

Registration No. 000-30813

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

POST EFFECTIVE AMENDMENT NO. 2 to SB-2

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

ALPHARX, INC.  
(Name of Small Business Issuer in its Charter)

Delaware	2834	98-0177440
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

200-168 Konrad Crescent  
Markham, Ontario, Canada, L3R 9T9  
(905) 479-3245  
(Address and Telephone Number of  
Principal Executive Offices and  
Principal Place of Business)

Michael Lee  
200-168 Konrad Crescent  
Markham, Ontario, Canada, L3R 9T9  
(905) 479-3245  
(Name, Address and Telephone Number  
of Agent for Service)

with copies to:

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Louisville, Kentucky 40202  
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Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement is declared effective.

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, other than

securities offered only in connection with dividend or interest reinvestment plans, check the following box ☒ [X]

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

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering ☒ [X]

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 statement 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, check the following box ☐ [ ]

#### **CALCULATION OF REGISTRATION FEE**

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED	PROPOSED MAXIMUM OFFERING PRICE	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE	AMOUNT OF REGISTRATION FEE
Common Stock	93,905,994	\$0.38 <sup>1</sup>	\$35,684,277	\$4522.00 <sup>2</sup>

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, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

**FILED WITH THE SEC AS OF DECEMBER 9, 2004**

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<sup>1</sup> Based on the average of the bid and asked prices on September 7, 2004.

<sup>2</sup> Previously Paid.

## **ALPHARX, INC.**

This prospectus has been issued and prepared by AlphaRx, Inc., a Delaware corporation whose principal place of business is 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9 (905) 479-3245. This prospectus covers 93,905,994 shares of our common stock that may be offered for resale by the selling security holders named in this prospectus and the persons to whom such selling security holders may transfer their shares. The selling security holders acquired their common stock and warrants to purchase common stock directly from us in private placements that were exempt from the registration requirements of federal and state securities laws. We will not receive any proceeds from the sale of these shares by the selling security holders, but we will receive proceeds from the exercise of the warrants, if any.

Our common stock is quoted on the Over the Counter Market under the symbol "ALRX." On December 8, 2004, our last reported sale price of our common stock on the Over the Counter Market was \$0.145 per share.

The selling security holders may sell their shares from time to time on the Over the Counter Market or otherwise, in one or more transactions at fixed prices, at prevailing market prices at the time of sale or at prices negotiated with purchasers. The selling security holders will be responsible for any commissions or discounts due to brokers or dealers. We will pay substantially all expenses of registration of the shares covered by this prospectus.

**Investing in our common stock involves risk. Please see "RISK FACTORS" beginning on page 4.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

Filed with the SEC as of December 9, 2004.

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All dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligations to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

## **PROSPECTUS SUMMARY**

### About This Prospectus

This prospectus is part of a registration statement we filed with the U.S. Securities and Exchange Commission. You should rely only on the information provided in this prospectus. The selling security holders are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock. Applicable SEC rules may require us to update this prospectus in the future. This preliminary prospectus is subject to completion prior to this offering.

### THE OFFERING:

Common stock offered by the selling security holders: 93,905,994

Use of Proceeds: We will not receive proceeds from the sale of shares by the selling security holders.

## **FORWARD-LOOKING STATEMENTS**

This prospectus contains "forward-looking" statements that involve risks and uncertainties. Forward-looking statements include statements about the desired or believed utility and market for our potential products, future of the biotechnology and biopharmaceutical industry, statements about future business plans and strategies, and most other statements that are not historical in nature. Because forward-looking statements involve risks and uncertainties, there are factors, including those discussed below, that could cause actual results to be materially different from any future results, performance or achievements expressed or implied. Accordingly, readers should not place undue reliance on forward-looking statements. We undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

## **RISK FACTORS**

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and the other information contained in this prospectus before deciding to invest in our common stock. The risks described below are not the only ones facing our company. Additional risks not presently known to us or which we currently consider immaterial may also adversely affect our business. We have attempted to identify the major factors under the heading "Risk Factors" that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors. If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose part or all of your investment.

### Business Factors

We have incurred net losses to date and depend on outside capital.

We will require substantial funds to: (1) continue our research and development programs, (2) acquire technologies by license or purchase, and (3) conduct preclinical studies and clinical trials. We will almost certainly need to raise additional capital to fund our operations repeatedly. We may raise such capital through public or private equity financings, partnerships, debt financings, bank borrowings, or other sources. Our capital requirements will depend upon numerous factors, including the following:

- o the establishment of collaborations
- o the development of competing technologies or products
- o changing market conditions
- o the cost of protecting our intellectual property rights
- o the progress of our research and development programs, the progress of our collaborations and receipt of any option/license, milestone and royalty payments resulting from those collaborations
- o technology acquisition opportunities

Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we may curtail operations significantly or even cease operations. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, you may experience dilution of your proportionate ownership of the company.

Our lack of operating experience may cause us difficulty in managing our growth. We have no experience in manufacturing or procuring products in commercial quantities and conducting other later-stage phases of the regulatory approval process, and we have only

limited experience in negotiating, establishing and maintaining strategic relationships. Our ability to manage our growth, if any, will require us to improve and expand our management and our operational and financial systems and controls. If our management is unable to manage growth effectively, our business and financial condition would be materially harmed. In addition, if rapid growth occurs, it may strain our operational, managerial and financial resources.

Our business is subject to technological obsolescence. Biotechnology and related pharmaceutical technology have undergone and are subject to rapid and significant change. We expect that the technologies associated with biotechnology research and development will continue to emerge rapidly. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any compounds, products or processes that we develop may become obsolete before we recover any expenses incurred in connection with developing these products.

We face intense competition in the biotechnology and pharmaceutical industries. We have numerous competitors in the United States and elsewhere. Our competitors include major, multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations, than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of these competitors have significant products that have been approved or are in development and operate large, well-funded research and development programs.

Our competitors may succeed in developing or licensing technologies and products that are more effective or less costly than any we are developing. Our competitors may succeed in obtaining United States Food and Drug Administration ("FDA") or other regulatory approvals for product candidates before we do. In particular, we face direct competition from many companies focusing on delivery technologies. Products resulting from our research and development efforts, if approved for sale, may not compete successfully with our competitors' existing products or products under development.

We will depend on third parties to manufacture and market our products. We do not have, and do not intend to develop, internal facilities for the manufacture of any of our products for clinical or commercial production. We will need to develop relationships with third-party manufacturing resources, enter into collaborative arrangements with licensees or other parties which have established manufacturing capabilities or elect to have other third parties manufacture our products on a contract basis. We expect to be dependent on such collaborators or third parties to supply us in a timely way with products manufactured in compliance with standards imposed by the FDA and foreign regulators. The manufacturing facilities of contract manufacturers may not comply with

applicable manufacturing regulations of the FDA nor meet our requirements for quality, quantity or timeliness.

If we develop products eligible for commercial sale, we will need to rely on third parties such as licensees, collaborators, joint venture partners or independent distributors to market and sell those products. We may not be able to obtain access to a marketing and sales force with sufficient technical expertise and distribution capability. Also, we will not be able to control the resources and effort that a third party will devote to marketing our products. If we are unable to develop and maintain relationships for the necessary marketing and sales capabilities, we may fail to gain market acceptance for our products, and our revenues could be impaired.

We depend on key personnel to develop our products and pursue collaborations. We are highly dependent on Mr. Michael Lee, our President and Chief Executive Officer, and our other senior executives. The loss of any of these persons, or failure to attract or retain other key personnel, could prevent us from pursuing collaborations or developing our products and core technologies. We have not entered into an employment agreement with any of our senior executives.

Recruiting and retaining qualified scientific personnel to perform research and development work are critical to our success. There is intense competition for qualified scientists and managerial personnel from numerous pharmaceutical and biotechnology companies, as well as from academic and government organizations, research institutions and other entities. In addition, we may face particular difficulties because there are a limited number of scientists specializing in carbohydrate chemistry, a principal focus of our company.

We expect to rely on consultants and advisors, including our scientific and clinical advisors, to assist us in formulating our research and development strategy. Any of those consultants or advisors could be employed by other employers, or be self-employed, and might have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Such other employment, consulting or advisory relationships could place our trade secrets at risk, even if we require non-disclosure agreements. We may be unable to retain key employees or recruit additional qualified personnel. Because of the specialized scientific nature of our business, we are highly dependent upon qualified scientific, technical, and managerial personnel. There is intense competition for qualified personnel in our business. Therefore, we may not be able to attract and retain the qualified personnel necessary for the development of our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical, and managerial personnel in a timely manner would harm our research and development programs and our business.

We have incurred annual operating losses since our inception. As a result, at September 30, 2004, we had an accumulated deficit of approximately \$ 5,998,820. Our gross revenues for the years ended September 30, 2004 and September 30, 2003 were \$ 383,824 and \$52,925 respectively. Our revenues have not been sufficient to sustain our operations. As a result, we have sustained a loss of \$ 1,772,840 for the year ended September 30, 2004, compared to a loss of \$ 1,414,597 for the year ended September 30,



2003. Revenue for 2004 consisted primarily of revenue from sales of Flexogan in Canada. In order to achieve profitability our marketing activities will have to increase as well as our sales and there is no assurance that sales can increase to such a level. With continued research and development costs, we anticipate incurring losses for the foreseeable future.

We believe that satisfying our long-term capital requirements will require at least the successful commercialization of one of our over-the-counter health care products. However, our products may never become commercially successful, and we may never be profitable.

We face significant competition in the over-the-counter health care market. The over-the-counter health care market is highly competitive and is characterized by the frequent introduction of new products, including the migration of prescription drugs to the over-the-counter market, often accompanied by major advertising and promotional support. These introductions may adversely affect our business, especially because we compete in categories in which product sales are highly influenced by advertising and promotions. Our competitors include large over-the-counter pharmaceutical companies such as Pfizer, Inc. and Johnson and Johnson, consumer products companies such as Procter & Gamble Co., many of which have considerably greater financial and other resources than we do. Many of these competitors are better positioned to spend more on research and development, employ more aggressive pricing strategies, utilize greater purchasing power, build stronger vendor relationships and develop broader distribution channels than we. In addition, our competitors may use aggressive spending on trade promotions and advertising as a strategy for building market share, at the expense of their competitors, including us. If we are unable to introduce new and innovative products that are attractive to consumers, or are unable to allocate sufficient resources to effectively advertise and promote our products so that they achieve wide spread market acceptance, we may not be able to compete effectively, and our operating results and financial condition may be adversely affected.

If our pharmaceutical products receive regulatory approval, our competitors may eventually include large pharmaceutical companies with superior resources. We are engaged in a rapidly changing and highly competitive field. To date, we have concentrated our efforts primarily on one pharmaceutical product — Indaflex — for treating arthritis and other inflammatory indications. Like the market for any pharmaceutical product, the market for treating arthritis and these other indications has the potential for rapid, unpredictable and significant technological change. Competition is intense from specialized biotechnology companies, major pharmaceutical and chemical companies and universities and research institutions. We currently have no products approved for sale in the U.S. If we are successful in obtaining approval for one of our products, our future competitors will have substantially greater financial resources, research and development staff and facilities, and regulatory experience than we do. Major companies in the field of osteoporosis treatment include Novartis, Wyeth, Merck, Eli Lilly, Aventis and Procter & Gamble. Any one of these potential competitors could, at any time, develop products or a manufacturing process that could render our technology or products noncompetitive or obsolete.

Our technology or products could give rise to product liability claims. Our business exposes us to the risk of product liability claims that are a part of human testing, manufacturing and sale of pharmaceutical products. The administration of drugs to humans can result in product liability claims even if our products are not actually at fault for causing an injury. Furthermore, our products may cause, or may appear to cause, adverse side effects or potentially dangerous drug interactions that we may not learn about or understand fully until the drug is actually manufactured and sold.

Product liability claims can be expensive to defend and may result in large judgments against us. Even if a product liability claim is not successful, the adverse publicity, time, and expense involved in defending such a claim may interfere with our business. We may not have sufficient resources to defend against or satisfy these claims. We currently maintain \$5,000,000 in product liability insurance coverage and plan to increase this coverage as our products advance. However, these amounts may not be sufficient to protect us against losses or may be unavailable in the future on acceptable terms, if at all. This liability may result from claims made directly by consumers or by pharmaceutical companies or others selling such products.

It is possible that any insurance obtained will provide inadequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth. While we desire to reduce our risk by obtaining indemnity undertakings with respect to such claims from licensees and distributors of our products, we may not be able to obtain such undertakings and, even if we do, they may not be sufficient to limit our exposure to claims.

#### Proprietary Information

We believe our product candidates will be based on novel technologies. Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to:

- o obtain patent protection for our products or processes both in the United States and other countries;
- o protect trade secrets; and
- o prevent others from infringing on our proprietary rights.

We do not believe that our carbohydrate-drug conjugates will infringe any third-party patents covering the underlying drug. However, there can be no assurance that we will receive a patent for our carbohydrate-drug conjugates.

Since patent applications in the United States are maintained in secrecy until patents are issued, and since publication of discoveries in the scientific or patent literature often lag

behind actual discoveries, we cannot be certain that we are the first to make the inventions to be covered by the patent applications we have filed and those we intend to file. The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the U.S. and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease.

We cannot assure you that patent applications in which we have rights will ever issue as patents or that the claims of any issued patents will afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect our patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue such litigation or to protect our patent rights. An adverse outcome in litigation with respect to the validity of any of our patents could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. Third parties may independently develop such know-how or otherwise obtain access to our technology. While our employees, consultants and corporate partners with access to proprietary information generally will be required to enter into confidentiality agreements, these agreements may not be honored. We also rely on trade secrets to protect our inventions. Our policy is to include confidentiality obligations in all research contracts, joint development agreements and consulting relationships that provide access to our trade secrets and other know-how. However, parties with confidentiality obligations could breach their agreements causing us harm. If a secrecy obligation were to be breached, we may not have the financial resources necessary for a legal challenge. If licensees, consultants or other third parties use technological information independently developed by them or by others in the development of our products, disputes may arise from the use of this information and as to the ownership rights to products developed using this information. These disputes may not be resolved in our favor.

