BIOENVISION INC
Form POS AM
August 05, 2005

As filed with the Securities and Exchange Commission on August 5, 2005

Registration No. 333-115816

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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POST-EFFECTIVE AMENDMENT NO. 3 TO FORM S-3 ON

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

BIOENVISION, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4025857**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

345 Park Avenue, 41st Floor

New York, New York 10154

(212) 750-6700

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

David P. Luci, Esq.

Chief Financial Officer and General Counsel

Bioenvision, Inc.

345 Park Avenue, 41st Floor

New York, New York 10154

(212) 750-6700

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

Copy to:

Luke P. Iovine, III, Esq.

Paul, Hastings, Janofsky & Walker LLP

75 East 55th Street

New York, NY 10022

(212) 318-6000

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

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. |X|

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

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434 under the Securities Act, please check the following box. |_|

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

EXPLANATORY NOTE

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

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

SUBJECT TO COMPLETION DATED AUGUST 4, 2005

PRELIMINARY PROSPECTUS

Bioenvision, Inc.

27,083,742 Shares of Common Stock

This prospectus covers 27,083,742 shares of our common stock that the selling stockholders named herein may offer and sell from time to time.

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

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

Our common stock is included for quotation on the Nasdaq National Market under the symbol BIVN . The last reported sales price of shares of our common stock on August 1, 2005, was $7.65 per share.

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

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

The date of this prospectus is , 2005

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

SUMMARY

You should read the following summary together with the more detailed information regarding us and the securities being offered for sale by means of this prospectus and our financial statements and notes to those statements appearing elsewhere in this prospectus. The summary highlights information contained elsewhere in this prospectus. The terms Bioenvision, the company, we, our and us refer to Bioenvision, Inc. and its consolidated subsidiaries unless the context suggests otherwise. The term you refers to a prospective investor.

We are 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 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.

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 Virostat for Hepatitis C.

Products and pipeline

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

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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 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 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 calendar 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 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-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 our resource capability. 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 mid-2005 we began enrollment in a U.K., Phase IV study in post-menopausal advanced breast cancer, a Phase II study in pre-menopausal breast cancer and a Phase II study in neo-adjuvent, 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. 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. We anticipate 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.

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.

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. Information included or referred to on our website is not incorporated by reference in or otherwise a part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

The Offering

Common stock offered by selling stockholders	27,083,742 shares.
Common stock to be outstanding as of August 1, 2005	40,569,567 shares.
Use of proceeds	We will not receive any proceeds from the sale of shares in this offering. We may receive consideration upon the exercise of options and will receive consideration upon the conversion of warrants which we intend to use for general corporate purposes.
Trading	Our common stock currently trade on the Nasdaq National Market under the symbol BIVN.
Risk Factors	You should carefully consider all of the information in this prospectus. In particular, you should evaluate the information under Risk Factors beginning on page 9 of this prospectus before deciding whether to invest in our common stock.
Plan of Distribution	The shares of common stock offered for resale may be sold by the selling stockholders pursuant to this prospectus in the manner described under Plan of Distribution on page 72.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables summarize our consolidated financial data. You should read the summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus, and the Management s Discussion and Analysis of Financial Condition and Results of Operations section and other financial information included in this prospectus.

	Year Ended June 30,					Nine Months Ende March 31,	
Income Statement Data	**2004**	**2003**	**2002**	**2001**	**2000**	**2005**	**2004**
	As Restated (1)	As Restated (1)	As Restated (1)			As Restated (2)	As Re
Revenues	$3,102,214	$504,857	$802,965	$245,455	$-	$3,660,220	$1,75
Cost of sales	-	-	-	-	-	229,417	-
Operating expenses							
Research and development	4,882,574	1,689,278	1,912,258	1,565,908	984,460	5,986,496	2,545
General and administrative	9,082,420	4,567,413	2,127,664	550,215	486,627	6,885,382	7,079
Depreciation and amortization	1,348,064	1,344,969	579,342	22,809	11,644	1,028,197	1,023
Total operating expenses	15,313,058	7,601,660	4,619,264	2,138,932	1,482,731	13,900,075	10,64
Loss from operations	(12,210,844)	(7,096,803)	(3,816,299)	(1,893,477)	(1,482,731)	(10,469,272)	(8,88
Other income (expense)	99,763	(186,426)	(2,172,682)	(228,787)	(12,778)	297,479	49,46
Loss from continuing operations	(12,111,081)	(7,283,229)	(5,988,981)	(2,122,264)	(1,495,509)	(10,171,793)	(8,84
Income tax benefit	1,459,814	2,117,103	1,168,145	-	-	-	1,065
Net loss	(10,651,267)	(5,166,126)	(4,820,836)	(2,122,264)	(1,495,509)	(10,171,793)	(7,77
Cumulative preferred stock dividend	(856,776)	(877,818)	(9,482,667)	-	-	(319,935)	(587,
Net loss available to shareholders	$(11,508,043)	$(6,043,944)	$(14,303,503)	$(2,122,264)	$(1,495,509)	$(10,491,728)	$(8,3
Basic and diluted shares outstanding	20,257,482	16,920,939	12,184,152	8,121,255	7,430,965	31,907,864	18,12
Basic and diluted net loss available to shareholders per share	$ (0.57)	$ (0.36)	$ (1.17)	$ (0.26)	$ (0.20)	$ (0.33)	$

