GENEREX BIOTECHNOLOGY CORP
Form 424B3
December 03, 2003

PROSPECTUS

GENEREX BIOTECHNOLOGY CORPORATION

3,859,974 Shares of Common Stock

We are registering 3,859,974 shares of our common stock for resale by the selling shareholders listed on pages 10-12.

- 1,989,974 of these shares are currently outstanding;
- 1,000,000 of these shares are to be issued to certain selling shareholders on January 31, 2004;
- 250,000 of these shares are issuable upon exercise of outstanding options; and
- 620,000 of these shares are issuable upon exercise of outstanding warrants.

The prices at which the selling shareholders may sell shares of our common stock will be determined by the prevailing market price for such shares or in negotiated transactions.

Our common stock is quoted on the NASDAQ SmallCap Market under the symbol "GNBT." The last sale price of our common stock on November 11, 2003, as reported by NASDAQ, was $1.71per share.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 2 to read about the factors you should consider before investing.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is November 24, 2003

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PROSPECTUS SUMMARY

About Generex

Generex Biotechnology Corporation is a Delaware corporation engaged in the research and development of injection-free methods for delivery of large molecule drugs. We are a development stage company.

To date, we have focused most of our efforts and resources on a platform technology to orally administer large molecule drugs by absorption through the walls of the mouth cavity. The mouth cavity is also known as the "buccal" cavity. Large molecule drugs include proteins, hormones, peptides and vaccines. Large molecule drugs, such as synthetic insulin, are presently administered almost exclusively by injection.

The initial product that we have been trying to develop is an oral insulin formulation for use in the treatment of diabetes. The formulation is sprayed into the mouth using our RapidMist(TM) device, a small and lightweight aerosol applicator that administers a metered dose for absorption. Absorption occurs through the mucous membranes in the buccal cavity.

We have also pursued the application of our technology for the buccal delivery of pharmaceutical products in addition to insulin, such as the buccal delivery of morphine, fentanyl citrate and low molecular weight heparin.

In August 2003, after the end of our most recent fiscal year, we acquired Antigen Express, Inc. (Antigen). Antigen is engaged in the research and development of technologies for the treatment of malignant, infectious, autoimmune and allergic diseases.

Our principal offices are located at 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2 and our telephone number is (416) 364-2551.

About This Prospectus

We are registering our common stock for resale by selling shareholders. The selling shareholders and the specific number of shares that they each may resell through this prospectus are listed on pages 10-12.

The shares offered for resale by this prospectus include the following:

- 2,989,974 shares of Common Stock;
- 250,000 options to purchase shares of Common Stock; and
- 620,000 warrants to purchase shares of Common Stock.

We issued or became obligated to issue an aggregate of 2,839,974 of these shares of our common stock to certain selling shareholders in connection with an Agreement and Plan of Merger (the "Merger"), dated as of August 8, 2003, among Generex, Antigen Express, Inc. ("Antigen"), and AGEXP Acquisition, Inc., our wholly owned subsidiary, in exchange for the outstanding capital stock of Antigen. We issued to certain selling shareholders an additional 150,000 shares of our common stock pursuant to service agreements between Generex and such shareholders. We are obligated to sell to a certain selling shareholder an additional 250,000 shares of our common stock upon such selling shareholder's exercise of options to purchase such shares. Lastly, we issued to certain selling shareholders warrants to purchase an aggregate 620,000 shares of our common stock.

This prospectus may only be used where it is legal to offer and sell the shares covered by this prospectus. We have not taken any action to register or obtain

permission for this offering or the distribution of this prospectus in any country other than the United States.

Information on Outstanding Shares

The number of shares outstanding before and after this offering are set forth below:

- Common stock outstanding before the offering.....27,672,260 shares of Common Stock
- Common stock to be outstanding after the offering.....29,467,260 shares of Common Stock

The number set forth above for the shares of common stock outstanding before this offering is the number of shares outstanding on October 30, 2003. The number of shares of common stock outstanding after this offering is based on the number of shares outstanding before the offering plus 1,000,000 shares issuable to Antigen shareholders without condition on January 31, 2004, which are included in this registration statement but have not been issued, and 870,000 shares - the maximum number of shares issuable upon the exercise of options and warrants that may be resold pursuant to this prospectus.

