for hormone-sensitive breast cancer upon completion of additional clinical studies. We originally obtained an exclusive license from Stegram Pharmaceuticals 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 secondary business strategy is to continue to develop our portfolio of ancillary products and technologies. We anticipate that revenues derived from clofarabine and Modrenal(R) and milestone payments and royalties from the ancillary products will permit us to further develop our portfolio of ancillary products and technologies.

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

## Edgar Filing: BIOENVISION INC - Form 424B5

### RISK FACTORS

You should carefully consider the following risks before you decide to buy our Common Stock. 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.

**WE HAVE A LIMITED OPERATING HISTORY, WHICH MAKES IT DIFFICULT TO EVALUATE OUR BUSINESS AND TO PREDICT OUR FUTURE OPERATING RESULTS**

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

**WE HAVE INCURRED NET LOSSES SINCE COMMENCING BUSINESS AND EXPECT FUTURE LOSSES**

To date, we have incurred significant net losses, including net losses of approximately \$11,574,000 for the fiscal year ended June 30, 2004 and \$2,960,325 for the three months ended September 30, 2004. At September 30, 2004, we had an accumulated deficit of approximately \$44,169,063. We anticipate that we may continue to incur significant operating losses for the foreseeable future. We may never generate material revenues or achieve profitability and, if we do achieve profitability, we may not be able to maintain profitability.

**CLINICAL TRIALS FOR OUR PRODUCTS WILL BE EXPENSIVE AND MAY BE TIME CONSUMING, AND THEIR OUTCOME IS UNCERTAIN, BUT WE MUST INCUR SUBSTANTIAL EXPENSES THAT MAY NOT RESULT IN ANY VIABLE PRODUCTS**

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

Historically, the results from pre-clinical testing and early clinical trials have often not been predictive of results obtained in later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Regulatory authorities may require additional clinical trials, which could result in increased costs and significant development delays. Clofarabine currently is at a pivotal stage of its development, but many of our other products and technologies are at various less mature stages of development including 1-

## Edgar Filing: BIOENVISION INC - Form 424B5

gossypol for which we have just commenced a Phase I clinical trial in the U.K. and gene therapy which is currently in pre-clinical and phase I clinical testing.

Completion of clinical trials for any product may take several years or 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;

-3-

- 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 September 30, 2004, our intangible assets associated with these products amounted to approximately \$14.3 million and constituted approximately 35% of our total assets and approximately 57% of our stockholders' equity. We amortize approximately \$1.3 million of this amount each year for the estimated useful life of these products of approximately 13 years.

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

IF OUR DEVELOPMENT AGREEMENT WITH GENZYME 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

Genzyme, and any third party to which Genzyme 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 Genzyme. While there are target dates for completion, that agreement allows Genzyme time to continue working beyond those dates under certain circumstances. For example, under the co-development agreement, ILEX (Genzyme's predecessor in interest) was required to complete Pivotal Phase II

## Edgar Filing: BIOENVISION INC - Form 424B5

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 Genzyme (successor in interest to 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 October 2003, Ilex filed the first part of a "rolling NDA" with the FDA.

If Genzyme fails to meet its obligations under the co-development agreement, we could lose valuable time in developing clofarabine for commercialization both in the U.S. and in Europe. We can not provide assurance that Genzyme will not fail to meet its obligations under the co-development agreement. Development of compounds to the stage of approval includes inherent risk at each stage of development that FDA, in its discretion, will mandate a requirement not foreseeable by us or by Genzyme. 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.

-4-

If delays in completion constitute a breach by Genzyme or there are certain other breaches of the co-development agreement by Genzyme, then, at our discretion, the primary responsibility for completion would revert to us, but there is no assurance that we would have the financial, managerial or technical resources to 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 Genzyme, our U.S. co-development partner since its acquisition of ILEX Oncology, which occurred on December 21, 2004. No assurance can be given that the operational and managerial relations with Genzyme will proceed favorably or that the timeline for development of clofarabine will not be elongated now that Genzyme has replaced ILEX as our US cancer marketing partner. If the U.S. regulatory timeline is elongated, this could materially and adversely affect the European regulatory timeline for the approval of clofarabine.