Patents issued to third parties may cover our products as ultimately developed. We may need to acquire licenses to these patents or challenge the validity of these patents. We may not be able to license any patent rights on acceptable terms or successfully challenge such patents. The need to do so will depend on the scope and validity of these patents and ultimately on the final design or formulation of the products and services that we develop. We may not be able to meet our obligations under those licenses that we do enter into. If we enter into a license agreement for intellectual property underlying any of

our products, and that license were to be terminated, we may lose our right to market and sell any products based on the licensed technology.

### Health Care Industry Factors

Health care cost containment initiatives may limit our returns. Our ability to commercialize our products successfully will be affected by the ongoing efforts of governmental and third-party payors to contain or reduce the cost of health care. Governmental and other third-party payors increasingly are attempting to contain health care costs by:

- o challenging the prices charged for health care products and services
- o limiting both coverage and the amount of reimbursement for new therapeutic products
- o denying or limiting coverage for products that are approved by the FDA but are considered experimental or investigational by third-party payors.
- o refusing in some cases to provide coverage when an approved product is used for disease indications in a way that has not received FDA marketing approval

In addition, the trend toward managed health care in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products.

Even if we succeed in bringing any products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the adoption of such proposals could make it difficult or impossible to sell our products.

Environmental regulations may affect our manufacturers and other contractors. Pharmaceutical research and development involves the controlled use of hazardous materials including but not limited to certain hazardous chemicals and radioactive materials. In connection with research, development and manufacturing activities, biotechnology and biopharmaceutical companies are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. As we have limited in-house research, development or manufacturing facilities, we may be affected by environmental regulations. Additionally, our contractors and others conducting research, development or manufacturing activities

for us may be required to incur significant costs to comply with environmental and health and safety regulations in the future, and this could in turn affect our costs of doing business and might ultimately interfere with timely completion of research or manufacturing programs if those third parties are unable to comply with environmental regulatory requirements.

Our research and development activities have involved, and will continue to involve, animal testing. Such activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas. To the extent the activities of these groups are successful, our business could be materially harmed.

### Stock Market Factors

Stock prices for biopharmaceutical and biotechnology companies are volatile. The market price for securities of biopharmaceutical and biotechnology companies historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. Fluctuations in the trading price or liquidity of our common stock may adversely affect our ability to raise capital through future equity financings.

Factors that may have a significant impact on the market price and marketability of our common stock include:

- o announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors
- o announcements by us or others of results of preclinical testing and clinical trials
- o developments or disputes concerning patent or other proprietary rights
- o adverse legislation, including changes in governmental regulation and the status of our regulatory approvals or applications
- o changes in health care policies and practices
- o economic and other external factors, including general market conditions

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. If a securities class action suit is filed against us, we would incur substantial legal fees and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

Purchasers of stock may be subject to substantial dilution.

We cannot guarantee that our Board of Directors will have a majority of independent directors in the future. In the absence of a majority of independent directors, our executive officers, who are also principal stockholders and directors, could establish policies and enter into transactions without independent review and approval thereof. This could present the potential for a conflict of interest between the Company and its stockholders generally and the controlling officers, stockholders or directors.

Our common stock is classified as a “penny stock” under SEC rules which may make it more difficult for our stockholders to resell our common stock. Our common stock is traded on the OTC Bulletin Board. As a result, the holders of our common stock may find it more difficult to obtain accurate quotations concerning the market value of the stock. Stockholders also may experience greater difficulties in attempting to sell the stock than if it was listed on a stock exchange or quoted on the Nasdaq National Market or the Nasdaq Small-Cap Market. Because AlphaRx common stock is not traded on a stock exchange or on Nasdaq, and the market price of the common stock is less than \$5.00 per share, the common stock is classified as a “penny stock.” Rule 15c-2 of the Securities Exchange Act of 1934 imposes additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as an “established customer” or an “accredited investor.” This includes the requirement that a broker-dealer must make a determination that investments in penny stocks are suitable for the customer and must make special disclosures to the customer concerning the risks of penny stocks. Application of the penny stock rules to our common stock could adversely affect the market liquidity of the shares, which in turn may affect the ability of holders of our common stock to resell the stock.

## **USE OF PROCEEDS**

We will not receive any proceeds from the sale of common stock by the selling security holders.

## **SELLING SECURITY HOLDERS**

The table below lists the selling stockholders and other information regarding the beneficial ownership of the common stock by each of the selling stockholders. The second column lists the number of shares of common stock beneficially owned by each selling stockholder as of October 7, 2004, based on each such selling stockholder’s ownership of common stock and warrants, assuming exercise of the warrants held by such selling stockholder without regard to any limitations on exercise. The third column lists the number of shares of common stock that may be resold under this prospectus. The fourth column lists the number of shares of common stock owned and the percentage of common stock owned after the resale of the common stock registered under this prospectus. None of the selling stockholders have had any material relationship with us within the past three years, with the exception of Sunrise Securities Corp. Sunrise Securities Corporation has served as AlphaRx’s investment banking advisor. Any selling stockholder who is an affiliate of a registered broker-dealer purchased his shares in the ordinary course of business. At the time of the purchase by any selling stockholder, each selling stockholder had no agreement or understanding, either direct or indirect, with any person to distribute any of the securities being registered under this prospectus. The total

number of shares of our common stock outstanding as of December 9, 2004 was 57,508,112. Beneficial ownership is determined in accordance with the rules of the Securities Exchange Commission, and includes voting and investment power with respect to shares. Shares of common stock subject to options or warrants that are currently exercisable or exercisable within 60 days after December 9, 2004 are deemed to be beneficially owned by the person holding such options for the purpose of computing the percentage ownership of such person but are not treated as outstanding for the purpose of computing the percentage ownership of any other shareholder. Under the terms of our warrants, a selling stockholder may not exercise such warrants to the extent such exercise would cause such selling stockholder, together with his or its affiliates, to beneficially own a number of shares of common stock which would exceed 4.99% of our then outstanding shares of common stock following such exercise, excluding for purposes of such determination shares of common stock issuable upon exercise of warrants which have not been exercised. The number of shares in the second and third columns does not reflect this limitation.

Name of Selling Stockholder	Common Stock Beneficially Owned Prior to Offering	Common Stock Offered by this Prospectus	Common Stock Owned After Offering
Ajax Partners	3,333,334	3,333,334	0
Balestra Spectrum	2,000,000	2,000,000	0
Basso Equity Opportunity	733,400	733,400	0
Basso MultiStrategy	2,600,000	2,600,000	0
BayStar Capital II, L.P. <sup>3</sup>	3,333,334	3,333,334	0
Bristol Investment Fund, Ltd.	2,666,666	2,666,666	0
Terence Byrne	200,000	200,000	0
CGT Management	2,666,666	2,666,666	0
Cordillera Fund LP	2,666,666	2,666,666	0
Cranshire Capital	3,333,334	3,333,334	0
De Parys Holdings	666,666	666,666	0
Enable Capital, LLC*	1,333,334	1,333,334	0
Richard Hollander	533,334	533,334	0
J. Mitchell Hull	666,666	666,666	0
John Lemak IRA Rollover Account	666,666	666,666	0
North Sound	133,334	133,334	0

<sup>3</sup> BayStar Capital Management, LLC is the General Partner of BayStar Capital II, L.P. Bay East L.P., Lawrence Goldfarb, and Steven M. Lamar are the three managing members of the general partner. Acting together they exercise shared voting and investment control over the securities beneficially owned by BayStar Capital II, L.P. Steve Derby is the general partner of Bay East L.P. BayStar Capital II, L.P. may be deemed to be an affiliate of SDS Capital Group SPC, Ltd. and therefore may be deemed to beneficially own shares held by SDS Capital Group SPC, Ltd. See footnote #4 below.

\* A registered broker-dealer with the NASD and each is an underwriter for this offering.

Legacy Fund, LLC			
North Sound Legacy International Ltd.	4,466,666	4,466,666	0
North Sound Institutional Fund, LLC	2,066,666	2,066,666	0
Sandor Capital Master Fund LP	1,333,334	1,333,334	0
Brad van Siclen	200,000	200,000	0
Verondica Investments Ltd.	666,666	666,666	0
Chu Yee-Wan	1,068,000	1,068,000	0
Theodore H. Friedman	800,000	800,000	0
Malcom Hoenlein	400,000	400,000	0
William Jeffrey	666,666	666,666	0
Yoni Leifer	1,312,293	1,312,293	0
Jay Lobell	700,000	700,000	0
Smithfield Fiduciary LLC <sup>4</sup>	3,333,334	3,333,334	0
SRG Capital	1,000,000	1,000,000	0
Ronald Urvater	680,000	680,000	0
Marie E. Roberts	400,000	400,000	0
Gilad Ottensoser	411,334	411,334	0
Merkin Venture Management, LLC	466,666	466,666	0
Sol Merkin	466,666	466,666	0
Kenneth Greif	1,333,334	1,333,334	0
Victor J. and Jody C. Dowling	2,000,000	2,000,000	0
Michael Berlin	1,333,334	1,333,334	0
Richard Stone	1,871,756	1,871,756	0
Shai Stern	1,124,100	1,124,100	0
WEC Partners, LLC	1,561,250	1,561,250	0
Bristol Investment Fund	3,118,333	3,118,333	0
Michael Weinberger	778,959	778,959	0
Vertical Ventures, LLC	1,556,250	1,556,250	0
Platinum Partners	777,917	777,917	0

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<sup>4</sup> Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and consequently has voting control and investment discretion over securities held by Smithfield. Glenn Dubin and Henry Swieca control Highbridge. Each of Highbridge, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield.



Global Fund			
SDS Capital Group <sup>5</sup>	7,804,170	7,804,170	0
Joshua Golomb	100,000	100,000	0
David Bartash	1,500,000	1,500,000	0
Paul Scharfer	6,206,240	6,206,240	0
Balesta Capital Partners LP	2,666,666	2,666,666	0
Nathan Low <sup>6</sup>	5,322,386	5,322,386	0
Derek Caldwell <sup>7</sup>	4,756,097	4,756,097	0
Sunrise Foundation Trust	281,078	281,078	0
Jay Rodin	328,000	328,000	0
John Gallagher	8,100	8,100	0
Legend Merchant Group, Inc.*	70,000	70,000	0
Randy Fields	42,000	42,000	0
Bartholomew International Investments, LLC <sup>8</sup>	1,000,000	1,000,000	0
Chai Lifeline, Inc.	374,333	374,333	0
Marcia Kuchar	20,000	20,000	0

## **MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS**

### Market for Our Common Stock

Our stock is traded in the over-the-counter market and its quotations are carried in the Electronic Bulletin Board of the National Association of Securities Dealers, Inc.

### Shares Subject to Future Issuance

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<sup>5</sup> SDS Management, LLC is the investment advisor of SDS Capital Group SPC, Ltd. Steve Derby is the managing member of SDS Management, LLC, and as such, has voting and investment control over the securities beneficially owned by SDS Capital Group SPC, Ltd. SDS Capital Group SPC, Ltd. may be deemed to be an affiliate of BayStar Capital II, L.P. and therefore may be deemed to beneficially own shares held by BayStar Capital II, L.P. See footnote #2 above.

<sup>6</sup> A warrant for one million shares of common stock held by Mr. Low is not exercisable until February 2, 2005 under the terms of the warrant despite being registered in this prospectus.

<sup>7</sup> A warrant for one million shares of common stock held by Mr. Caldwell is not exercisable until February 2, 2005 under the terms of the warrant despite being registered in this prospectus.

<sup>8</sup> A warrant for one million shares of common stock held by Bartholomew International Investments, LLC is not exercisable until February 2, 2005 under the terms of the warrant despite being registered in this prospectus.

Warrants, other than those issued to the selling security holders, have been issued for up to 670,275 shares of common stock at \$1.10 per share. These warrants expire on December 19, 2004. Warrants for an additional 250,000 shares of common stock at a price of \$0.05 per share expire on January 1, 2005. Warrants for an additional 75,524 shares of common stock at a price of \$0.65 per share expire on June 30, 2006. Finally, warrants for 3,000,000 shares of common stock at an exercise price of \$0.05 per share expire on July 21, 2007.

Related to the private placement of units which consist of common stock and warrants to purchase shares of common stock, our placement agent received partial compensation in the form of warrants to purchase 2,994,644 shares of common stock at \$0.15 per share, in lieu of cash compensation. These warrants expire on September 1, 2007. In connection with the issuance of convertible secured and unsecured promissory notes, our placement agent received a commission, part of which is in the form of warrants to purchase 2,287,669 shares of common stock at \$0.30 per share, expiring September 1, 2007.

There also exist warrants to purchase 45,135,652 shares of common stock at \$0.30 per share, issued to the subscribers of the private placement and holders of our convertible promissory notes. These warrants expire on September 1, 2007.

#### Stock Incentive Plans

Under prior stock incentive plans, we have options outstanding to purchase up to 1,720,000 shares of common stock as follows: Options with an exercise price of \$0.10 per share for 1,150,000 shares expire on June 30, 2010. Options with an exercise price of \$0.63 per share for 330,000 shares of common stock expire February 10, 2008. Options with an exercise price of \$0.69 per share for 150,000 shares of common stock expire February 10, 2008. Options with an exercise price of \$0.55 per share for 20,000 shares of common stock expire May 5, 2008. Finally, options with an exercise price of \$0.50 per share for 70,000 shares of common stock expire May 10, 2008.

The holders of a majority of our common stock recently approved a new stock option plan so that 24,000,000 shares of common stock may be issued. The Plan is intended to provide an incentive to our employees, to attract new employees, directors, consultants and service providers; to encourage the sense of proprietorship of such persons, and to stimulate the active interest of such persons in our development and financial success by providing them opportunities to purchase shares of the Company.