The numbers set forth above do not include 11,957,594 shares of our common stock that, as of the date of this prospectus, are issuable upon the exercise of outstanding options and warrants other than those covered by this prospectus. These additional options and warrants are exercisable at prices ranging from $1.00 to $25.15 per share, with a weighted average exercise price of $4.88 per share. The numbers set forth above also do not include shares of common stock that, as of the date of this prospectus, are issuable upon conversion of outstanding shares of our Series A Preferred Stock.

RISK FACTORS

Investment in our shares involves a high degree of risk. You should carefully consider the following discussion of risks as well as the other information in

this prospectus before purchasing our stock. You should also consider the information in our other reports filed (and to be filed after the date of this prospectus) with the Securities and Exchange Commission before purchasing our stock. Each of these risk factors could adversely affect our business, prospects, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

RISKS RELATED TO OUR FINANCIAL CONDITION

We have a history of losses, and will incur additional losses.

We are a development stage company with a limited history of operations, and do not expect ongoing revenues from operation in the immediately foreseeable future. To date, we have not been profitable and our accumulated net loss before preferred stock dividend was approximately $76,000,000 as of July 31, 2003. Our losses have resulted principally from costs incurred in research and development, including clinical trials, and from general and administrative costs associated with our operations. While we seek to attain profitability, we cannot be sure that we will ever achieve product and other revenue sufficient for us to attain this objective.

Our product candidates are in research or early stages of pre-clinical and clinical development. We will need to conduct substantial additional research, development and clinical trials. We will also need to receive necessary regulatory clearances both in the United States and foreign countries and obtain meaningful patent protection for and establish freedom to commercialize each of our product candidates. We cannot be sure that we will obtain required regulatory approvals, or successfully develop, commercialize, manufacture and market any product candidates. We expect that these activities, together with future general and administrative activities, will result in significant expenses in the foreseeable future.

To progress in product development or marketing, we will need additional capital which may not be available to us. This may delay our progress in product development or market.

We will require funds in excess of our existing cash resources:

- to proceed under our joint venture with Elan, which requires us to fund 80.1% of initial product development costs;
- to develop our buccal insulin product;
- to develop new products based on our buccal delivery technology, including clinical testing relating to new products;
- to develop or acquire other delivery technologies or other lines of business;
- to establish and expand our manufacturing capabilities;
- to finance general and administrative and research activities that are not related to specific products under development; and
- To finance the research and development activities of Antigen, our new subsidiary. We have agreed to fund at least $2,000,000 of Antigen expenditures during the first two years from the acquisition.

In the past, we have funded most of our development and other costs through equity financing. We anticipate that our existing capital resources will enable us to maintain currently planned operations through the next twelve months. However, this expectation is based on our current operating plan, which could change as a result of many factors, and we may need additional funding sooner than anticipated. To the extent operating and capital resources are insufficient to meet future requirements, we will have to raise additional funds to continue the development and commercialization of our products. Unforeseen problems, including materially negative developments in our joint venture with Elan, in our clinical trials or in general economic conditions could interfere with our ability to raise additional equity capital or materially adversely affect the terms upon which such funding is available.

It is possible that we will be unable to obtain additional funding as and when we need it. If we were unable to obtain additional funding as and when needed, we could be forced to delay the progress of certain development efforts. Such a scenario poses risks. For example, our ability to bring a product to market and obtain revenues could be delayed, our competitors could develop products ahead of us, and/or we could be forced to relinquish rights to technologies, products or potential products.

New equity financing could dilute current shareholders.

If we raise funds through equity financing to meet the needs discussed above, it will have a dilutive effect on existing holders of our shares by reducing their percentage ownership. The shares may be sold at a time when the market price is low because we need the funds. This will dilute existing holders more than if our stock price was higher. In addition, equity financings normally involve shares sold at a discount to the current market price.