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

## Edgar Filing: BIOENVISION INC - Form 424B5

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

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

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

OUR INDUSTRY IS SUBJECT TO EXTENSIVE GOVERNMENT REGULATION AND OUR PRODUCTS REQUIRE OTHER REGULATORY APPROVALS WHICH MAKES IT MORE EXPENSIVE TO OPERATE OUR BUSINESS

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

-5-

agencies and equivalent foreign authorities. In our material contracts with vendors providing any portion of these types of services, we seek assurances that our vendors comply and will continue to maintain compliance with all applicable rules and regulations. This is the case, for example, with respect to our contracts with Ferro Pfanstiehl and Penn Pharmaceuticals. No assurance can be given that our most significant vendors will continue to comply with these rules and regulations.

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



## Edgar Filing: BIOENVISION INC - Form 424B5

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

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

FDA Approval Process. We have a variety of products under development, including line extensions of existing products, reformulations of existing products and new products. All "new drugs" must be the subject of an FDA-approved new drug application before they may be marketed in the United States. All generic equivalents to previously approved drugs or new dosage forms of existing drugs must be the subject of an FDA-approved abbreviated new drug application before they may be marketed in the United States. In both cases, the FDA has the authority to determine what testing procedures are appropriate for a particular product and, in some instances, has not published or otherwise identified guidelines as to the appropriate procedures. The FDA has the authority to withdraw existing new drug application and abbreviated application approvals and to review the regulatory status of products marketed under the enforcement policy. The FDA may require an approved new drug application or abbreviated application for any drug product marketed under the enforcement policy if new information reveals questions about the drug's safety or effectiveness. All drugs must be manufactured in conformity with current good manufacturing practices and drugs subject to an approved new drug application or abbreviated application must be manufactured, processed, 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

## Edgar Filing: BIOENVISION INC - Form 424B5

unknown problems with a product, manufacturer or facility may result in restrictions on the product or manufacturer, including withdrawal of the product from the market.

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

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

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

**WE MAY NOT BE SUCCESSFUL IN RECEIVING ORPHAN DRUG STATUS FOR CERTAIN OF OUR PRODUCTS OR, IF THAT STATUS IS OBTAINED, FULLY ENJOYING THE BENEFITS OF ORPHAN DRUG STATUS**

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

## Edgar Filing: BIOENVISION INC - Form 424B5

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

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

-7-

received orphan drug designation for its drug. In that case, the FDA would refrain from approving an application by us to market our competing product for seven years, subject to limitations. Competing products may receive orphan drug designations and FDA marketing approval before the products under development by us.

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

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

THE USE OF OUR PRODUCTS MAY BE LIMITED OR ELIMINATED BY PROFESSIONAL GUIDELINES WHICH WOULD DECREASE OUR SALES OF THESE PRODUCTS AND, THEREFORE, OUR REVENUE AND CASH FLOWS

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

## Edgar Filing: BIOENVISION INC - Form 424B5

treatment which may from time to time show activity at lower doses.

GENERIC PRODUCTS WHICH THIRD PARTIES MAY DEVELOP MAY RENDER OUR PRODUCTS NONCOMPETITIVE OR OBSOLETE

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

BECAUSE MANY OF OUR COMPETITORS HAVE SUBSTANTIALLY GREATER CAPABILITIES AND RESOURCES, THEY MAY BE ABLE TO DEVELOP PRODUCTS BEFORE US OR DEVELOP MORE EFFECTIVE PRODUCTS OR MARKET THEM MORE EFFECTIVELY WHICH WOULD LIMIT OUR ABILITY TO GENERATE REVENUE AND CASH FLOW