The Board of Directors administers the Plan, or at their discretion, powers of administration can be delegated to a committee. The committee, subject to Board approval, or the Board if the committee is not constituted, shall have full power and authority to determine any matter which is necessary or desirable for, or incidental to, the administration of the Plan.

Under the new 2004 Option Plan we issued the following options on November 15, 2004: options to purchase up to 12,720,000 shares of common stock with an exercise price of \$0.15 per share; options to purchase up to 250,000 shares of common stock with an

exercise price of \$0.40 per share; options to purchase up to 110,000 shares of common stock with an exercise price of \$0.45 per share; and options to purchase up to 140,000 shares of common stock with an exercise price of \$0.50 per share. A total of 13,220,000 options were issued, all of which expire on November 15, 2014. There remains up to 10,780,000 options to be issued under the 2004 Option Plan. These options were issued to management, directors and consultants and vest 100% on November 15, 2005 as to 12,720,000 options and November 15, 2004 as to the remaining 500,000 options which were allocated to our consultants. For specific details please refer to the Executive Compensation section.

#### Shares Eligible for Sale Pursuant to Rule 144 under the Securities Act

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including an affiliate, as that term is defined in Rule 144 under the Securities Act, who has beneficially owned shares for at least one year is entitled to sell, within any three-month period, a number of such shares that does not exceed the greater of (1) one percent of the then outstanding shares of common stock (approximately 575,081 shares as of December 9, 2004) or (2) the average weekly trading volume in the common stock in the Over-the-Counter market during the four calendar weeks preceding the date on which notice of such sale is filed, provided certain requirements concerning availability of public information, manner of sale and notice of sale are satisfied. In addition, our affiliates must comply with the restrictions and requirements of Rule 144, other than the one-year holding period requirement, in order to sell shares of common stock which are not restricted securities.

Under Rule 144(k), a person who is not an affiliate and has not been an affiliate for at least three months prior to the sale and who has beneficially owned shares for at least two years may resell such shares without compliance with the foregoing requirements. In meeting the one- and two-year holding periods described above, a holder of shares can include the holding periods of a prior owner who was not an affiliate. The one- and two-year holding periods described above do not begin to run until the full purchase price or other consideration is paid by the person acquiring the shares from the issuer or an affiliate.

#### Dividends

We have never declared any cash dividends and do not anticipate paying such dividends in the near future. We anticipate all earnings, if any, over the next 24 months will be retained for future development efforts. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependant on our results of operations, financial conditions, contractual restrictions, and other factors deemed relevant by the Board of Directors. We are under no contractual restrictions in declaring or paying dividends to our common stock holders.

### **PLAN OF OPERATION**

We expect to generate losses from operations for at least the next several years due to substantial additional research and development costs, including costs related to clinical

trials. Our future capital requirements will depend on many factors, in particular our progress in and scope of our research and development activities, and the extent to which we are able to enter into collaborative efforts for research and development and, later, manufacturing and marketing products. We may need additional capital to the extent we acquire or invest in businesses, products and technologies. If we should require additional financing due to unanticipated developments, additional financing may not be available when needed or, if available, we may not be able to obtain this financing on terms favorable to us or to our stockholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, or may adversely affect our ability to operate as a going concern. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result.

## CAPITALIZATION

The following table sets forth our capitalization as of December 9, 2004 and also our capitalization as adjusted to reflect the sale of 27,224,034 shares of our common stock that we sold in our recent private placement transaction. This table should be read in conjunction with our financial statements including related notes, the Selected Financial Data section of this prospectus, and Management's Discussion and Analysis section of this prospectus.

Holders	Quantity	As a % of total outstanding	As a % on a fully diluted basis
Management	9,469,305	16.47%	6.88%
Other Common	7,550,777	13.13%	5.48%
Converted Promissory Note Holders	8,955,809	15.57%	6.51%
New Common resulting from Private Placement	27,224,034	47.34%	19.78%
Common Issued in lieu of Commission	4,308,187	7.49%	3.13%
<b>TOTAL OUTSTANDING</b>	<b>57,508,112</b>	<b>100.00%</b>	
Warrants resulting from Conversion of Promissory Note Holders	17,911,618		13.01%
Warrants resulting from Private Placement	27,224,034		19.78%
Other warrants	3,995,799		2.90%
Warrants Issued in lieu of	5,282,312		3.84%

Commission

Options	25,720,000	18.69%
Total Fully Diluted	137,641,875	100.00%

### **SELECTED FINANCIAL DATA**

The income statement data for the period from October 1, 2003 through September 30, 2004 and balance sheet data at September 30, 2004, are derived from our financial statements that have been audited by Schwartz, Levitsky, Feldman LLP and are qualified by reference to those audited financial statements and related notes to the statements, which are included elsewhere in this prospectus. You should read the data set forth below in conjunction with "Plan of Operation," above, and the financial statements and notes included in this prospectus.

### **DESCRIPTION OF THE BUSINESS**

AlphaRx, formerly known as Logic Tech International Inc., was incorporated in Delaware on August 8, 1997 as an intellectual property holding company whose mission was to identify, acquire and develop new technologies or products and devise commercial applications to be taken to market through licensing or joint venture partners. Logic Tech International Inc. was renamed AlphaRx Inc. on January 28, 2000 and our common stock commenced trading on the OTC Pink Sheets under the symbol "AHRX" on July 25, 2000. On October 12, 2000, our common stock ceased trading on the Pink Sheets L.L.C. and began trading on the Over The Counter Bulletin Board ("OTCBB") under the same symbol. Subsequent to March 19, 2002, our symbol was changed to "ALRX" after a consolidation of our common stock on a 1 for 5 basis. All references to our common stock have been retroactively restated. We have one subsidiary, AlphaRx Canada Limited. AlphaRx Canada Limited was incorporated under the laws of the province of Ontario in order to streamline sales of the Company's products in the Canadian market. It is wholly owned by us.

We are a pharmaceutical company, engaged in the research development and market of innovative therapeutic products using advanced drug delivery technologies, which we believe, can be combined with a broad range of therapeutic products.

#### Strategy and Recent Developments

In January 2003, we acquired the world-wide exclusive commercialization rights of VT1, a potential cancer therapeutic compound, from Select Therapeutics Inc. Given our recent experience with Flexogan, Indaflex and our new focus on drug delivery products and plans to evolve into a sales and marketing organization, we have decided VT1 no longer meets our strategic objective and the VT1 program has been terminated.

In August 2003, we licensed Indaflex, our lead pharmaceutical product, to Industria Farmaceutica Andromaco, S.A. de C.V. ("Andromaco") for commercialization in Mexico.

We will receive royalties from future product sales. Mexican health authorities have given approval to Andromaco to commence sales of Indaflex in Mexico.

In August 2003, we delivered our first shipment of Flexogan to Loblaw's Group, one of the largest mass market retailers in Canada. We continue to make progress on Flexogan sales in Canada. A regional or local roll-out in the United States is being contemplated for some point in 2005.

We believe the market for advanced drug delivery systems is large and growing. Based on published data, the market for orally-administered drugs that utilize drug delivery systems is expected to increase to approximately \$50 billion in 2005 from approximately \$10 billion in 1995. We also believe that pharmaceutical companies that do not themselves have drug delivery technology expertise will rely upon third parties, such as AlphaRx, to apply such technologies to their product candidates.

We intend to use our proprietary drug delivery technologies in collaborative arrangements with pharmaceutical companies to formulate their existing commercialized drugs and modified dosage versions of their existing commercialized drugs, as well as drugs under development by them. By improving drug efficacy and reducing side effects, we believe our drug delivery technologies will provide pharmaceutical companies with the opportunity to enhance the commercial value of their existing products and new drug candidates. We also intend to develop either independently or jointly certain off-patent and over-the-counter ("OTC") products utilizing our proprietary drug delivery technologies.

We are an operating stage pharmaceutical company, engaged in the research development and market of innovative therapeutic products using advanced drug delivery technologies, which we believe, can be combined with a broad range of therapeutic products.

#### Principal Product and Services and Principal Markets

Insoluble or poorly soluble drugs are a major problem for the pharmaceutical industry, with over one-third of the drugs listed in the United States' Pharmacopoeia being insoluble or poorly soluble in water. Further, most approaches used to overcome insolubility result in clinical problems ranging from poor and erratic bioavailability to serious side effects.

Our strategy is to develop patentable improved formulations of such drugs that are soluble in human medicines. We are engaged in developing novel formulations of existing drugs that are insoluble or poorly soluble in water, utilizing our proprietary Bioadhesive Colloidal Dispersion ("BCD") drug delivery systems. Our BCD drug delivery technology includes two different approaches to improve the effectiveness of insoluble drugs and provide new methods of delivery, namely, (i) CLD (Colloidal Lipid Dispersion System) and (ii) SECRET (Self Emulsifying Controlled Release Tablet System). The BCD drug delivery technology is designed to develop drugs with major medical advantages, such as lower dosing, fewer side effects and alternative dosage

forms, as well as commercial advantages, such as extended patent protection and broader use.

Our central strategy is to seek alliances with pharmaceutical companies which will assist us in completing the reformulation and development of the drugs and which will initiate clinical trials and commercialize the products.

### Product Pipeline

We have a number of drugs under development, of which certain ones have been successfully reformulated, utilizing our BCD technology. The following table summarizes our principal product development initiatives:

<b>Brand Name</b>	<b>Application</b>	<b>Delivery Route</b>	<b>Stage</b>
<b>Pharmaceuticals</b>			
2.5% Indaflex	Osteoarthritis	Topical	Phase I/II Planned
Rifampicin SLN	Tuberculosis	Oral	Formulation
Gentamicin	Sepsis	Oral	Formulation
<b>Consumer Health (OTC)</b>			
Flexogan	Analgesic	Topical	Market
NuProm	Acne Control	Topical	Formulation
V-Relief	Ant-fungal	Topical	Formulation

The products listed in the above table are in various stages of development. We are presently focusing on Indaflex™ which has shown excellent activities in the animal model, addresses a multi-billion dollar market and where we believe there would be limited competition. Indaflex is our topical NSAID (Non-Steroidal Anti-inflammatory Drug) formulation intended to be used in the treatment of arthritis. Arthritis is the most common chronic condition in North America and afflicts an estimated 10% of the world's population. Indaflex's active ingredient, Indomethacin, has long-standing and proven clinical treatment record. With our enhanced proprietary delivery system, their clinical effectiveness is thought to be significantly enhanced. Topical Indaflex delivery, we believe, may circumvent the significant GI side-effects found with orally ingested NSAID. We expect to initiate a clinical trial for Indaflex in the coming year.

### Flexogan

Flexogan is a topical analgesic emulsion, which delivers commonly prescribed NSAIDs, camphor, menthol and methyl salicylate. Simply stated, Flexogan is a deep penetrating cream that provides temporary relief from pain associated with joints, muscles and minor arthritis. Flexogan is available in three formulations and formats. Flexogan does not irritate the skin, causing its active ingredients to actively penetrate the skin due to our

CLD formulation. The medical ingredients in Flexogan produce a counter-irritant sensation of warmth or cooling, which stimulates sensory receptors in the nearby muscles and joints. Flexogan is being distributed into Canadian mass market drug, retail and food stores.

### NuProm

NuProm is an acne fighter formulated with solubilized benzoyl peroxide for effective delivery to target sites underneath the skin. This increases the delivery of benzoyl peroxide to the pores. NuProm has just entered into feasibility studies, but it is anticipated that it will be distributed in Canada as an over-the-counter medication. Any distribution in the United States will require FDA approval.

### Overview of the Drug Delivery Industry

Drug delivery companies apply proprietary technologies to create pharmaceutical products utilizing drugs developed by others. These products are generally novel, cost-effective dosage forms that may provide any of several benefits, including better control of drug concentration in the blood, improved safety and efficacy, and ease of use and improved patient compliance. We believe drug delivery technologies can provide pharmaceutical companies with a means of developing new products as well as extending existing patents.

The increasing need to deliver medication to patients efficiently and with fewer side effects has accelerated the development of new drug delivery systems. Today, medication can be delivered to a patient through many different means of delivery, including transdermal (through the skin), injection, implant and oral methods. These delivery methods, however, continue to have certain limitations. Transdermal patches are often inconvenient to apply, can be irritating to the skin and the rate of release can be difficult to control. Injections are uncomfortable for most patients. Implants generally are administered in a hospital or physician's office and frequently are not suitable for home use.

Oral administration remains the preferred method of administering medication. Conventional oral drug administration, however, also has limitations in that capsules and tablets have limited effectiveness in providing controlled drug delivery, resulting frequently in drug release that is too rapid (causing incomplete absorption of the drug), irritation to the gastrointestinal (GI) tract and other side effects. In addition capsules and tablets cannot provide localized therapy.

In recent years, drug delivery companies have been able to develop innovative and efficient solutions to some of the limitations of conventional oral drug administration. We believe our BCD Systems have the potential to offer similar opportunities of improved therapy and extended patent life to pharmaceutical and biotechnology companies.

### Bioadhesive Colloidal Dispersion (BCD™) Systems



Our proprietary Bioadhesive Colloidal Dispersion (“BCD”) oral and topical drug delivery technologies permit formulations of drug-containing polymeric units that allow controlled delivery of an incorporated hydrophobic drug. Although our formulations are proprietary, the polymers utilized in our BCD Systems are commonly used in the food and drug industries. By using different formulations of the polymers, we believe our BCD Systems are able to provide continuous, controlled delivery of drugs of varying molecular complexity and solubility.