Our research and development and marketing efforts are highly dependent at present on corporate collaborators and other third parties who may not devote sufficient time, resources and attention to our programs, which may limit our efforts to successfully develop and market potential products.

Because we have limited resources, we have sought to enter into collaboration agreements with other pharmaceutical companies that will assist us in developing, testing, obtaining governmental approval for and commercializing products using our platform technology. Any collaborator with whom we may enter into such collaboration agreements may not support fully our research and commercial interests since our program may compete for time, attention and resources with such collaborator's internal programs. Therefore, these collaborators may not commit sufficient resources to our program to move it forward effectively, or our program may not advance as rapidly as it might if we had retained complete control of all research, development, regulatory and commercialization decisions.

RISKS RELATED TO OUR TECHNOLOGY

Because our technologies and products are at an early stage of development, we cannot expect revenues in the foreseeable future.

We have no products approved for commercial sale at the present time. To be profitable, we must successfully research, develop, obtain regulatory approval for, manufacture, introduce, market and distribute our products under development. We may not be successful in one or more of these stages of the development of our products, and/or any of the products we develop may not be commercially viable.

While over 750 patients with diabetes have been dosed with our oral insulin formulation at approved facilities in seven countries, our clinical program has not reached a point where we are prepared to apply for regulatory approvals to market the product in any country. Until we have developed a commercially viable product which receives regulatory approval, we will not receive revenues from ongoing operations.

We will not receive revenues from operations until we receive regulatory approval to sell our products. Many factors impact our ability to obtain approvals for commercially viable products.

We have no products approved for commercial sale by drug regulatory authorities. We have begun the regulatory approval process for our oral insulin formulation, buccal morphine and fentanyl products.

Pre-clinical and clinical trials of our products, and the manufacturing and marketing of our technology, are subject to extensive, costly and rigorous regulation by governmental authorities in the United States, Canada and other countries. The process of obtaining required regulatory approvals from the FDA and other regulatory authorities often takes many years, is expensive and can vary significantly based on the type, complexity and novelty of the product candidates. For these reasons, it is possible we will never receive approval for one or more product candidates.

Delays in obtaining United States or foreign approvals for our products could result in substantial additional costs to us, and, therefore, could adversely affect our ability to compete with other companies. If regulatory approval is ultimately granted, the approval may place limitations on the intended use of the product we wish to commercialize, and may restrict the way in which we are permitted to market the product.

Due to legal and factual uncertainties regarding the scope and protection afforded by patents and other proprietary rights, we may not have meaningful protection from competition.

Our long-term success will substantially depend upon our ability to protect our proprietary technology from infringement, misappropriation, discovery and duplication and avoid infringing the proprietary rights of others. Our patent rights, and the patent rights of biotechnology and pharmaceutical companies in general, are highly uncertain and include complex legal and factual issues. Because of this, our pending patent applications may not be granted. These uncertainties also mean that any patents that we own or will obtain in the

future could be subject to challenge, and even if not challenged, may not provide us with meaningful protection from competition. Due to our financial uncertainties, we may not possess the financial resources necessary to enforce our patents. Patents already issued to us or our pending applications may become subject to dispute, and any dispute could be resolved against us.

Because a substantial number of patents have been issued in the field of alternative drug delivery and because patent positions can be highly uncertain and frequently involve complex legal and factual questions, the breadth of claims obtained in any application or the enforceability of our patents cannot be predicted. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subject to further proceedings limiting their scope, will provide significant

proprietary protection or competitive advantage, or will be circumvented or invalidated.

Also because of these legal and factual uncertainties, and because pending patent applications are held in secrecy for varying periods in the US and other countries, even after reasonable investigation we may not know with certainty whether any products that we (or a licensee) may develop will infringe upon any patent or other intellectual property right of a third party. For example, we are aware of certain patents owned by third parties which such parties could attempt to use in the future in efforts to affect our freedom to practice some of the patents that we own or have applied for. Based upon the science and scope of these third party patents, we believe that the patents that we own or have applied for do not infringe any such third party patents, however, these uncertainties mean that we cannot know for certain whether we could successfully defend our position, if challenged. We may incur substantial costs if we are required to defend ourselves in patent suits brought by third parties. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process.