Competition in our industry is intense. Potential competitors in the United States and Europe are numerous and include pharmaceutical, chemical and biotechnology companies, most of which have substantially greater capital resources, marketing experience, research and development staffs and facilities

-8-

than us. Potential competitors for certain indications of our lead drugs include, with respect to clofarabine, Schering AG, which markets fludarabine, and certain generic drug companies in Europe which could market fludarabine upon expiry of the patent protections held by Schering. Potential competitors with respect to Modrenal(R) include Astra-zeneca and Novartis, which market tamoxifen and other aromatase inhibitors, which could be used by clinicians as first and second line therapies in patients with hormone sensitive, advanced, post-menopausal breast cancer prior to a Modrenal(R) regimen of treatment. No assurance can be given that the ongoing business activities of our competitors will not have a material adverse effect on our business prospects and projections going forward.

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

## Edgar Filing: BIOENVISION INC - Form 424B5

IF WE FAIL TO KEEP UP WITH RAPID TECHNOLOGICAL CHANGE AND EVOLVING THERAPIES, OUR TECHNOLOGIES AND PRODUCTS COULD BECOME LESS COMPETITIVE OR OBSOLETE

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

WE DEPEND ON OTHERS FOR CLINICAL TESTING OF OUR PRODUCTS WHICH COULD DELAY OUR ABILITY TO DEVELOP PRODUCTS

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

WE DEPEND ON OTHERS TO MANUFACTURE OUR PRODUCTS AND HAVE NOT MANUFACTURED THEM IN SIGNIFICANT QUANTITIES

We have never manufactured any products in commercial quantities, and the products being developed by us may not be suitable for commercial manufacturing in a cost-effective manner. Manufacturers of products developed by us will be subject to current good manufacturing practices prescribed by the FDA or other rules and regulations prescribed by foreign regulatory authorities. We may not be able to enter into or maintain relationships either domestically or abroad with manufacturers whose facilities and procedures comply or will continue to comply with current good manufacturing practices or applicable foreign requirements. Failure by a manufacturer of our products to comply with current good manufacturing practices or applicable foreign requirements could result in significant time delays or our inability to commercialize or continue to market a product and could have a material adverse effect on our sales of products and, therefore,

-9-

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 outside of the UK or be successful in gaining market acceptance for proprietary products

## Edgar Filing: BIOENVISION INC - Form 424B5

or for other products. We currently have very limited sales and marketing capabilities outside of the UK. We currently employ six full-time sales employees and two full-time marketing employees. To market any products directly, we will need to develop a more fulsome marketing and sales force with technical expertise and distribution capability or contract with other pharmaceutical and/or health care companies with distribution systems and direct sales forces. To the extent that we enter into co-promotion or other licensing arrangements, any revenues to be received by us will be dependent on the efforts of third parties. The efforts of third parties may not be successful. Our failure to establish marketing and distribution capabilities or to enter into marketing and distribution arrangements with third parties could have a material adverse effect on our revenue and cash flows.

### IF WE LOSE KEY MANAGEMENT OUR BUSINESS WILL SUFFER

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

### NEED FOR ADDITIONAL PERSONNEL

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

### OUR MANAGEMENT AND INTERNAL SYSTEMS MIGHT BE INADEQUATE TO HANDLE OUR POTENTIAL GROWTH

Our success will depend in significant part on the expansion of our operations and the effective management of growth. This growth has and will continue to place a significant strain on our management and information systems and resources and operational and financial systems and resources. To manage future growth, our management must continue to improve our operational and financial systems and expand, train, retain and manage our employee base. Our management may not be able to manage our growth effectively. If

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

WE DEPEND ON PATENT AND PROPRIETARY RIGHTS TO DEVELOP AND PROTECT OUR TECHNOLOGIES AND PRODUCTS, WHICH RIGHTS MAY NOT OFFER US SUFFICIENT PROTECTION

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

## Edgar Filing: BIOENVISION INC - Form 424B5

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

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

We require our employees, consultants, members of the scientific advisory board and parties to collaborative agreements to execute confidentiality agreements upon the commencement of employment or consulting relationships or a collaboration with us. These agreements may not provide meaningful protection

-11-

of our trade secrets or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information.