The BCD Systems are designed to provide orally and topically administered, conveniently dosed, cost-effective drug therapy in a continuous, controlled delivery over multiple hours. We believe our BCD Systems may provide one or more of the following therapeutic advantages over conventional methods of drug administration:

- **Enhanced Safety and Efficacy.** We believe our BCD Systems may improve the ratio of therapeutic effect to toxicity by decreasing the initial peak concentrations of a drug, associated with toxicity, while maintaining levels of the drug at therapeutic, subtoxic concentrations for an extended period of time. Many drugs demonstrate optimal efficacy when concentrations are maintained at therapeutic levels over an extended period of time. When a drug is administered intermittently, the therapeutic concentration is often exceeded for some period of time, and then rapidly drops below effective levels. Excessively high concentrations are a major cause of side effects, while subtherapeutic concentrations are ineffective.
- **Greater Patient and Caregiver Convenience.** We believe our BCD Systems may permit once-daily dosing for certain drugs that are currently required to be administered several times daily, thereby promoting compliance with dosing regimens. Patient noncompliance with dosing regimens has been associated with increased costs by prolonging treatment duration, increasing the likelihood of secondary or tertiary disease manifestation and contributing to over-utilization of medical personnel and facilities. By improving patient compliance, providers and third-party payors may reduce unnecessary expenditures and improve therapeutic outcomes.
- **Expanding the Types of Drugs Capable of Oral Delivery.** Some drugs, including certain proteins (complex organic compounds of high molecular weight containing numerous amino acids) and peptides (low molecular weight compounds consisting of two or more amino acids), because of their large molecular size and susceptibility to degradation in the GI tract, must currently be administered by injection or by continuous infusion, which is typically done in a hospital or other clinical setting. We believe our BCD Systems may permit some of these drugs to be delivered orally and/or transdermally.
- **Proprietary Reformulation of Generic Products.** We believe our BCD Systems offer the potential to produce improved proprietary formulations of off-patent drugs, differentiated from the existing generic products by reduced dosing requirements, improved efficacy, decreased toxicity or additional indications.

## Distribution Methods of the Products and Services

We intend to have the BCD Systems used with as many pharmaceutical products as possible. Our primary strategy is to establish collaborative relationships with pharmaceutical and biotechnology companies to develop improved therapeutic products utilizing our BCD Systems technology. The products will be jointly developed, with the collaborative partner having primary responsibility to clinically test, manufacture, market and sell the product, and we retaining ownership of our technologies. We believe that our partnering strategy will enable it to reduce our cash requirements while developing a larger potential product portfolio. By providing new formulations of existing products using the BCD Systems, we believe it will not only be able to offer our partners improved products but also may provide them with the ability to extend the life of their patents on such products, especially attractive to pharmaceutical companies whose patents on existing products are close to expiration. We hope that collaborations with pharmaceutical and biotechnology companies will provide near-term revenues from sponsored development activities and future revenues from license fees and royalties relating to the sale of products.

We also intend to develop over-the-counter (OTC) and/or off-patent drug products utilizing our BCD Systems, either independently or jointly by entering into collaborative partnerships with pharmaceutical, biotechnology or other healthcare companies. To reduce costs and time-to-market, we intend to select those products that treat indications with clear-cut clinical end-points and that are reformulations of existing compounds already approved by the FDA. We believe that products utilizing the BCD Systems will provide favorable product differentiation in the highly competitive generic and OTC drug product markets at costs below those of other drug delivery systems, thereby enabling us and our collaborative partners to compete more effectively in marketing improved off-patent and OTC drug products. We are also seeking to establish alliances with overseas sales and marketing partners for the initial sale of our future generic products. We believe that due to the more favorable regulatory environments in some foreign countries, it may be able to generate revenues from these markets while awaiting FDA approval in the United States.

## Competition

There are other companies that have oral drug delivery technologies that compete with the BCD Systems. The competitors have oral tablet products designed to release the incorporated drugs over time. To our knowledge, each of these companies has a patented technology with attributes different from those of ours, and in some cases with different sites of delivery to the GI tract. We believe that we are the only drug delivery company that is currently using polymeric based colloidal dispersion controlled release technologies to develop products for oral and transdermal drug delivery systems for enhanced solubility and bioavailability of poorly water soluble drugs. We believe that this combination of oral and transdermal drug delivery technologies differentiates us from other oral drug delivery companies and will enable us to attract pharmaceutical companies to incorporate their proprietary drugs into the BCD Systems and also to differentiate any OTC and/or off-patent drugs that utilize the BCD Systems from those of other drug delivery companies.

Competition in the areas of pharmaceutical products and drug delivery systems is intense and is expected to become more intense in the future. Competing technologies may prove superior, either generally or in particular market segments, in terms of factors such as cost, consumer satisfaction or drug delivery profile. Our principal competitors in the business of developing and applying drug delivery systems all have substantially greater financial, technological, marketing, personnel and research and development resources than us. In addition, we may face competition from pharmaceutical and biotechnology companies that may develop or acquire drug delivery technologies. Many of our potential collaborative partners have devoted and are continuing to devote significant resources in the development of their own drug delivery systems and technologies. Products incorporating our technologies will compete both with products employing advanced drug delivery systems and with products in conventional dosage forms. New drugs or future developments in alternate drug delivery technologies may provide therapeutic or cost advantages over any potential products which utilize the BCD Systems. There can be no assurance that developments by others will not render any potential products utilizing the BCD Systems noncompetitive or obsolete. In addition, our competitive success will depend heavily on entering into collaborative relationships on reasonable commercial terms, commercial development of products incorporating the BCD Systems, regulatory approvals, protection of intellectual property and market acceptance of such products.

#### Patents, Trademarks and Proprietary Rights

It is our policy to file patent applications in the United States and foreign jurisdictions for our intellectual property related to our BCD Drug Delivery System. We currently have one issued United States patent and three United States patent pending applications and have applied for patents in two foreign countries which are still pending. No assurance can be given that our patent applications will be approved or that any issued patents will provide competitive advantages for the BCD Drug Delivery Systems or our technologies or will not be challenged or circumvented by competitors. With respect to any patents which may issue from our applications or which may be issued to us or that we may not otherwise acquire, there can be no assurance that claims allowed will be sufficient to protect the drug delivery technologies associated with such patents. Patent applications in the United States are maintained in secrecy until a patent issues, and we cannot be certain that others have not filed patent applications for technology covered by our pending applications or that we were the first to file patent applications for such technology. Competitors may have filed applications for, or may have received patents and may obtain additional patents and proprietary rights relating to, compounds or processes that may block our patent rights or compete without infringing our patent rights. In addition, there can be no assurance that any patents issued to us will not be challenged, invalidated or circumvented, or that the rights granted under them will provide proprietary protection or commercial advantage to us.

We also rely on trade secrets and proprietary know-how which it seeks to protect, in part, through confidentiality agreements with employees, consultants, collaborative partners and others. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any such breach or that our trade secrets will not otherwise become known or be independently developed by competitors. Although

potential collaborative partners, research partners and consultants are not given access to our proprietary trade secrets and know-how until they have executed confidentiality agreements, these agreements may be breached by the other party thereto or may otherwise be of limited effectiveness or enforceability.

## Trademarks

We have registered the following trademarks in Canada: "BCD", "Flexogan", "Indaflex", "AlphaRx", "PhytoScience", "NuProm", and "LipoLette". We have registered the following trademarks in the United States: "Flexogan", "Indaflex", "LipoBloc", "NuProm", "Oralife". We have also registered "Flexogan" in the Peoples Republic of China. In connection with our Internet web site, we have registered with Network Solutions, Inc., the internet domain name "AlphaRx.com" for our corporate website.

## Proprietary Information

Much of our technology is dependent upon the knowledge, experience and skills of key scientific and technical personnel. To protect the rights to our proprietary technology, our policy requires all employees and consultants to execute confidentiality agreements that prohibit the disclosure of confidential information to anyone outside AlphaRx. These agreements also require disclosure and assignment to AlphaRx of discoveries and inventions made by such persons while devoted to Company activities.

## Manufacturing, Marketing and Sales

We do not have and do not intend to establish in the foreseeable future internal manufacturing capabilities. Rather, we intend to use the facilities of our collaborative partners or those of contract manufacturers to manufacture products using the BCD Systems. Our dependence on third parties for the manufacture of products using the BCD Systems may adversely affect our ability to develop and deliver such products on a timely and competitive basis. There may not be sufficient manufacturing capacity available to us when, if ever, it is ready to seek commercial sales of products using the BCD Systems. In addition, we expect to rely on our collaborative partners or to develop distributor arrangements to market and sell products using the BCD Systems. We may not be able to enter into manufacturing, marketing or sales agreements on reasonable commercial terms, or at all, with third parties. Failure to do so would have a material adverse effect on us.

Applicable Good Manufacturing Practice requirements and other rules and regulations prescribed by foreign regulatory authorities will apply to the manufacture of products using the BCD Systems. We will depend on the manufacturers of products using the BCD Systems to comply with current Good Manufacturing Practices and applicable foreign standards. Any failure by a manufacturer of products using the BCD Systems to maintain current Good Manufacturing Practices or comply with applicable foreign standards could delay or prevent their commercial sale. This could have a material adverse effect on us.

## Government Regulation

We are subject to regulation under various federal laws regarding pharmaceutical products and also various federal and provincial laws regarding, among other things, occupational safety, environmental protection, hazardous substance control and product advertising and promotion. In connection with our research and development activities, AlphaRx is subject to federal, provincial and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials and wastes. We believe that we have complied with these laws and regulations in all material respects and we have not been required to take any action to correct any material noncompliance.

In the United States, pharmaceutical products, including any drugs utilizing the BCD Drug Delivery Systems, are subject to rigorous regulation by the United States Food and Drug Administration (“FDA”). If we fail to comply with applicable requirements, we or our officers or employees may be subject to administrative or judicially imposed sanctions such as civil penalties, criminal prosecution, injunctions, product seizure or detention, product recalls, total or partial suspension of production, FDA withdrawal of approved applications or FDA refusal to approve pending new drug applications, pre-market approval applications, or supplements to approved applications.

Prior to commencement of clinical studies involving human beings, preclinical testing of new pharmaceutical products is generally conducted on animals in the laboratory to evaluate the potential efficacy and the safety of the product. The results of these studies are submitted to the FDA as a part of an IND application, which must become effective before clinical testing in humans can begin. Typically, clinical evaluation involves a time consuming and costly three-phase process. In Phase I, clinical trials are conducted with a small number of subjects to determine the early safety profile and the pharmacokinetic pattern of a drug. In Phase II, clinical trials are conducted with groups of patients afflicted with a specific disease in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In Phase III, large-scale, multi-center, comparative trials are conducted with patients afflicted with a target disease in order to provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data which have been accumulated to that point and our assessment of the risk/benefit ratio to the patient.

The results of the preclinical and clinical testing on drugs are submitted to the FDA in the form of an NDA for approval prior to commencement of commercial sales. In responding to an NDA, the FDA may grant marketing approval, request additional information or deny the application if the FDA determines that the application does not satisfy its regulatory approval criteria. There can be no assurance that approvals will be granted on a timely basis, if at all. This process of developing a drug candidate and conducting all the required tests, then filing an NDA and finally obtaining FDA approval often takes multiple years, even when the tests are completed on a timely basis and the FDA grants approval to an NDA. Failure to receive approval for any products utilizing the BCD Drug Delivery Systems could have a material adverse effect on us.

OTC products that comply with monographs issued by the FDA are subject to various FDA regulations such as current Good Manufacturing Practices requirements, general and specific OTC labeling requirements (including warning statements), the restriction against advertising for conditions other than those stated in product labeling, and the requirement that in addition to approved active ingredients OTC drugs contain only safe and suitable inactive ingredients. OTC products and manufacturing facilities are subject to FDA inspection, and failure to comply with applicable regulatory requirements may lead to administrative or judicially imposed penalties. If an OTC product differs from the terms of a monograph, it will, in most cases, require FDA approval of an NDA for the product to be marketed.

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 certain of our products outside of the U.S. before submitting an application for U.S. approval to the FDA. The regulatory procedures for approval of new pharmaceutical products vary significantly among foreign countries. 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 EU approval mechanism in place, each EU country may nonetheless impose our own procedures and requirements, many of which are time consuming and expensive, and some EU 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, and approval in any single country may not be a meaningful indication that the product will thereafter be approved in another country.

### Research and Development

We conduct our research and development activities through collaborative arrangements with universities, contract research organizations and independent consultants. We are also dependent upon third parties to conduct clinical studies, obtain FDA and other regulatory approvals and manufacture and market a finished product.

We anticipate incurring significant development expenditures in the future as we continue our efforts to develop our present technologies and new formulations, and as we begin to research other technologies and to expand clinical studies of certain products. While we do not plan to establish any sizable laboratories of our own, we plan to establish laboratory facilities to conduct research and development and manufacture of batch forms, or small amounts used for clinical evaluations.

### Product Liability

Our business involves exposure to potential product liability risks that are inherent in the production and manufacture of pharmaceutical products. Any such claims could have a

material adverse effect on us. We currently maintain \$5,000,000 in product liability insurance and plan to increase this coverage as our products advance. There can be no assurance that:

- we will be able to maintain product liability insurance on acceptable terms;
- we will be able to secure increased coverage as the commercialization of the BCD Systems proceeds; or
- any insurance will provide adequate protection against potential liabilities.

### **PLAN OF DISTRIBUTION**

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

The selling stockholders may also engage in short sales against the box, puts and calls and other transactions in our securities or derivatives of our securities and may sell or deliver shares in connection with these trades.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. Enable Growth LLC and Legend Merchant Group, Inc. are underwriters for the purpose of this offering. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if



required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

## **LEGAL PROCEEDINGS**

Farhad Walji vs. AlphaRx, Inc. and AlphaRx Canada Limited was filed in the Supreme Court of British Columbia on August 23, 2002. Farhad Walji has filed a claim asking for \$25,000 plus interest for allegedly providing \$20,000 pursuant to a subscription agreement to purchase common shares of AlphaRx's stock and damages resulting from lost opportunity. The Company has denied any liability in this case and is currently defending this action vigorously. Nonetheless, the value of the entire claim has been accrued in our financial statements as a contingent liability.