RISKS RELATED TO MARKETING OF OUR POTENTIAL PRODUCTS

We may not become, or stay, profitable even if our products are approved for sale.

Even if we obtain regulatory approval to market our oral insulin product or any other product candidate, many factors may prevent the product from ever being sold in commercial quantities. Some of these factors are beyond our control, such as:

- acceptance of the formulation by health care professionals and diabetic patients;
- the availability, effectiveness and relative cost of alternative diabetes treatments that may be developed by competitors; and
- the availability of third-party (i.e., insurer and governmental agency) reimbursements.

We may not be able to compete with diabetes treatments now being developed and marketed, or which may be developed and marketed in the future by other companies.

Our oral insulin product will compete with existing and new therapies for treating diabetes, including administration of insulin by injection. We are aware of a number of companies currently seeking to develop alternative means of delivering insulin, as well as new drugs intended to replace insulin therapy at least in part. In the longer term, we also face competition from companies that seek to develop cures for diabetes through techniques for correcting the genetic deficiencies that underlie diseases such as diabetes.

We will have to depend upon others for marketing and distribution of our products, and we may be forced to enter into contracts limiting the benefits we may receive from, and the control we have over, our products. We intend to rely

on collaborative arrangements with one or more other companies that possess strong marketing and distribution resources to perform these functions for us.

We may not be able to enter into beneficial contracts, and we may be forced to enter into contracts for the marketing and distribution of our products that substantially limit the potential benefits to us from commercializing these products. In addition, we will not have the same control over marketing and distribution that we would have if we conducted these functions ourselves.

Numerous pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations are engaged in the development of alternative drug delivery systems or new drug research and testing including oral delivery systems, intranasal delivery systems, transdermal systems, and colonic absorption systems. Many of these companies have greater research and development, experience, manufacturing, marketing, financial and managerial resources than we do. Accordingly, our competitors may succeed in developing competing technologies, obtaining FDA approval for products or gaining market acceptance more rapidly than we can.

If government programs and insurance companies do not agree to pay for or reimburse patients for our products, we will not be successful.

Sales of our potential products depend in part on the availability of reimbursement by third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. FDA approval of health care products does not guarantee that these third party payors will pay for the products. Even if third party payors do accept our product, the amounts they pay may not be adequate to enable us to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement.

RISKS RELATING TO POTENTIAL LIABILITIES

We face significant product liability risks, which may have a negative effect on our financial condition.

The administration of drugs to humans, whether in clinical trials or commercially, can result in product liability claims whether or not the drugs are actually at fault for causing an injury. Furthermore, our products may cause, or may appear to cause, serious adverse side effects (including death) or potentially dangerous drug interactions that we may not learn about or understand fully until the drug has been administered to patients for some time. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a severe negative effect on our financial condition. We maintain product liability insurance in amounts we believe to be commercially reasonable for our current level of activity and exposure, but claims could exceed our coverage limits. Furthermore, due to factors in the insurance market generally and our own experience, we may not always be able to purchase sufficient insurance at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with our business.

Outcome of an arbitration proceeding with Sands Brothers may result in adverse effects upon Generex.

On October 2, 1998, Sands Brothers & Co. Ltd., a New York City-based investment banking and brokerage firm, initiated an arbitration against us under New York Stock Exchange rules. Sands alleged that it had the right to receive, for nominal consideration, approximately 1.5 million shares of our common stock. Sands based its claim upon an October 1997 letter agreement that was purported by Sands to confirm an agreement appointing Sands as the exclusive financial advisor to Generex Pharmaceuticals, Inc., a subsidiary that we acquired in late 1997. In exchange therefor, the letter agreement purported to grant Sands the

right to acquire 17% of Generex Pharmaceuticals' common stock for nominal consideration. Sands claimed that its right to receive shares of Generex Pharmaceuticals' common stock applies to Generex Biotechnology common stock since outstanding shares of Generex Pharmaceuticals' common stock were converted into shares of Generex Biotechnology common stock in the acquisition. Sands' claims also included additional shares allegedly due as a fee related to that acquisition, and $144,000 in monthly fees allegedly due under the terms of the purported agreement.