BECAUSE WE HAVE INTERNATIONAL OPERATIONS, WE WILL BE SUBJECT TO RISKS OF CONDUCTING BUSINESS IN FOREIGN COUNTRIES

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

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

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

We do not engage in forward currency transactions which means we are susceptible to fluctuations in the U.S. dollar against foreign currencies such as the pound sterling. Accordingly, as the value of the dollar becomes weaker against the pound sterling, ongoing services provided by our UK employees, 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



## Edgar Filing: BIOENVISION INC - Form 424B5

associated with our drug development activities.

WE CANNOT PREDICT OUR FUTURE CAPITAL NEEDS AND WE MAY NOT BE ABLE TO SECURE ADDITIONAL FINANCING WHICH COULD AFFECT OUR ABILITY TO OPERATE AS A GOING CONCERN

As of September 30, 2004, we had stockholders' equity of approximately \$24,867,000 and net working capital of approximately \$16,396,000. However, we may need additional financing to continue to fund the research and development and marketing programs for our products and to generally expand and grow our business. For example, we will need to employ a European sales force within the next twelve months to capitalize on the commercial potential for clofarabine and Modrenal(R) if and to the extent our lead drugs are at market in Europe by mid-2005. To the extent that we will be required to fund operating losses, our financial position would deteriorate. There can be no assurance that we will be able to find significant additional financing at all or on terms favorable to us. If equity securities are issued in connection with a financing, dilution to our stockholders would result, and if additional funds are raised through the incurrence of debt, we may be subject to restrictions on our operations and finances. Furthermore, if we do incur debt, we may be limiting our ability to repurchase capital stock, engage in mergers, consolidations, acquisitions and asset sales, or alter our lines of business or accounting methods, even though these actions would otherwise benefit our business.

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.

-12-

THE PRICES WE CHARGE FOR OUR PRODUCTS AND THE LEVEL OF THIRD-PARTY REIMBURSEMENT MAY DECREASE AND OUR REVENUES COULD DECREASE

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

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

OUR PRODUCTS MAY BE SUBJECT TO RECALL

## Edgar Filing: BIOENVISION INC - Form 424B5

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

WE MAY FACE EXPOSURE FROM PRODUCT LIABILITY CLAIMS AND PRODUCT LIABILITY INSURANCE MAY NOT BE SUFFICIENT TO COVER THE COSTS OF OUR LIABILITY CLAIMS RELATED TO TECHNOLOGIES OR PRODUCTS

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

THE PRICE OF OUR COMMON STOCK IS LIKELY TO BE VOLATILE AND SUBJECT TO WIDE FLUCTUATIONS

The market price of the securities of biotechnology companies has been especially volatile. Thus, the market price of our Common Stock is likely to be subject to wide fluctuations. For the twelve month period ended December 31, 2004, our closing stock price has ranged from a high of \$11.75 to a low of \$4.10. If our

-13-

revenues do not grow or grow more slowly than we anticipate, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our Common Stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in

## Edgar Filing: BIOENVISION INC - Form 424B5

investor confidence or otherwise fails, the market price of our Common Stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, companies that have experienced volatility in the market price of their stock have been the subject of securities class action litigation. If we were to become the subject of securities class action litigation, it could result in substantial costs and a diversion of management's attention and resources.