## **MANAGEMENT**

The following table sets forth, as of December 9, 2004, the name, age, and position of each of our executive officers and directors:

<u>Name</u>	<u>Age</u>	<u>Position</u>	<u>Term</u>
Michael M. Lee	41	Chairman of the Board of Directors	
		Chief Executive Officer	Since 8/8/1997
Marcel Urbanc, C.A.	48	Chief Financial Officer	
Joseph Schwarz, Ph.D	50	Chief Scientist	
Michael Weisspapir,			
MD, Ph.D	48	Chief Medical Officer	
Sandro Persia	34	Secretary/Treasurer	
Dr. David Milory	53	Director	Since 4/15/2003
Dr. Ford Moore	53	Director	Since 4/15/2003

Michael M. Lee: Mr. Lee is a founder of the Company. Mr. Lee has over 15 years of business experience in the areas of high tech development, marketing and corporate finance. Mr. Lee holds a B.Sc. in Applied Mathematics from the University of Western Ontario. Mr Lee founded the company in August 1997.

Marcel Urbanc, C.A: Mr. Urbanc obtained his Chartered Accountant designation in 1985 after articling with Arthur Andersen & Co. for 3 years. Prior to joining the Company, Mr. Urbanc served as Controller and then VP Finance & CFO of Oasis Technology Ltd., a software company involved in transaction processing from 1994 to 2002. During his tenure at Oasis private equity funding of approximately \$45,000,000 was raised. Mr Urbanc has been with the company since March, 2003.

Joseph Schwarz, Ph.D.: Dr. Schwarz is the chief scientist of the Company. Dr. Schwarz has extensive experience in the research and development of controlled release drug delivery systems, his areas of expertise cover controlled delivery of drugs, colloidal and microcorpusculate drug delivery systems, submicron emulsions (SME), transdermal delivery (topical and systemic). Dr. Schwarz has published more than 40 articles in various scientific journals and has written over 20 patents and patent applications. Dr. Schwarz was the senior scientist at Pharmos Ltd., a publicly traded U.S. pharmaceuticals company from 1991 to 1995. From 1995 to 1997 he was the senior scientist in the research and development department of TEVA Pharmaceuticals Ltd. From 1997 to 1998, Dr. Schwarz was the senior scientist of D-PHARM, a pharmaceuticals concern located in Israel. From 1998 to 1999 Dr. Schwarz served as a part time consultant to the Company and has been with the company since that time.

Michael Weisspapir, M.D.: Ph.D. Dr. Weisspapir has 19 years of successful experience in experimental medicine and extensive experience in interdisciplinary research and development in experimental pharmacology, immunopharmacology, toxicology and neuroscience. Prior to joining the Company, Dr. Weisspapir held a variety of research positions at the University of Tel Aviv and Rabin Medical Center, Israel and the University Health Network, University of Toronto, Canada.

Sandro Persia: Mr. Persia joined Logic Tech Corp. in 1989 as Marketing Manager and promoted to Vice President in 1996. Mr. Persia has extensive business experience in high tech marketing and sales. Mr. Persia holds a diploma in business administration from the Seneca College.

David Milroy, D.D.S. M.R.C.D. (C): Dr. Milroy is a Certified Oral & Maxillofacial Surgeon and has been in private practice in Richmond Hill, Woodbridge, and Port Hope, Ontario for the past twenty years. He graduated from the University of Toronto, Faculty of Dentistry with a Doctor of Dental Surgery degree in 1976 and a Residency in Oral & Maxillofacial Surgery at the University of Toronto, Toronto General and Toronto Doctor's Hospitals in 1982.

Ford Moore, D.D.S. F.R.C.D. (C): Dr. Moore is a a certified Oral & Maxillofacial Surgeon, is engaged in a full-time private practice in Newmarket, Ontario which he established in 1981. Dr. Moore graduated from the University of Toronto with a Doctor of Dental Surgery degree in 1976, and completed a hospital Residency in Oral Surgery and Anesthesia at Toronto General Hospital, Toronto Doctor's Hospital and the University of Toronto in 1980.

All directors will hold office until the next annual stockholders meeting and until their successors have been elected or qualified or until their death, resignation, retirement,

removal, or disqualification. Vacancies on the board will be filled by a majority vote of the remaining directors. Officers of the Company serve at the discretion of the Board of Directors. No director, officer, significant employee or consultant has been convicted in a criminal proceeding.

No director, officer, significant employee or consultant has been permanently or temporarily enjoined, barred, suspended or otherwise limited from involvement in any type of business, securities or banking activities. No director, officer, significant employee or consultant has been convicted of violating a federal or state securities or commodities law.

None of the Directors receive a fee for serving as Directors of the Company. Directors are reimbursed for direct out-of-pocket expenses for attendance at meetings of the Board of Directors and for expenses incurred for and on behalf of the Company.

#### **SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

<u>Title of Class</u>	<u>Name and Address of Beneficial Owner</u>	<u>Amount and Nature of Beneficial Ownership</u>	<u>Percent of Class</u>
Common Stock	Michael Lee, Chief Executive Officer/ Chairman of the Board of Directors 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9	7,580,726	13.18%
Common Stock	Dr. Ford Moore, Director 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9	492,579	0.86%
Common Stock	Dr. David Milroy, Director 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9	300,000	0.52%
Common Stock	Joseph Schwarz, Chief Scientist 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9	602,500	1.05%
Common Stock	Michael Weisspapir, Chief Medical Officer 200-168 Konrad Crescent,	457,500	0.80%

	Markham, Ontario, Canada, L3R 9T9		
Common Stock	Marcel Urbanc, Chief Financial Officer 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9	20,000	0.03%
Common Stock	Sandro Persia, Secretary 200-168 Konrad Crescent, Markham, Ontario, Canada, L3R 9T9	16,000	0.03%
Common Stock	Directors and Executive Officers as a Group (7 persons)	9,469,305	16.47%

## **DESCRIPTION OF SECURITIES**

We are registering shares of our \$0.0001 par value common stock. The following description of our common stock is only a summary. For a complete description of our common stock, you should refer to our Certificate of Incorporation and Bylaws as in effect upon the effective date of this prospectus, which are included as exhibits to the registration statement of which this prospectus is a part and the provisions of applicable Delaware law.

The holders of our common stock are entitled to one vote per share held of record on all matters submitted to a vote of our stockholders. Our Certificate of Incorporation does not provide for cumulative voting. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our Board of Directors out of funds legally available for that purpose. In the event of our liquidation, dissolution, or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities. Holders of our common stock have no preemptive or other subscription or conversion rights. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of our common stock are fully paid and non-assessable. As of December 9, 2004, there were 137,641,875 shares of our common stock on a fully diluted basis.

## **MANAGEMENT'S DISCUSSION AND ANALYSIS**

### **RESULTS OF OPERATIONS**

## **YEAR ENDED SEPTEMBER 30, 2004 AS COMPARED TO YEAR ENDED SEPTEMBER 30, 2003**

### **Gross Revenue and Gross Margin**

Gross revenue for the year ended September 30, 2004 increased to \$383,824 from \$52,925 for the year ended September 30, 2003, an increase of 625%. The increase is attributable to our first full year of commercial sales of Flexogan products in Canada coupled with marketing programs which started to increase consumer awareness and acceptance of Flexogan. .

The gross margins on sales of Flexogan products was \$ 230,501 or 60% of gross sales for the year ended September 30, 2004 as compared to \$ 33,415 or 63% of gross sales for the year ended September 30, 2003. Gross margins as a percentage of sales have decreased due to increased competition in the pain relief segment. The increased competition placed pricing pressure on our products which, in turn, required price reductions to remain competitive. We anticipate further competitive pressures to continue.

### **Net Losses**

Net losses for the year ended September 30, 2004 increased to \$1,772,840 from \$1,414,597 for the comparable period ended September 30, 2003, an increase of \$358,243 or 25%. This increase in net losses is principally attributed to an increase in Flexogan marketing activities when compared to prior year.

### **Selling and Administrative Expenses**

Selling and administrative expenses consist primarily of sales and marketing expenditures, personnel costs related to management functions, finance, office overheads, insurance, and professional fees related to legal, and audit, and tax matters. Selling and administrative expenses for the year ended September 30, 2004 increased to \$1,383,557 from \$ 1,225,140 for the year ended September 30, 2003, an increase of \$158,417 or approximately 13%. The increase is primarily due to the increase in sales and marketing expenses, related to the Canadian roll-out of Flexogan.

For the year ended September 30, 2004 we incurred approximately \$786,243 in sales and marketing expenditures as compared to \$322,603 incurred for the same period a year ago, an increase of \$463,640 or 144%. The increase is primarily due to a full year of marketing Flexogan in Canada as compared to less than six months of marketing initiatives during the same period a year ago. We also commenced marketing research activities in the U.S., and sales activities in Asia with no comparable activities in the prior year.

Administration expenses totalled \$597,314 for the year ended September 30, 2004 as compared to \$902,537 incurred in the same period a year ago, a decrease of approximately \$305,223 or 34%. We did not incur any expenses related to stock option

granting during the year ended September 30, 2004 as compared to \$280,594 incurred in stock option expenses for the year ended September 30, 2003.

### **Research and Development Expenses**

Research and development expenses include costs for scientific personnel, supplies, equipment, outsourced clinical and other research activities, consultants, patent filings, depreciation of research and development equipment, and office overheads directly related to research and development.

Research and development expenses for the year ended September 30, 2004 totaled \$360,467 as compared to \$186,241 incurred for the same period a year ago, an increase of \$174,226 or approximately 94%. In preparation for clinical trials of our topical cream – Indaflex, we incurred approximately \$192,000 for the year ended September 30, 2004. Research and development for our other topical creams continued during fiscal 2004 at a pace similar to 2003.

### **Depreciation Expense**

We incurred \$36,447 in depreciation expense for the year ended September 30, 2004 as compared to \$26,764 for the same period a year ago, an increase of \$9,683 or approximately 36%. We purchased approximately \$139,000 of research and development machinery and equipment during fiscal 2004 as well as about \$12,500 in other capital assets for a total capital asset purchase of \$151,445 as compared to \$36,197 in capital asset purchases for the same period a year ago. This, in turn, generated substantially all of the incremental depreciation expense.

### **Other Income and Expenses**

Other income and expenses totaled \$222,870 net expense for the year ended September 30, 2004 as compared to \$9,867 net expense for the same period a year ago, an increase of \$213,003. During fiscal 2004 we wrote off previously acquired VT-1 commercialization rights in the amount of \$229,999. Commercialization of VT-1 was prohibitive from a cost perspective, and attempts to resell these rights have not been successful.

### **Net Loss**

The above mentioned income and expenses resulted in a net loss of \$1,772,840 for the year ended September 30, 2004 as compared to a net loss of \$1,414,597 incurred in the same period a year ago.

## **YEAR ENDED SEPTEMBER 30, 2003 AS COMPARED TO YEAR ENDED SEPTEMBER 30, 2002**

### **Sales**

Sales for the year ended September 30, 2003 increased to \$52,925 from \$282 for the comparable period ended September 30, 2002, an increase of 18,667%. The significant increase is attributable to our first commercial sale of the Flexogan products. The gross margin on the sale of our Flexogan products was \$33,415 for the year ended September 30, 2003 as compared to \$223 for the comparable period ended September 30, 2002.

### **Net Losses**

Net losses for the year ended September 30, 2003 increased to \$1,414,597 from \$1,019,290 for the comparable period ended September 30, 2002, an increase of 39%. This increase in net losses is principally attributed to stock option expenses.

### **Expenses**

General and administrative expenses for the year ended September 30, 2003 increased to \$1,225,140 from \$532,551 for the year ended September 30, 2002, an increase of 130%. The increase in general and administrative expenses during 2003 was due in part to a non-reoccurring expense of \$280,594 related to the grant of stock options.

Research and development expenses include costs for scientific personnel, supplies, equipment, outsourced clinical and other research activities, consultants, patent filings, depreciation, utilities, administrative expenses and an allocation of corporate costs.

Research and development expenses for the year ended September 30, 2003 decreased to \$186,241 from \$445,637 for the year ended September 20, 2002, a decrease of 58%. The decrease in research and development expenses was primarily due to a voluntary consulting fee reduction accepted by all of our scientific officers.

Included in our general and administrative expenses were costs associated with marketing and inventory logistics. Marketing and inventory logistics expenses for the year ended September 30, 2003 increased to \$322,603 from \$0 for the year ended September 20, 2002.

### **Liquidity and Capital Resources**

Since inception, we have financed operations primarily from the issuance of common stock and promissory notes and expect to continue this practice to fund our ongoing activities.

We currently do not have sufficient resources to complete the commercialization of all of our proposed products or to carry out our business strategy. Therefore, we will likely need to raise substantial additional capital to fund our operations sometime in the future. We cannot be certain that any financing will be available when needed. Any additional equity financings may be dilutive to our existing shareholders, and debt financing, if available, may involve restrictive covenants on our business.

We expect to continue to spend capital on:

- research and development programs;
- preclinical studies and clinical trials;
- regulatory processes; and
- third party manufacturers and marketing partners to manufacture and market our products for us.

The amount of capital we may need will depend on many factors, including:

- the progress, timing and scope of our research and development programs;
- the progress, timing and scope of our preclinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals;
- the time and cost necessary to establish our own sales and marketing capabilities or to seek marketing partners to market our products for us;
- the time and cost necessary to respond to technological and market developments; and
- new collaborative, licensing and other commercial relationships that we may establish.

Our inability to raise capital would have a material adverse effect on our operations.

## **DESCRIPTION OF PROPERTY**

We lease approximately 2,930 square feet in Markham, Ontario, under a lease which expires on November 30, 2008 for approximately \$2,600 a month. We believe that our existing properties are sufficient for our administrative, research and development needs for the foreseeable future.

## **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Except as otherwise disclosed in this prospectus, during the past two years, there have been no material transactions, series of similar transactions or currently proposed transactions, to which the Company was or is to be a party, in which the amount involved exceeds \$60,000 and in which any director or executive officer, or any security holder who is known to the Company to own of record or beneficially more than five percent of the Company's common stock, or any member of the immediate family of any of the foregoing persons, had a material interest.