	June 30,					March 31,	
Balance Sheet Data	**2004**	**2003**	**2002**	**2001**	**2000**	**2005**	**2004**
	As Restated (1)	As Restated (1)	As Restated (1)			As Restated (2)	As Restated (2)
Cash & cash equivalents	$19,165,675	$8,219,686	$12,882,52	21	$15	$70,624,9	$17,848,813
Intangibles, net	14,563,660	15,779,399	16,921,79	23,698	20,991	13,799,9	14,801,470
Total assets	42,170,844	26,173,132	32,380,54	782,885	139,253	93,374,0	40,119,394
Total current liabilities	3,460,419	2,264,896	2,395,59	1,966,538	1,342,845	5,281,09	8,657,668
Total debt	-	-	-	-	-	-	-
Total shareholder s equity (deficit)	30,800,827	21,323,737	25,554,55	(2,482,516)	(1,203,592)	80,530,6	29,901,335

	Year Ended June 30,					Nine Months Ended March 31,	
Summary Cash Flow Data	**2004**	**2003**	**2002**	**2001**	**2000**	**2005**	**2004**
	As Restated (1)	As Restated (1)	As Restated (1)			As Restated (2)	As Restated (2)
Net Cash (used in) Operating Activities	(4,641,193)	(4,411,581)	(2,675,11	(1,056,835)	(1,945,157)	(7,263,78	(3,651,771)
Net Cash (used in) provided by Investing Activities	(130,917)	(541,254)	(455,500)	(1,760)	11,616	(478,791)	(33,888)
Net Cash provided by Financing Activities	15,730,847	-	16,013,13	4,127,241	1,942,696	59,201,83	3,314,786

(1) See note 9 of the audited consolidated financial statements which are included in this prospectus.

(2) See note I of the unaudited consolidated financial statements which are included in this prospectus.

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.

Risks Related to Our Business

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

Since our inception in August of 1996, we have been primarily engaged in organizational activities, including developing a strategic operating plan, 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 a limited operating history upon which an evaluation of our performance and prospects can be made.

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

To date, we have incurred significant net losses, including net losses of approximately $11,508,000 for the fiscal year ended June 30, 2004 and $10,492,000 for the nine months ended March 31, 2005. At March 31, 2005, we had an accumulated deficit of approximately $48,156,000. 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 are expensive and time consuming, and may not result in any viable products.

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

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

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

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

unforeseen safety issues or side effects;

lack of efficacy during the clinical trials; or

government or regulatory delays.

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

Our ancillary products include OLIGON and Methylene Blue which are anti-microbial agents that we acquired in February 2002. As of March 31, 2005, the net intangible assets associated with these products amounted to approximately $13.8 million and constituted approximately 15% of our total assets and approximately 17% 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®, over the next two years. If we determine 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, which could result in a material impact on our future results of operations.

We depend on our development agreement with Genzyme and if it does not proceed as planned, we may incur delay in the commercialization of clofarabine, which would delay our ability to generate revenues and cash flow from the sale of clofarabine.

We have a co-development agreement with Genzyme, and pursuant to that agreement, Genzyme and any third party to which Genzyme grants a sublicense or transfer its obligations, has primary responsibility for conducting clinical trials and administering regulatory compliance and approval matters in the United States and Canada. While there are target dates for completion, the agreement permits Genzyme 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 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.

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 U.S. 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®, 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® in prostate cancer patients. This Phase II Clinical Trial is being conducted at the Mass General Hospital in Boston, MA. To our knowledge, Modrenal® has not been tested in this indication in the past and there can be no assurance that Modrenal® will be an effective therapy in prostate cancer. Further, our long-term drug development objectives for Modrenal® include attempting to test the drug and get approval in the U.S. for treatment of advanced post-menopausal breast cancer patients. These trials will take significant time and resource and no assurance can be given that developing the drug in this indication will result in a U.S. approval for Modrenal® in advanced post-menopausal breast cancer patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our business strategy involves obtaining orphan drug designation for certain of the oncology products we have under development. Although clofarabine has received orphan drug designation with the FDA and 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 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 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®, 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®, envision, initially, that Modrenal® would be used as second or third line therapy, only after patients with advanced post-menopausal breast cancer receive regimens of tamoxifen and/or aromatase inhibitors (or similar drug) treatments. If generic drug companies develop a compound which is more effective than either clofarabine or Modrenal® in these areas of unmet clinical need, or equally as effective but at lower doses, it could adversely affect our market and/or render our drugs obsolete.

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

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

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

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

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

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

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

We rely on a limited number of manufacturers to operate our business and our products have not been manufactured in significant quantities. If these manufacturers experience problems or favor our competitors, we could fail to obtain sufficient quantities of products we require to operate our business successfully.