After several arbitration and court proceedings, on October 29, 2002, the Appellate Division of the New York Supreme Court issued a decision remanding the issue of damages to a new panel of arbitrators and limiting the issue of damages before the new panel to reliance damages which is not to include an award of lost profits. Reliance damages are out-of-pocket damages incurred by Sands.

On November 27, 2002, Sands filed with the Appellate Division a motion to reargue the appeal, or, in the alternative, for leave to appeal to the Court of Appeals of New York from the order of the Appellate Division. On March 18, 2003, the Appellate Division denied Sands' motion.

Despite the recent favorable decisions, the case is still ongoing and our ultimate liability cannot yet be determined with certainty. Our financial condition would be materially adversely affected to the extent that Sands receives shares of our common stock for little or no consideration or substantial monetary damages as a result of this legal proceeding. We are not able to estimate an amount or range of potential loss from this legal proceeding at the present time.

RISKS RELATED TO THE MARKET FOR OUR STOCK

If our stock is delisted from the NASDAQ SmallCap Market and/or becomes subject to Penny Stock regulations, the market price for our stock may be reduced and it may be more difficult for you to sell our stock.

On June 5, 2003, our common stock was delisted from the NASDAQ National Market because of our failure to maintain a minimum of $10,000,000 in stockholders' equity. On June 5, 2003, our stock began trading on the NASDAQ SmallCap Market. NASDAQ SmallCap has its own standards for continued listing, including a minimum of $2.5 million stockholders' equity. As of July 31, 2003, our stockholders' equity was $5,856,965.

In addition, for continued listing on the NASDAQ SmallCap Market, our stock price must be at least $1.00. During periods in fiscal 2002 and the beginning of fiscal 2003, our share price dropped to close to $1.00 per share. If we do not meet this requirement in the future, we may be subject to delisting by NASDAQ.

If our stock is delisted from NASDAQ, there will be less interest for our stock in the market. This may result in lower prices for our stock and make it more difficult for you to sell your shares.

If our stock is not listed on NASDAQ and fails to maintain a price of $5.00 or more per share, our stock would become subject to the SEC's "Penny Stock" rules. These rules require a broker to deliver, prior to any transaction involving a Penny Stock, a disclosure schedule explaining the Penny Stock Market and its risks. Additionally, broker/dealers who recommend Penny Stocks to persons other than established customers and accredited investors must make a special written suitability determination and receive the purchaser's written agreement to a

transaction prior to the sale. In the event our stock becomes subject to these rules, it will become more difficult for broker/dealers to sell our common stock. Therefore shareholders may have more difficulty selling our common stock in the public market.

The price of our shares may be volatile.

There may be wide fluctuation in the price of our shares. These fluctuations may be caused by several factors including:

- announcements of research activities and technology innovations or new products by us or our competitors;
- changes in market valuation of companies in our industry generally;
- variations in operating results;
- changes in governmental regulations;
- developments in patent and other proprietary rights;
- public concern as to the safety of drugs developed by us or others;
- results of clinical trials of our products or our competitors' products; and
- regulatory action or inaction on our products or our competitors' products.

From time to time, we may hire companies to assist us in pursuing investor relations strategies to generate increased volumes of investment in our shares. Such activities may result, among other things, in causing the price of our shares to increase on a short-term basis.

Furthermore, the stock market generally and the market for stocks of companies with lower market capitalizations and small biopharmaceutical companies, like us, have from time to time experienced, and likely will again experience significant price and volume fluctuations that are unrelated to the operating performance of a particular company.