## **MARKET FOR COMMON EQUITY**

Our common stock is traded over-the-counter and its quotations are carried in the Electronic Bulletin Board of the National Association of Securities Dealers, Inc. The following table sets forth the range of high and low bid quotations for our common stock for the periods indicated from sources we deem reliable.

<b>Fiscal Quarter</b>	<b>Three Month Period Ended</b>	<b>High</b>	<b>Low</b>
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Fiscal 2003 Q1	December 31, 2002	\$0.56	\$0.51
Fiscal 2003 Q2	March 31, 2003	\$0.41	\$0.36
Fiscal 2003 Q3	June 30, 2003	\$0.48	\$0.30
Fiscal 2003 Q4	September 30, 2003	\$0.35	\$0.30
Fiscal 2004 Q1	December 31, 2003	\$0.45	\$0.14
Fiscal 2004 Q2	March 31, 2004	\$0.50	\$0.14
Fiscal 2004 Q3	June 30, 2004	\$0.53	\$0.37
Fiscal 2004 Q4	September 30, 2004	\$0.47	\$0.28

These quotations are over-the-counter market quotations that reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

As of December 5, 2004, there are approximately 104 holders of record of our common stock. This total does not include an indeterminate number of shareholders who may hold their shares in “street form”. We have never declared a dividend for our common stock and do not anticipate doing so in the foreseeable future.

#### Equity Compensation Plan Information\*

	Number of Securities to be issued upon exercise of outstanding options, warrants, and rights	Weighted- Average Exercise Price of outstanding options, warrants, and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first two columns
Equity Compensation Plans Approved by Security Holders	14,940,000	\$0.174	10,780,000
Equity Compensation Plans Not Approved by Security Holders	None	None	None
Total	14,940,000	\$0.174	10,780,000

\*Under the new 2004 Stock Option Plan recently approved by our stockholders and explained above, approximately 24,000,000 million shares of common stock are available as management options. On November 15, 2004 we granted 13,220,000 options to management and consultants, leaving 10,780,000 options available for future allocations.

## EXECUTIVE COMPENSATION

The table below summarizes the compensation received by our chief executive officer for the fiscal years ended September 30, 2004, 2003 and 2002 and each other of our current executive officers who received compensation in excess of \$60,000 for services rendered during any of those years (“named executive officers”). None of our other executive officers received compensation in excess of \$60,000 during such years.

### SUMMARY COMPENSATION TABLE

<u>Form of Compensation</u>	<u>Name and Principal Position</u>			
	<u>Michael Lee, Chief Executive Officer</u>	<u>Joseph Schwarz, Chief Scientist</u>	<u>Michael Weisspapir, Chief Medical Officer</u>	<u>Marcel Urbanc, Chief Financial Officer</u>
Salary and Year	2004 - \$29,531	2004 - \$22,731	2004 - \$59,100	2004 - \$36,218
	2003-\$83,652	2003-\$56,992	2003-\$46,992	2003-\$13,000
	2002-\$230,000	2002-\$150,000	2002-\$114,000	2002-\$0
Annual Bonus	\$0 for each year	\$0 for each year	\$0 for each year	\$0 for each year
Other Annual Compensation	\$0 for each year	\$0 for each year	\$0 for each year	\$0 for each year
Restricted Stock Awards and Year	2004 -\$ 0	2004 -\$ 0	2004 -\$ 0	\$0 for each year
	2003-\$172,500*	2003-\$122,500**	2003-\$97,500***	
	2002-\$360,000*	2002-\$240,000**	2002-\$180,000***	

Securities Underlying SARs	2004 – 0	2004 – 0	2004 - 0	2004 - 0
	2003-150,000*	2003-80,000**	2003-80,000***	2003-80,000****
	2002-0	2002-0	2002-0	2002-0
LTIP Payouts	\$0 for each year	\$0 for each year	\$0 for each year	\$0 for each year
All Other Compensation	\$0 for each year	\$0 for each year	\$0 for each year	\$0 for each year

\* Michael Lee was granted during the fiscal year ended September 30, 2003 a five year option to purchase 150,000 shares of restricted stock with an exercise price of \$0.69 per share. Further, Mr. Lee accepted 172,500 shares of restricted common stock in lieu of salary for the for the first two fiscal quarters of 2003, 360,000 shares of restricted common stock in lieu of salary for the first three fiscal quarters of 2002 and 260,000 shares of restricted common stock in lieu of salary for the fiscal year ended 2000 and for the first fiscal quarter of 2001.

\*\* Dr. Joseph Schwarz was granted during the fiscal year ended September 30, 2003 a five year option to purchase 80,000 shares of restricted stock with an exercise price of \$0.63 per share. Further, Dr. Schwartz accepted 122,500 shares of restricted common stock in lieu of salary for first two fiscal quarters of 2003, accepted 240,000 shares of restricted common stock in lieu of salary for the first three fiscal quarters of 2002 and 240,000 shares of restricted common stock in lieu of salary for the fiscal year ended 2000 and for the first fiscal quarter of 2001.

\*\*\* Dr. Michael Weisspapir was granted during the fiscal year ended September 30, 2003 a five year option to purchase 80,000 shares of restricted stock with an exercise price of \$0.63 per share. Further, Dr. Weisspapir accepted 97,500 shares of restricted common stock in lieu of salary for first two fiscal quarters of 2003, accepted 180,000 shares of restricted common stock in lieu of salary for the first three fiscal quarters of 2002 and 180,000 shares of restricted common stock in lieu of salary for the fiscal year ended 2000 and for the first fiscal quarter of 2001.

\*\*\*\* Marcel Urbanc was granted during the fiscal year ended September 30, 2003 a five year option to purchase 80,000 shares of restricted stock with an exercise price of \$0.63 per share.

#### Option Grants in Last Fiscal Year and subsequent to Fiscal Year End

We did not grant any options to any of our executive officers, employees or consultants during the fiscal year ended September 30, 2004. On November 15, 2004 we granted 12,720,000 options on the following terms to the following individuals: Michael Lee, CEO- 6,000,000; J. Schwarz, Chief Scientist- 3,000,000; M. Weisspapir, Chief Medical

Officer – 3,000,000; S. Persia, Secretary – 20,000; M. Urbanc, CFO – 20,000; Dr. D.Milroy, Director – 380,000; Dr. F. Moore, Director – 300,000. All of the aforementioned options are exercisable at \$0.15, vest 100% on November 15, 2005 and expire on November 15, 2014. In addition we granted 500,000 options to our consultants, all of which vest immediately, and all of which expire on November 15, 2014 as follows: 250,000 exercisable at \$0.40; 20,000 exercisable at \$0.45; 20,000 exercisable at \$0.45; 50,000 exercisable at \$0.45; 20,000 at \$0.45; 100,000 exercisable at \$0.50; and 40,000 exercisable at \$0.50.

### **CHANGES IN ACCOUNTANTS**

On December 29, 2003, we dismissed Philip K. Yeung, (“Yeung”) the principal accountant previously engaged to audit AlphaRx’s financial statements and on December 31, 2003 retained Schwartz Levitsky Feldman LLP (“Schwartz”) as the principal accountants to replace Yeung. The Company’s board of directors approved the change of accountants from Yeung to Schwartz.

The audit reports of Yeung on AlphaRx’s financial statements for the fiscal years ending September 30, 2002 and September 30, 2001 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles, except such reports were modified to include an explanatory paragraph for a going concern uncertainty.

In connection with the audits of the fiscal years ending September 30, 2002 and September 30, 2001 including the subsequent interim periods since engagement through December 29, 2003, the date of dismissal, the Company had no disagreements with Yeung with respect to accounting or auditing issues of the type discussed in Item 304(a)(iv) of Regulation S-B. Had there been any disagreements that were not resolved to their satisfaction, such disagreements would have caused Yueng to make reference in connection with their opinion to the subject matter of the disagreement. In addition, during that time there were no reportable events (as defined in Item 304(a)(1)(iv) of Regulation S-B).

During the fiscal years ending September 30, 2002 and September 30, 2001 including the subsequent interim periods since engagement through December 29, 2003, the date of Yeung’s dismissal, and prior to the appointment of Schwartz, AlphaRx (or anyone on its behalf) did not consult with Schwartz regarding any of the accounting or auditing concerns stated in Item 304(a)(2) of Regulation S-B. Since there were no disagreements or reportable events (as defined in Item 304(a)(2) of Regulation S-B), we did not consult Schwartz in respect to these matters during the time periods detailed herein.

### **INDEMNIFICATION OF OFFICERS AND DIRECTORS AND DISCLOSURE OF THE SECURITIES AND EXCHANGE COMMISSION POSITION**

Subsection (a) of Section 145 of the Delaware General Corporation Law empowers a corporation to indemnify any person who was or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation)

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

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

Section 145 further provides that to the extent a director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of Section 145, or in defense of any claim, issue or matter therein, he or she shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him or her in connection therewith; that the indemnification provided by Section 145 shall not be deemed exclusive of any other rights to which the indemnified party may be entitled; and that the scope of indemnification extends to directors, officers, employees or agents of a constituent corporation absorbed in a consolidation or merger and persons serving in that capacity at the request of the constituent corporation for another. Section 145 also empowers the corporation to purchase and maintain insurance on behalf of a director or officer of the corporation against any liability asserted against him or her or incurred by him or her in any such capacity or arising out of his or her status as such whether or not the corporation would have the power to indemnify him or her against such liabilities under Section 145.

Our Bylaws specify that we shall indemnify our directors, officers, employees and agents because he or she was or is a director, officer, employee or agent was or is serving at our request as a director, officer, employee or agent of another entity to the full extent that such right of indemnity is permitted by the laws of the State of Delaware. This provision

of the Bylaws is deemed to be a contract between us and each director and officer who serves in such capacity at any time while such provision and the relevant provisions of the Delaware General Corporation Law are in effect, and any repeal or modification thereof shall not offset any action, suit or proceeding theretofore or thereafter brought or threatened based in whole or in part upon any such state of facts.

Section 102(b)(7) of the Delaware General Corporation Law enables a corporation in its certificate of incorporation to limit the personal liability of members of its board of directors for violation of a director's fiduciary duty of care. This Section does not, however, limit the liability of a director for breaching his or her duty of loyalty, failing to act in good faith, engaging in intentional misconduct or knowingly violating a law, or from any transaction in which the director derived an improper personal benefit. This Section also will have no effect on claims arising under the federal securities laws. Our Certificate of Incorporation limits the liability of our directors as authorized by Section 102(b)(7).

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of us pursuant to the foregoing provisions, or otherwise, we have been advised that it is the opinion of the Securities and Exchange Commission that such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### **EXPENSES OF ISSUANCE AND DISTRIBUTION**

Pursuant to the terms of our recent round of financing through a private placement transaction, we will pay all expenses associated with this registration on behalf of the selling security holders.

We have currently incurred a commission to Sunrise Securities Corp. for services in connection with the private placement equal to 10% of the gross proceeds (paid for in the form of common stock) together with warrants exercisable at \$.30 per share for common stock equal to 10% of the shares of common stock sold in the private placement).

We have incurred legal fees of approximately \$83,000 and escrow agent fees of approximately \$5,000. We have also incurred accountant fees of approximately \$2,000.

#### **RECENT SALES OF UNREGISTERED SECURITIES**

In the past three years, we have made the following sales of unregistered securities:

- On December 3, 2001, we sold 538,000 shares of our common stock to four individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S as promulgated by the Securities and Exchange Commission. The consideration for these shares consisted of \$0.50 per share. There were no commissions associated with this sale.
- On December 14, 2001, we sold 17,500 shares of our common stock to one individual outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares

- consisted of \$0.45 per share. There were no commissions associated with this sale.
- On December 19, 2001, we sold 84,779 shares of our common stock to three individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.45 per share. There were no commissions associated with this sale.
  - On December 31, 2001, we issued 124,000 shares of our common stock to three individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S in lieu of salary. The deemed value of this salary was \$0.50 per share. There were no commissions associated with this sale.
  - On January 2, 2002, we issued 101,520 shares of our common stock to an individual outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.25 per share. There were no commissions associated with this sale.
  - On January 11, 2002, we issued 100,000 shares of our common stock to two individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.15 per share. There were no commissions associated with this sale.
  - On March 11, 2002, we issued 254,000 shares of our common stock to four individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S in lieu of salary. The deemed value of this salary was \$0.50 per share. There were no commissions associated with this sale.

On March 19, 2002, we effectuated a 5 to 1 reverse stock split.

- On September 30, 2002, we issued 1,257,278 shares of our common stock to four individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.40 per share. There were no commissions associated with this sale.
- On December 19, 2002, we issued 1,321,185 shares of our common stock to eighteen individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of an average price \$0.52 per share. There were no commissions associated with this sale.
- On January 10, 2003, we issued 596,263 shares of our common stock to six individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.55 per share. There were no commissions associated with this sale.
- On March 17, 2003, we issued 20,000 shares of our common stock to an individual outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.55 per share. There were no commissions associated with this sale.

- On March 31, 2003, we issued 452,500 shares of our common stock to four individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S in lieu of salary. The deemed value of this salary was \$0.40 per share. There were no commissions associated with this sale.
- On June 26, 2003, we issued 75,524 shares of our common stock to three individuals outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of \$0.45 per share. There were no commissions associated with this sale.
- On September 2, 2003, we issued 5,000 shares of our common stock to an individual outside the United States in reliance upon the exemption from registration afforded by Regulation S. The consideration for these shares consisted of services rendered to us. There were no commissions associated with this sale.
- On November 20, 2003, we issued 50,000 shares of our common stock to an individual in reliance upon the exemption from registration afforded by Rule 506 of Regulation D. The consideration for these shares consisted of services rendered to us. The deemed value of these services was equal to \$0.30 per share. There were no commissions associated with this sale.
- On February 28, 2004, we issued promissory notes convertible into our common stock to 10 individuals in reliance upon the exemption from registration afforded by Rule 506 of Regulation D. The consideration for these shares was equal to \$0.10 per share of common stock. We paid commissions in connection with this issuance of 974,126 shares of our common stock and 1,948,252 warrants to purchase common stock to our placement agent.
- On July 21, 2004, and September 2, 2004, we issued 27,224,034 shares of our common stock to 38 individuals in reliance upon the exemption from registration afforded by Rule 506 of Regulation D. The consideration for these shares consisted of \$0.15 per share. We paid commissions in connection with this issuance of 2,994,644 shares of our common stock and 2,994,644 warrants to purchase common stock to our placement agent.