### CERTAIN EVENTS COULD RESULT IN A DILUTION OF HOLDERS OF OUR COMMON STOCK

As of December 23, 2004, we had 32,482,949 shares of Common Stock outstanding, 2,250,000 shares of Series A Convertible Preferred Stock outstanding which are currently convertible into 4,500,000 shares of Common Stock and common stock equivalents, and warrants and stock options, convertible or exercisable into 11,389,363 shares of our Common Stock. The exercise and conversion prices of the common stock equivalents range from \$0.74 to \$8.80 per share. We have also reserved for issuance an aggregate of 4,500,000 shares of Common Stock for a stock option plan for our employees. Historically, from time to time, we have awarded our Common Stock to officers of the Company, in lieu of cash compensation, although we do not expect to do so in the future. As of January 3, 2005, (i) we have 30,164,746 shares of common stock registered under the Securities Act and (ii) the sale of shares of Common Stock underlying 4,500,000 options are registered under the Securities Act on Form S-8. The future resale of these shares and shares underlying stock options and warrants will result in a dilution to your percentage ownership of our Common Stock and could adversely affect the market price of our Common Stock.

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

### FORWARD LOOKING STATEMENTS

Our disclosure and analysis in this prospectus, the applicable prospectus supplement and the documents incorporated by reference into this prospectus and the applicable prospectus supplement contain forward-looking statements, which provide information regarding our current expectations, plans, objectives and forecasts of future events. Words such as "may," "will," "believe," "estimate," "anticipate," "plan," "expect," "may affect," and "intend", or statements concerning "potential" or "opportunity" and similar expressions or the negative thereof, are intended to identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements include, without limitation:

- o statements about our drug development and commercialization goals and expectations;
- o potential regulatory approvals;
- o our plans for and anticipated results of our clinical development

## Edgar Filing: BIOENVISION INC - Form 424B5

activities;

- o the potential advantage of our drug candidates;
- o statements about our future capital requirements, the sufficiency of our capital resources to meet those requirements and the expected composition of our capital resources; and
- o other statements that are not historical facts.

-14-

Forward looking statements are based on the judgment of management at the time the statements are made. Inaccurate assumptions and known and unknown risks and uncertainties can affect the accuracy of forward-looking statements. Our actual results could differ materially from those stated in or implied by forward-looking statements for a number of reasons, including the risks described in the sections of this prospectus and the applicable prospectus entitled "Risk Factors," in our other public filings, press releases and statements by our management. Other factors besides those described in this prospectus, the applicable prospectus supplement and in our other public filings, press releases and statements by our management could also affect actual results.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus or the applicable prospectus supplement. We undertake no obligation to publicly update any forward-looking statement to reflect new information, events or circumstances, whether anticipated or unanticipated, or to conform the statement to actual results or changes in our expectations. You should, however, review the factors, risks and other information we provide in the reports we file from time to time with the SEC.

### USE OF PROCEEDS

Unless otherwise indicated in the applicable prospectus supplement, we intend to use any net proceeds from the sale of Common Stock offered by this prospectus for additional working capital and other general corporate purposes, including, but not limited to, further development of our lead products and increased sales and marketing expenses related to the commercial launch of our products. Until we have used the net proceeds, we may invest them in short-term marketable securities.

### DESCRIPTION OF CAPITAL STOCK

#### DESCRIPTION OF COMMON STOCK

Number of Authorized and Outstanding Shares. Our Certificate of Incorporation authorizes the issuance of 70,000,000 shares of common stock, \$.001 par value per share, of which 32,482,949 shares were outstanding on December 23, 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

## Edgar Filing: BIOENVISION INC - Form 424B5

preferred stock, voting together as a class at a stockholders meeting at which a quorum is present, can elect all of the directors nominated for election at the meeting.

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

Transfer Agent. Shares of common stock are registered at the transfer agent and are transferable at such office by the registered holder (or duly authorized attorney) upon surrender of the common stock certificate, properly endorsed. No transfer shall be registered unless we are satisfied that such transfer will not result in a violation of any applicable federal or state securities laws. The transfer agent for our common stock is American Stock Transfer & Trust Company, 59 Maiden Lane, New York, New York 10038.