Our outstanding Special Voting Rights Preferred Stock and provisions of our Certificate of Incorporation could delay or prevent the acquisition or sale of Generex.

Holders of our Special Voting Rights Preferred Stock have the ability to prevent any change of control of Generex. Our Vice President of Research and Development, Dr. Pankaj Modi, owns all of our Special Voting Rights Preferred Stock. In addition, our Certificate of Incorporation permits our Board of Directors to designate new series of preferred stock and issue those shares without any vote or action by the shareholders. Such newly authorized and issued shares of preferred stock could contain terms that grant special voting rights to the holders of such shares that make it more difficult to obtain shareholder approval for an acquisition of Generex or increase the cost of any such acquisition.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

We have made statements in this prospectus that are forward-looking statements

within the meaning of the Private Securities Litigation Reform Act of 1995. This Act limits our liability in any lawsuit based on forward-looking statements we have made. All statements, other than statements of historical facts, included in this prospectus that address activities, events or developments that we expect or anticipate will or may occur in the future, including such matters as our projections, future capital expenditures, business strategy, competitive strengths, goals, expansion, market and industry developments and the growth of our businesses and operations, are forward-looking statements. These statements can be identified by introductory words such as "expects", "plans", "intends", "believes", "will", "estimates", "forecasts", "projects" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts.

Our forward-looking statements address, among other things:

- our expectations concerning product candidates for our technology;
- our expectations concerning existing or potential development and license agreements for third-party collaborations and joint ventures;
- our expectations of when different phases of clinical activity may commence; and
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

- the inherent uncertainties of product development based on a new and as yet not fully proven drug delivery technology;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations when tested clinically;
- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory approval to market product candidates; and
- adverse developments in our joint venture with a subsidiary of Elan Corporation, plc regarding buccal morphine.

Additional factors that we think could cause our actual outcomes and results to differ materially from the forward-looking statements also include those discussed above under the caption "Risk Factors."

Because of the risks and uncertainties associated with forward-looking statements, you should not place undue reliance on them. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

AVAILABILITY OF ADDITIONAL INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission ("SEC"). Our filings are available to the public over the internet at the SEC's web site at http://www.sec.gov. You may also read and copy any document we file at the SEC's Public Reference Rooms in Washington, D.C. and Chicago, Illinois. The Public Reference Room in Washington, D.C. is located at 450 Fifth Street, N.W. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Rooms.

The SEC allows us to "incorporate by reference" in this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. Information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until all shares offered by this prospectus are sold:

- Annual Report on Form 10-K for the fiscal year ended July 31, 2003, as amended.
- Current Reports on Form 8-K filed on August 15, 2003 and 8-K/A filed on September 9, 2003.
- Definitive Proxy Statement on Schedule 14A filed on October 14, 2003.
- Preliminary Proxy Statements on Schedule 14A filed on filed on October 3, 2003 and October 7, 2003.
- The description of our common stock contained in our registration statement on Form 10 filed on December 14, 1998, as amended by a Form 10/A filed on February 24, 1999, and including any amendment or report subsequently filed for the purpose of updating the description.

You may request a copy of these filings at no cost. Please direct your requests to Mark Fletcher, Executive Vice President and General Counsel, 33 Harbour Square, Suite 202, Toronto, Ontario, Canada M5J 2G2 (telephone 416/364-2551).

You should rely only on the information incorporated by reference or provided in this prospectus or any prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front page of those documents.

This prospectus is part of a registration statement on Form S-3 (Registration No. 333-110493) filed with the SEC under the Securities Act of 1933. This prospectus does not contain all of the information set forth in the registration statement. You should read the entire registration statement for further information about us and our common stock.

DILUTION

Purchasers of common stock offered pursuant to this prospectus will incur dilution in their investment that is approximately equal to the difference

between the price which they pay for the shares and stockholders' equity per share of the shares. As of July 31, 2003, the book value of our stockholders' equity was approximately $0.23 per share of common stock.