## **EXPERTS**

The validity of the common stock offered hereby will be passed upon for us by Pedley Zielke Gordinier & Pence, PLLC, of Louisville, Kentucky.

## **WHERE TO FIND ADDITIONAL INFORMATION**

We have filed a registration statement on Form SB-2 under the Securities Act of 1933, as amended, with the SEC with respect to the common stock offered pursuant to this prospectus. This prospectus, which forms a part of the registration statement, does not contain all of the information included in the registration statement and amendments thereof and the exhibits thereto, which may be read and copied at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website that contains the registration



statement of which this prospectus is a part. The address of the SEC's website is <http://www.sec.gov>.

We are also subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and therefore file with the SEC annual and quarterly reports, proxy statements, and other information required under the Exchange Act. These filings are also available at the SEC's website referenced above.

## **UNDERTAKINGS**

We will file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933 (the "Act"). We will reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in this registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement. We will include any additional or change material information on the plan of distribution.

We will treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering. Additionally, we will file a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

Insofar as indemnification for liabilities arising under the Act may be permitted to our directors, officers and controlling persons pursuant to any indemnification agreement, insurance or any provision of Delaware corporate law, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

In accordance with the requirements of the Act, the registrant certifies that it has reasonable grounds to believe that it meets all the requirements for filing on Form SB-2 and authorized this registration statement to be signed on its behalf by the undersigned, in the city of Markham, Ontario, Canada, on December 9, 2004.

**ALPHARX, INC.**

By: /s/ Michael Lee

Title: December 9, 2004

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

/s/ Michael Lee

MICHAEL LEE, CEO and Chairman of the Board of Directors

Dated: December 9, 2004

/s/ Marcel Urbanc

MARCEL URBANC, Chief Financial Officer

Dated: December 9, 2004

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DR. FORD MOORE, Director\*

Dated: \_\_\_\_\_

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DR. DAVID MILROY, Director\*

Dated: \_\_\_\_\_

\*Executed under a Power of Attorney previously filed with the Securities and Exchange Commission

**ALPHARx, INC.**

CONSOLIDATED FINANCIAL STATEMENTS AND AUDIT REPORT  
SEPTEMBER 30, 2004 AND SEPTEMBER 30, 2003

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING  
FIRM**

To the Board of Directors and Stockholders of  
AlphaRx, Inc.

We have audited the accompanying consolidated balance sheets of AlphaRx, Inc. (incorporated in the State of Delaware) as at September 30, 2004 and 2003 and the related consolidated statements of operations, cash flows and stockholders' equity for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of AlphaRx, Inc. as at September 30, 2004 and 2003 and the results of its operations and its cash flows for the years then ended in accordance with generally accepted accounting principles in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Should the Company be unable to continue as a going concern, certain assets and liabilities will have to be adjusted to their liquidation values.

Toronto, Ontario, Canada  
November 12, 2004

/s/Schwarz Levitsky Feldman LLP  
Chartered Accountants

**ALPHARx, INC.**

**CONSOLIDATED BALANCE SHEETS**

**AS AT SEPTEMBER 30, 2004 AND 2003**

September 30,	2004	2003
<b>CURRENT ASSETS</b>		
Cash and Cash Equivalents	\$ 2,856,042	\$ 24,520
Accounts Receivable, net (note 3)	49,930	27,662
Prepaid Expenses	67,640	3,690
Inventory (note 4)	<u>180,272</u>	<u>141,905</u>
<b>TOTAL CURRENT ASSETS</b>	3,153,884	197,777
 <b>PROPERTY, PLANT &amp; EQUIPMENT, net (note 5)</b>	 241,533	 126,535
<b>OTHER ASSETS</b>		
Licensing Right (note 6)	<u>1</u>	<u>230,000</u>
<b>TOTAL ASSETS</b>	<u><u>3,395,418</u></u>	<u><u>554,312</u></u>
 <b>CURRENT LIABILITIES</b>		
Accounts Payable and Accrued Liabilities (note 7)	279,071	254,724
Notes Payable (note 8 and 17)	665,900	474,837
Litigation Liabilities (note 9)	<u>25,000</u>	<u>25,000</u>
<b>TOTAL CURRENT LIABILITIES</b>	<u>969,971</u>	<u>754,561</u>
 <b>CONTINGENCIES &amp; COMMITMENTS (note 9 and 10)</b>		
 <b>SHAREHOLDERS' EQUITY (DEFICIENCY)</b>		
Common Stock: \$ 0.0001 par value,		
Authorized 250,000,000 shares; issued and		
outstanding 52,304,642 shares (2003 – 100,000,000	5,232	1,692
authorized; 16,920,082 issued and outstanding) (note 11)		
Additional paid-in capital	8,419,035	4,024,039
Deficit	<u>(5,998,820)</u>	<u>(4,225,980)</u>
<b>TOTAL SHAREHOLDERS' EQUITY (DEFICIENCY)</b>	<u>2,425,447</u>	<u>(200,249)</u>
 <b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)</b>	 <u><u>\$ 3,395,418</u></u>	 <u><u>\$ 554,312</u></u>

**ALPHARx, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**FOR THE YEARS ENDED SEPTEMBER 30, 2004 AND 2003**

Year ended September 30,	2004	2003
SALES	\$ 383,824	\$ 52,925
COST OF SALES	<u>153,323</u>	<u>19,510</u>
GROSS MARGIN	230,501	33,415
SELLING AND ADMINISTRATIVE EXPENSES	1,383,557	1,225,140
RESEARCH AND DEVELOPMENT EXPENSES	360,467	186,241
DEPRECIATION	<u>36,447</u>	<u>26,764</u>
LOSS FROM OPERATIONS	(1,549,970)	(1,404,730)
OTHER INCOME AND EXPENSES		
Other Income	7,129	10,133
Write down of Licensing Rights (note 6)	(229,999)	
Loss on Investment		(20,000)
	<u>(222,870)</u>	<u>(9,867)</u>
LOSS BEFORE INCOME TAXES	(1,772,840)	(1,414,597)
INCOME TAX (note 12)	<u>--</u>	<u>--</u>
NET LOSS	<u>\$ (1,772,840)</u>	<u>\$ (1,414,597)</u>
NET LOSS PER COMMON SHARE, BASIC & DILUTED	<u>(0.08)</u>	<u>(0.09)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	<u>22,741,117</u>	<u>15,858,421</u>

**ALPHARx, INC.**

**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY  
FOR THE YEARS ENDED SEPTEMBER 30, 2004 AND 2003**

	<u>Common Stock</u>		<u>Additional</u>	<u>Retained</u>	<u>Total</u>
	<u>Number of</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Earnings</u>	<u>Shareholders'</u>
	<u>Shares</u>		<u>Capital</u>	<u>(Deficit)</u>	<u>Equity</u>
Balance at September 30, 2002	15,327,341	\$1,533	\$2,897,277	\$(2,811,383)	\$87,427
Issuances of Common Stock	1,592,741	159	846,168		846,327
Issuance of Stock Options for consulting services			280,594		280,594
Net loss for the Year ending September 30, 2003				(1,414,597)	(1,414,597)
Balance at September 30, 2003	16,920,082	1,692	4,024,039	(4,225,980)	(200,249)
Issuances of Common Stock for consulting, legal services	100,000	11	29,990		30,001
Conversion of Promissory Notes	3,752,340	375	374,859		375,234
Commission on Promissory Notes and Common Stock Issued	4,308,186	431	580,120		580,551
Issuances of Common Stock	27,224,034	2,723	3,410,027		3,412,750
Net Loss for the Year ending September 30, 2004				(1,772,840)	(1,772,840)
	<u>52,304,642</u>	<u>\$5,232</u>	<u>\$8,419,035</u>	<u>\$(5,998,820)</u>	<u>\$2,425,447</u>

**ALPHARx, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**FOR THE YEARS ENDED SEPTEMBER 30, 2004 AND 2003**

September 30,	2004	2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (1,772,840)	\$ (1,414,597)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	36,447	26,764
Write down of licensing rights	229,999	
Shares Issued For Services Rendered	610,552	273,436
Options Issued For Services Rendered		280,594
Changes in assets and liabilities:		
Increase in Inventory	(38,367)	(89,764)
Increase in Accounts Receivable	(22,268)	(27,662)
(Increase) Decrease in Prepaid Expenses	(63,950)	25,695
Increase in Accounts Payable and Accrued Liabilities	<u>24,347</u>	<u>230,044</u>
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<u>(996,080)</u>	<u>(695,490)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of Licensing Rights		(230,000)
Purchase of Machinery & Equipment	<u>(151,445)</u>	<u>(36,197)</u>
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<u>(151,445)</u>	<u>(266,197)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Repayment of bank indebtedness		(9,202)
Issuance of Notes Payable, net (note 8 and 17)	191,063	422,518
Proceeds from Issuance of Common Stock (net)	<u>3,787,984</u>	<u>572,891</u>
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<u>3,979,047</u>	<u>986,207</u>
<b>NET INCREASE IN CASH</b>	2,831,522	24,520
<b>CASH, beginning of year</b>	<u>24,520</u>	<u>0</u>
<b>CASH, and Cash Equivalents, end of year</b>	<u><u>\$ 2,856,042</u></u>	<u><u>\$ 24,520</u></u>
<b><i>SUPPLEMENTARY DISCLOSURE:</i></b>		
The statement of cash flows using indirect method as defined under Statement of Financial Accounting Standard of No. 95.		
Income Tax Paid	<u>\$ 0</u>	<u>\$ 0</u>
Interest Paid	<u>\$ 154,674</u>	<u>\$25,186</u>



## **ALPHARX INC.**

### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**SEPTEMBER 30, 2004 AND 2003**

#### **NOTE 1. NATURE OF BUSINESS AND GOING CONCERN**

ALPHARX, INC. (the “Company”) was incorporated under the laws of the State of Delaware on August 8, 1997. The Company is an emerging pharmaceutical company specializing in the formulation of therapeutic products using proprietary drug delivery technologies. The company was formally known as LOGIC TECH INTERNATIONAL, INC., and had its corporate name amended during fiscal year 2000.

Effective July 1, 2003 the Company acquired all of the shares of AlphaRx Canada Limited for nominal value of \$1. AlphaRx Canada Limited was dormant until this time. AlphaRx Canada Limited was incorporated under the laws of Ontario in order to streamline sales of the Company’s products in the Canadian market. Prior to this time AlphaRx Canada Limited had no material assets or any liabilities and was wholly owned by the President & CEO of the Company. The consolidated financial statements reflect the activities of the Company and of AlphaRx Canada Limited – its wholly owned subsidiary. All material inter-company accounts and transactions have been eliminated.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, they do not include any adjustments relating to the realization of the carrying value of assets or the amounts and classification of liabilities that might be necessary should the company be unable to continue as a going concern. Continuance of the company as a going concern is dependent on its future profitability and on the on-going support of its shareholders, affiliates and creditors.

#### **NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

This summary of significant accounting policies of ALPHARX, INC. is presented to assist in understanding the Company’s financial statements. The financial statements and notes are representations of the Company’s management who is responsible for their integrity and objectivity. These accounting policies conform to generally accepted accounting principles in the United States of America and have been consistently applied in the preparation of the financial statements.

##### **Cash and Cash Equivalents**

Cash and cash equivalents includes cash on hand, amounts on deposit with banks, and any other highly liquid investments purchased with a maturity of three months or less. The carrying amount approximates fair value because of the short maturity of those instruments.

##### **Fair Value of Financial Instruments**

The carrying amount of the Company's account receivables, accounts payable, accrued liabilities, litigation liabilities and notes payable approximates fair value because of the short maturity of these instruments.

#### Long-Term Financial Instruments

The fair value of each of the Corporation's long-term financial assets is based on the amount of future cash flows associated with each instrument discounted using an estimate of what the Company's current borrowing rate for similar instruments of comparable maturity would be.

It is of the management's opinion that the Company is not exposed to significant interest rate risk, credit risk or currency risks arising from these financial instruments.

#### Inventory

Inventory is recorded at the lower of cost and net realizable value. Cost is determined on the first-in first-out basis.

#### Foreign Currency Translation

The Company maintains the books and records of the subsidiary in Canadian dollars, its functional currency. The records of the Canadian subsidiary are converted to US dollars, the reporting currency. The translation method used is the current rate method which is the method mandated by SFAS 52 where the functional currency is the foreign currency. Under the current rate method all assets and liabilities are translated at the current rate, stockholder's equity accounts are translated at historical rates and revenues and expenses are translated at average rates for the year.

#### Earnings or Loss Per Share

The Company adopted FAS No.128, "Earnings per Share", which requires disclosure on the financial statements of "basic" and "diluted" earnings (loss) per share. Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding for the year. Diluted earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding plus common stock equivalents (if dilutive) related to stock options and warrants for each year.

#### Income Taxes

The Company accounts for income tax under the provision of Statement of Financial Accounting Standards No. 109, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statement or tax returns. Deferred income taxes are provided using the liability method. Under the liability method, deferred income taxes are recognized for all significant temporary differences between the tax and financial statement bases of assets and liabilities.

Effects of changes in enacted tax laws on deferred tax assets and liabilities are reflected as adjustments to tax expense in the period of enactment. Deferred tax assets may be reduced, if deemed necessary based on a judgmental assessment of available evidence, by a valuation allowance for the amount of any tax benefits which are more likely, based on current circumstances, not expected to be realized.