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

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

We are highly dependent on our Chief Executive Officer to develop our lead drug. Dr. Wood has an employment agreement with us, dated December 31, 2002, for an initial term of one year which automatically extends for 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 us in the near future. Dr. Wood is one of our founders and he is intimately familiar with the science that underlies our lead drugs and ancillary technologies. He also maintains a position on the 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 us, the development of our drugs would be significantly delayed and otherwise would be adversely impacted, and we may be unable to maintain and develop these important relationships.

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

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

Our success will depend in significant part on the expansion of our operations and the effective management of growth. This growth has and will continue to place a significant strain on our management and information systems and resources and operational and financial systems and resources. To manage future growth, our management must continue to improve our operational and financial systems and expand, train, retain and manage our employee base. Our management may not be able to manage our growth effectively. If our systems, procedures, controls, and resources are inadequate to support our operations, our expansion would be halted or delayed and we could lose our opportunity to gain significant market share or the timing with which we would otherwise gain significant market share. Any inability to manage growth effectively may harm our ability to institute our business plan. The strain on our systems, procedures, controls and resources is further heightened by the fact that our executive office and operational development facilities are located in separate time zones (New York, New York and Edinburgh, Scotland, respectively).

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

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

foreign countries. Thus, we and our 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 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.

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

We have the right to manufacture, market and distribute our lead drugs, clofarabine and Modrenal®, in territories outside of the U.S. Specifically, we currently market Modrenal® in the United Kingdom and upon receiving European approval for clofarabine, we intend to market the drug throughout Europe. Further, 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:

difficulty in establishing or managing distribution relationships;

different standards for the development, use, packaging, pricing and marketing of our products and technologies;

our inability to locate qualified local employees, partners, distributors and suppliers;

the potential burden of complying with a variety of foreign laws, trade standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and

general geopolitical risks, such as political and economic instability, changes in diplomatic and trade relations, and foreign currency risks.

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

We 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 March 31, 2005, we had stockholders equity of approximately $80,531,000 and net working capital of approximately $68,795,000. 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® 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.

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

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

Third-party payors may attempt to control costs further by selecting exclusive providers of their pharmaceutical products. If third-party payors were to make this type of arrangement with one or more of our

competitors, they would not reimburse patients for purchasing our competing products. For example, if a third-party payor in the U.K. were to pay patients for regimens of aromatase inhibitor treatment but not treatments of Modrenal®, this would cause a decline in sales of Modrenal®. This lack of reimbursement would diminish the market for products developed by us and would have a material adverse effect on us.

Our products may be subject to recall.

Product recalls may be issued at our discretion or by the 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.

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

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

We 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, then 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. Neither Grant Thornton LLP nor our current auditors have been asked to form a conclusion on those measures.

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

We 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.

Risks Related to the Offering and Ownership of our Common Stock

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

The market price of the securities of biotechnology companies has been especially volatile. Thus, the market price of our common stock is likely to be subject to wide fluctuations. For the twelve month period ended June 30, 2005, our closing stock price has ranged from a high of $11.74 to a low of $5.17. If our revenues do not grow or grow more slowly than we anticipate, or, if operating or capital expenditures exceed our expectations and cannot be adjusted accordingly, or if some other event adversely affects us, the market price of our common stock could decline. In addition, if the market for pharmaceutical and biotechnology stocks or the stock market in general experiences a loss in investor confidence or otherwise fails, the market price of our common stock could fall for reasons unrelated to our business, results of operations and financial condition. The market price of our stock also might decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, companies that have experienced volatility in the market price of their stock have been the subject of securities class action litigation. If we were to become the subject of securities class action litigation, it could result in substantial costs and a diversion of management s attention and resources.

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

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

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

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

- our board of directors approves the transaction before the third party acquires 15% of our common stock;
- the third party acquires at least 85% of our common stock at the time its ownership exceeds the 15% level; or
- our board of directors and two-thirds of the shares of our common stock not held by the third party vote in favor of the transaction.

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

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

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

Our existing principal stockholders, executive officers and directors beneficially own, in the aggregate, approximately 52% of our outstanding common stock. As a result, these stockholders will, if they so choose, be able to substantially control all matters requiring stockholder approval. These matters include the election of directors and approval of significant corporate transactions, such as a merger, consolidation, takeover or other business combination involving us. Our existing principal stockholders, executive officers and directors may have

interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership could also adversely affect the market price of our common stock or reduce any premium over market price that an acquirer might otherwise pay.

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

As of August 1, 2005, we had 40,569,567 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 11,472,413 shares of our common stock. The exercise and conversion prices of the common stock equivalents range from $0.74 to $8.87 per share. We have also reserved for issuance an aggregate of 4,500,000 shares of common stock for a stock option plan for our employees. Historically, from time to time, we have awarded our common stock to our officers, in lieu of cash compensation, although we do not expect to do so in the future. As of August 1, 2005, we have the sale of shares of common stock underlying 4,500,000 options are registered under the Securities Act on Form S-8. The future resale of these shares underlying stock options will result in a dilution to your percentage ownership of our common stock and could adversely affect the market price of our common stock.

The terms of our 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

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

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

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

USE OF PROCEEDS

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

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