### DESCRIPTION OF PREFERRED STOCK

Number of Authorized Shares. Our certificate of incorporation authorizes the issuance of up to 20,000,000 shares of preferred stock, par value \$.001 per share, in one or more series with such limitations and restrictions as may be determined in the sole discretion of our board of directors, with no further authorization by stockholders required for the creation and issuance thereof.

-15-

We have designated 5,920,000 shares of our preferred stock as Series A convertible preferred stock, of which 2,225,000 shares were issued and outstanding as of December 23, 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.

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

DELAWARE LAW AND CERTAIN BY-LAW PROVISIONS

## Edgar Filing: BIOENVISION INC - Form 424B5

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

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

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

### PLAN OF DISTRIBUTION

We may sell our securities from time to time by any method permitted by the Securities Act of 1933, including in the following ways:

- o through one or more underwriters on a firm commitment or best efforts basis;
- o directly to one or more purchasers;
- o through agents;

-16-

- o through broker-dealers, who may act as agents or principals, including a block trade in which a broker or dealer so engaged will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o in privately negotiated transactions; and
- o in any combination of these methods of sale.

The applicable prospectus supplement will set forth:

- o the specific terms of the offering of our securities, including the name or names of any underwriters, dealers or agents;
- o the purchase price of the securities and the proceeds to us from the sale;
- o any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation;

## Edgar Filing: BIOENVISION INC - Form 424B5

- o the initial offering price to the public and any discounts or concessions allowed or reallocated or paid to dealers; and
- o the name of any securities exchange on which the securities may be listed.

Any public offering price, discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

We expect that any common stock sold pursuant to a prospectus supplement will be listed on the Nasdaq National Market.

The distribution of the securities may be effected from time to time in one or more transactions at a fixed price or prices (which may be changed), at market prices prevailing at the time of sale, at prices related to the prevailing market prices or at negotiated prices.

Offers to purchase our securities may be solicited by agents designated by us from time to time. Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from us. Broker-dealers or agents may also receive compensation from the purchasers of the securities for whom they sell as principals. Each particular broker-dealer will receive compensation in amounts negotiated in connection with the sale, which might be in excess of customary commissions. Broker-dealers or agents and any other participating broker-dealers participating in the distribution of our securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions.

If required under applicable state securities laws, we will sell the securities only through registered or licensed brokers or dealers. In addition, in some states, we may not sell securities unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and complied with.

If the securities are sold by means of an underwritten offering, we will execute an underwriting agreement with an underwriter or underwriters, and the names of the specific managing underwriter or underwriters, as well as any other underwriters, and the terms of the transaction, including commissions, discounts and any other compensation of the underwriters and dealers, if any, will be set forth in the applicable prospectus supplement, which will be used by the underwriters to make resales of the securities. Under agreements into which we may enter, underwriters, dealers and agents who participate in the distribution of the securities may be entitled to indemnification by us against some liabilities, including liabilities under the Securities Act.

If we use underwriters for an offering of securities, the underwriters may acquire the securities for their own accounts. The underwriters may resell the securities from time to time in one or more transactions at a fixed price or prices, which may be changed, at varying prices determined by the underwriters at the time of sale, or at negotiated prices. We also may, from time to time, authorize underwriters acting as our agents to offer and sell the securities upon the terms and conditions as will be set forth in the applicable prospectus

-17-

supplement. In connection with the sale of the securities, underwriters may be deemed to have received compensation from us in the form of underwriting discounts or commissions and also may receive commissions from purchasers of

## Edgar Filing: BIOENVISION INC - Form 424B5

the securities. Underwriters may sell the securities to or through dealers, who may receive compensation in the form of discounts, concessions from the underwriters and/or commissions from the purchasers of the securities.