## Property and Equipment

Property and equipment are stated at cost. Depreciation is calculated by using Modified Accelerated Cost Recovery System Method for financial reporting as well as income tax purposes at rates based on the following estimated useful lives:

Furniture and Fixtures	7 years
Machinery and Equipment	3 - 7 years
Automobile	5 years
Leasehold Improvements	10 years

The Company capitalizes expenditures that materially increase assets' lives and expenses ordinary repairs and maintenance to operations as incurred. When assets are sold or disposed or otherwise fully depreciated, the cost and related accumulated depreciation are removed from the accounts and any gain or loss is included in the statement of income and retained earnings.

## Research and Development

All research and development costs are charged to expense as incurred. These costs include research and development, travel to explore and evaluate new products, product licensing, and various legal and professional fees incurred for preparation of patent applications.

## Revenue Recognition

Sales represent the invoiced value of goods supplied to customers. Revenues are recognized upon the passage of title to the customers, provided that the collection of the proceeds from sales are reasonably assured. A reserve for returns is considered periodically based on actual or anticipated returns from customers. The Company policy is not to accept returns, however, under certain circumstances returns are accepted to maintain good customer relations.

## Use of Estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect certain reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. These estimates are reviewed periodically and as adjustments become necessary, they are reported in earnings in the period in which they become known.

## Long-Lived Assets

The Company adopted the provisions of SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of which has been superseded by SFAS No. 144. SFAS No. 144 requires that long-lived assets to be held and used by an entity be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Management used its best estimate of the

undiscounted cash flows to evaluate the carrying amount and have determined that no impairment has occurred.

### Intangible Assets

Intangible assets with an indefinite useful economic life are tested annually for impairment and periodically if events or circumstances warrant such a test in accordance with SFAS 142. An impairment loss is recognized if the carrying amount exceeds the fair value.

### Concentrations of Credit Risks and Revenues

The Company's receivables are unsecured and are generally due in 30 Days. Currently, the Company does not have a diverse customer base as approximately 75% of revenues were derived from two customers during the year ended September 30, 2004. The Company is however, continuously broadening its customer base in order to increase revenues and reduce economic dependency on these two customers. The majority of the Company's customers are blue chip, publicly traded companies.

### Recent Pronouncements

SFAS No. 144 – Accounting for the Impairment or Disposal of Long-Lived Assets. This standard supercedes SFAS No. 121 – Accounting for the impairment of long-lived assets and for Long-Lived Assets to be Disposed of. This standard requires that businesses recognize impairment when the financial statement carrying amount of long-lived asset or asset group exceeds its fair value and is not recoverable. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001.

SFAS No. 145 – Rescission of FASB Statements No.4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections. SFAS 145 updates, clarifies and simplifies existing accounting pronouncements. SFAS 145 rescinds Statement No.4, which required all gains and losses from extinguishment of debt to be aggregated and, if material, classified as extraordinary items, net of related income tax effect. As a result, the criteria in APB Opinion No. 30 will now be used to classify those gains and losses because Statement No. 4 has been rescinded. Statement No. 44 was issued to establish accounting requirements for the effects of transition to provisions of the Motor Carrier Act of 1980. Because the transition has been completed, Statement No. 44 is no longer necessary.

SFAS No. 146 – Accounting for Cost Associated with Exit or Disposal Activities. SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. Previous accounting guidance was provided by Emerging Issues Task Force ("EITF") Issue No. 94-3. SFAS 146 replaces EITF94-3. The Statement is to be applied prospectively to exit or disposal activities initiated after December 31, 2002.

SFAS No.147 – Acquisition of certain Financial Institutions, an amendment of SFAS 72 and 144 and SFAS interpretation number 9 issued October 2002 and relates to acquisitions of financial institutions.

SFAS No. 148 – Accounting for Stock Based Compensation-Transition and Disclosure, an amendment of SFAS 123 issued December 2002 and permits two additional transition methods for entities that adopt the fair value based method of accounting for stock based employee

compensation to avoid the ramp-up effect arising from prospective application. This statement also improves the prominence and clarity of the pro-forma disclosures required by SFAS 123.

SFAS No. 149 – Amendment of SFAS 133 on derivative instruments and hedging activities. This statement amends and clarifies financial accounting and reporting for derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS 133, accounting for derivative instruments and hedging activities.

SFAS No. 150– Accounting for certain financial instruments with characteristics of both liabilities and equity. This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity.

The Company believes that the above standards would not have a material impact on its financial position, results of operations or cash flows.

### NOTE 3. ACCOUNTS RECEIVABLE

	2004	2003
Accounts receivable	\$ 51,576	\$ 29,742
Less: Allowance for doubtful accounts	<u>1,646</u>	<u>2,080</u>
	<u>\$ 49,930</u>	<u>\$ 27,662</u>

The Company carries accounts receivable at the amounts it deems to be collectible. Accordingly, the Company provides allowances for accounts receivable it deems to be uncollectible based on management's best estimates. Recoveries are recognized in the period they are received. The ultimate amount of accounts receivable that becomes uncollectible could differ from those estimated.

### NOTE 4. INVENTORY

Inventory comprised the following:

	2004	2003
Raw materials	\$ 59,844	\$ 26,757
Finished goods	<u>120,428</u>	<u>115,148</u>
	<u>\$ 180,272</u>	<u>\$ 141,905</u>

### NOTE 5. PROPERTY, PLANT & EQUIPMENT

	2004	2003
Furniture & Fixtures	25,089	11,656
Machinery & Equipment	293,475	170,072
Automobile	<u>--</u>	<u>22,067</u>
COST	<u>338,512</u>	<u>205,632</u>
Less: Accumulated depreciation/amortization		

Leasehold Improvements	3,573	460
Furniture & Fixtures	8,679	5,709
Machinery & Equipment	84,727	59,496
Automobile	--	13,432
	<u>96,979</u>	<u>79,097</u>
NET	<u>\$ 241,533</u>	<u>\$ 126,535</u>

#### **NOTE 6. LICENSING RIGHT**

In January 2003, the Company entered into a sub-licence agreement with a third party drug research company for the world-wide commercialization of an experimental cancer drug. The cost of this sub-licence agreement was \$230,000 which was paid by cash of \$190,000 and shares with a value of \$40,000. Costs to bring this drug to market are currently prohibitive for the Company, and having unsuccessfully attempted to resell these commercialization rights, they have been written down to a nominal value.

#### **NOTE 7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES**

Accounts payable and accrued liabilities are comprised of the following:

	2004	2003
Trade Accounts Payable	\$ 177,962	\$ 205,654
Accrued Liabilities	<u>101,109</u>	<u>49,070</u>
	<u>\$ 279,071</u>	<u>\$ 254,724</u>

#### **NOTE 8. NOTES PAYABLE**

At September 30, 2004, the Company has notes payable including accrued interest of \$665,900. (September 30, 2003 - \$474,837). Of these notes, \$520,347 are secured by a first priority interest in all of the intellectual property and other assets of the Company. These notes, bearing interest at 10% per annum, are convertible into shares of common stock at a conversion price of \$0.10. The remaining notes are unsecured and bear interest at 0%-12% per annum. See also subsequent event note below. All notes including accrued interest were repaid subsequent to year end or converted into common stock plus warrants to purchase common stock.

#### **NOTE 9. LITIGATION LIABILITY**

The Company is a defendant in a lawsuit, filed by a prospective investor alleging breach of contract, which seeks damages totaling \$25,000. The Company believes the suit is without merit, however, to remain conservative, the entire claim has been accrued in the financial statements.

#### **NOTE 10. COMMITMENTS**

##### Leases

The Company leases automobile and computer equipment as well as its main premises. The aggregate minimum annual payments due under these leases are as follows:

<u>Year</u>	<u>Amount</u>
2005	\$32,374
2006	\$32,374
2007	\$28,736
2008	\$28,406
2009	\$ 5,309

#### **NOTE 11. COMMON STOCK**

During July, 2004, the majority of the Company's stockholders, by written consent, agreed to increase the authorized number of common shares to 250,000,000 from the existing authorization for 100,000,000.

The Company is hence authorized to issue 250,000,000 shares of common stock. As of September 30, 2004, there remains issued and outstanding 52,304,642 shares of such common stock which has a stated par value of \$0.0001 per share.

During the year, the Company issued 100,000 shares of common stock at a price of \$0.30 per share for consulting and legal services; \$375,234 of convertible promissory notes were converted into 3,752,340 shares of common stock at \$0.10 per share; 1,313,542 shares were issued in lieu of cash commission for the placement of promissory notes at a value of \$131,354; 27,224,034 shares were issued at \$0.15 per share in connection with a private placement, and 2,994,644 shares were issued in lieu of cash commission at a value of \$449,197 in connection with the private placement of stock. Total proceeds from the private placement, net of cash value of all commissions and other issuance expenses of \$90,304, was \$3,412,750.

#### **NOTE 12. INCOME TAXES**

The tax effect of significant temporary differences representing deferred tax assets is as follows:

	<b>2004</b>	<b>2003</b>
Deferred tax assets:		
Operating loss carry forwards	\$ 1,927,500	\$ 1,455,175
Valuation allowance	<u>1,927,500</u>	<u>1,455,175</u>
Net deferred tax assets	<u>0</u>	<u>0</u>

These losses expire in varying amounts between 2010 and 2024.

#### **NOTE 13. STOCK OPTION PLANS**

The Company has a Stock Option Plan (Plan) under which officers, key employees, certain independent contractors, and non-employee directors may be granted options to purchase shares of the Company's authorized but unissued common stock. Since the fiscal year of 2001, the option plan was terminated. Under this Plan, the option exercise price is US\$0.10. Outstanding

stock options granted under the Plan will remain in effect until the expiration date specified in those options. Options currently expire no later than 10 years from the grant date and generally vest within five years. Proceeds received by the Company from exercises of stock options are credited to common stock and additional paid-in capital. Additional information with respect to the Plan's stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price
Options exercisable at September 30, 2003 and 2004	1,150,000	\$0.10

The Company adopted a new option plan on February 10, 2003 under which options to purchase 1,500,000 common shares will be granted to certain key employees and directors. Under the Plan, the option exercise price and its fair market value are determined to be US\$0.50 -US\$0.69. All options will expire on February 10, 2008 and will vest, and become exercisable in three instalments. Proceeds received by the Company from exercises of stock options are credited to common stock and additional paid-in capital. Additional information with respect to the Plan's stock option activity is as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at February 10, 2003 (plan adoption)	0	
Granted during fiscal 2003	645,000	\$0.63
Exercised	0	\$0.00
Cancelled during fiscal 2003	75,000	\$0.63
Outstanding as of September 30, 2004	570,000	\$0.63
Options exercisable at September 30, 2004	406,667	\$0.63

The Company granted 645,000 options to consultants during fiscal 2003. The fair value of each option granted during 2003 was recorded as consulting expense using the Black-Scholes option pricing model.

No stock options were granted during the year ended September 30, 2004.

The Company, via written consent from a majority of the holders of common stock, approved the adoption of a new option plan during July, 2004. Under this plan the Company can issue up to 24,000,000 options to purchase common stock. As of September 30, 2004 no options under this plan had been formally allocated. No further options will be granted under the previous two plans. See also subsequent event note below.

#### **NOTE 14. WARRANTS**

The Company has the following warrants outstanding to purchase common stock at September 30, 2004:



Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$1.10, expiring December 19, 2004.	670,275
Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.65 expiring June 17, 2006.	75,524
Warrants issued in return for financial advisory services whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.05, expiring September 1, 2007. This warrant can only be exercised after January 29, 2005.	3,000,000
Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.05, expiring January 1, 2005.	250,000
Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.15, expiring September 1,, 2007.	2,994,642
Warrants issued in conjunction with financing costs whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.30, expiring September 1, , 2007.	2,287,669
Warrants issued in conjunction with conversion of promissory notes and in conjunction with the private placement completed during July and September, 2004. One warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.30, expiring September 1, 2007.	<u>34,728,712</u>
	<u>44,006,822</u>

The Company also has an obligation to honor warrants which result from conversion of certain remaining promissory notes. Upon conversion of the remaining secured convertible promissory notes, the Company must issue warrants whereby one warrant entitles the holder to purchase one share of common stock at an exercise price of \$0.30, expiring September 1, 2007. Should the remaining convertible promissory notes be converted, the Company must issue warrants to purchase 10,406,940 shares of common stock. See also subsequent event note below. The remaining convertible promissory notes were converted subsequent to year end.

#### **NOTE 15. SEGMENTED INFORMATION**

The Company, after reviewing its reporting systems, has determined that it has one reportable segment and geographic segment. The Company's operations are all related to the research,

design, manufacture and sales of therapeutic products. All revenue generated to date result from sales in Canada. All assets of the business are located in Canada.

#### **NOTE 16. RECLASSIFICATIONS**

Certain amounts from prior year have been reclassified to conform with current year's presentation.

#### **NOTE 17. SUBSEQUENT EVENTS**

On October 8, 2004 holders of \$260,208 in convertible promissory notes converted the notes into 2,602,083 shares of common stock plus warrants to purchase 5,204,160 shares of common stock at an exercise price of \$0.30 per share. The warrants expire on September 1,, 2007.

On October 28, 2004, holders of \$260,139 in convertible promissory notes converted the notes into 2,601,389 shares of common stock plus warrants to purchase 5,202,780 shares of common stock at an exercise price of \$0.30 per share. The warrants expire September 1, 2007.

On October 29, 2004 all remaining unsecured promissory notes totalling \$145,554 were repaid by the Company. As a result of the above mentioned conversions and repayments, all debt reflected on the balance sheet as at September 30, 2004 has been extinguished.

On November 15, 2004 the Company issued 13,220,000 options to purchase common stock to 14 individuals including management, directors and consultants. Of these, 12,720,000 options were issued to management and directors, are exercisable at \$0.15 per share, and expire on November 15, 2014. The remaining 500,000 options were issued to consultants, are exercisable between \$0.40 and \$0.50 per share, and expire on November 15, 2014.