Any underwriting compensation paid by us to underwriters or agents in connection with any offering of the securities and any discounts, concessions or commissions allowed by underwriters to participating dealers will be set forth in the applicable prospectus supplement. Underwriters, dealers and agents participating in the distribution of our securities may be deemed to be underwriters, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions.

If so indicated in the applicable prospectus supplement, we may authorize underwriters, dealers or agents to solicit offers from certain types of institutions to purchase securities from us at the public offering price set forth in the applicable prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a future date. Institutions with which delayed delivery contracts may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions, and other institutions. The applicable prospectus supplement will set forth the commission payable for solicitation of such offers.

Our securities may be offered to the public either through underwriting syndicates represented by managing underwriters or directly by the managing underwriters. If any underwriters are utilized in the sale of the securities, the underwriting agreement will provide that the obligations of the underwriters are subject to specified conditions precedent. If we sell our securities to one or more underwriters on a firm commitment basis, then the underwriters will be obligated to purchase all of the securities offered if any are purchased.

We may grant to the underwriters options to purchase additional securities to cover over-allotments, if any, at the public offering price with additional underwriting discounts or commissions, as may be set forth in the applicable prospectus supplement. If we grant any over-allotment option, the terms of the over-allotment option will be set forth in the applicable prospectus supplement.

In connection with any offering, persons participating in the offering, such as any underwriters, may purchase and sell the securities in the open market. These transactions may include over-allotment and stabilizing transactions and purchases to cover syndicate short positions created in connection with the offering. Stabilizing transactions consist of bids or purchases for the purpose of preventing or retarding a decline in the market price of the securities and syndicate short positions involve the sale by underwriters of a greater number of securities than they are required to purchase from us in the offering. Underwriters also may impose a penalty bid, whereby selling concessions allowed to syndicate members or other broker-dealers in respect of the securities sold in the offering for their account may be reclaimed by the syndicate if the securities are repurchased by the syndicate in stabilizing or covering transactions. These activities may stabilize, maintain or otherwise affect the market price of the securities, which may be higher than the price that might prevail in the open market, and these activities, if commenced, may be discontinued at any time.

Any underwriters, dealers or agents involved in any distribution or sale of our securities may be customers of, engage in transactions with or perform services for us from time to time.

We will bear all costs, expenses and fees in connection with the



## Edgar Filing: BIOENVISION INC - Form 424B5

registration of the securities as well as the expense of all commissions and discounts, if any, attributable to the sales of the securities by us.

### LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, 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.

-18-

### EXPERTS

Our auditors are Grant Thornton LLP. Our consolidated financial statements as at and for the years ended June 30, 2004 and June 30, 2003 included in our annual report on Form 10-KSB for the year ended June 30, 2004 and incorporated by reference herein, have been incorporated by reference herein in reliance upon the report of Grant Thornton LLP, independent registered public accountants, given on the authority of said firm as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

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

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

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

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

### INCORPORATION BY REFERENCE

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

## Edgar Filing: BIOENVISION INC - Form 424B5

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

- o Our definitive proxy statement dated October 28, 2004, relating to our December 2004 annual meeting of stockholders, filed on October 28, 2004;
- o Our annual report on Form 10-KSB for the year ended June 30, 2004 filed on September 24, 2004; and
- o Our quarterly report on Form 10-QSB for the quarter ended September 30, 2004, filed on November 15, 2004.

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

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request of such person, a copy of any or all of the documents referred to

-19-

above which have been or may be incorporated by reference into this prospectus (other than the exhibits to such documents). Requests for such documents should be directed to Bioenvision Inc., 345 Park Avenue, 41st floor, New York, New York 10154, Attention: David P. Luci (telephone: (212) 750-6700).

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You should not rely on any unauthorized information. This prospectus does not offer to sell or solicit an offer to buy any shares in any jurisdiction in which it is unlawful. The information in this prospectus is current as of the date on the cover.

### DISCLOSURE OF COMMISSION POSITION ON 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.

-20-

[Bioenvision Logo]