USE OF PROCEEDS

We will not receive any proceeds from the resale of shares covered by this prospectus.

SELLING SHAREHOLDERS

The following table lists each person who may resell shares pursuant to this prospectus and, in addition, sets forth:

- the number of shares of outstanding common stock registered for sale and beneficially owned by each prior to the offering;
- the number of shares of outstanding common stock registered for sale by each in the offering and issuable on January 31, 2004;
- the number of shares registered for sale by each in the offering and issuable upon exercise of options or warrants;
- the total number of shares registered for sale by each in the offering; and
- the number of shares of common stock owned by each after the offering, assuming each sells all of the shares registered for his or her benefit.

Name	Outstanding Shares (1)	Registered Shares Issuable Upon Exercise of Options or Warrants (2)	Total Shares Registered for Sale (3)
ARE-ONE Innovations Drive, LLC	2293		2293
Klaus & Janet Boese	4587		4587
David Brook	56063		56063
Nigel & Freydis Campbell	15290		15290
Cantab Holdings, Ltd.	21406		21406
David Chella	317		317
Leonard Chess	317		317
R.S. DuFresne, Jr.	15290		15290
Alvin Greenberg	4587		4587
Adele Gulfo	96790		96790
Sun America, as Custodian fbo Adele Gulfo	50966		50966
Joseph V. Gulfo	447996		447996
Sun America, as Custodian fbo Joseph V. Gulfo	18754		18754
Vincent J. Gulfo	50966		50966
Tony & Judith Hugli	1846		1846
Barbara Humphreys	149842		149842
Daniel Humphreys	140624		140624
David Humphreys	140624		140624
Harvey Humphreys	132513		132513

Robert Humphreys	319614		319614
Rosalie Humphreys	270123		270123
Jack T. Johansen	125887		125887
Thomas R. Johnson	21406		21406
Brian Leyland-Jones	317		317
Jacky Knopp, Jr.	9174		9174
Edward J. Lary	19877		19877
Patricia Livingston as Trustee of the Philip O. Livingston 12/01/89 Trust	25483		25483
Philip O. Livingston	25483		25483
Massachusetts Biomedical Initiatives	117675		117675
George S. Mennen, William G. Mennen, IV, Trustee	76450		76450
William G. Mennen, IV	31600		31600
Richard Morningstar	58611		58611
James Mule	317		317
James W. & Susan Ogilvie	12691		12691
Nicholas M. Passarelli	9938		9938

Name	Outstanding Shares(1)	Registered Shares Issuable Upon Exercise of Options or Warrants (2)	Total Shares Registered for Sale (3)
Susan Pierce	317		317
Saul M. Reck	5097		5097
Ralph Reisfield	317		317
Frederic M. Richards	7198		7198
Stephen Saltzman	13761		13761
Marvin G. Schorr	35677		35677
Eli Secarz	317		317
Robert K. Snider (estate)	15290		15290
David K. Stone	61160		61160
Turnstone Ventures, LP	76450		76450
University of Massachusetts Medical Center	63707		63707
Salvatore & Grace Vinciguerra	15290		15290
Jeptha Wade	38226		38226
Per H. Wickstrom	7645		7645
Minzhen Xu	23805		23805
Global Advisory Services, LLC	300000		150000
Mark A. Fletcher	13360	250000	250000
Gunn Allen Financial, Inc.	0	600000	600000
Bristol Investment Group, Inc.	0	20000	20000
TOTAL STOCK	3,153,334	870,000	3,859,974

(1) Includes all (x) outstanding shares beneficially owned by the shareholder as of the date hereof and (y) outstanding shares owned by the shareholder, held by the company and issuable to the shareholder on January 31, 2004.

(2) Includes all options owned by the shareholder which are exercisable within 60 days of the date hereof, with the exception of warrants to purchase 300,000 shares of our common stock issuable to Gunn Allen Financial, Inc., which are exercisable on January 1, 2004.

(3) See (1) and (2).

(4) Assumes sale of all shares offered by this prospectus. No selling shareholder owns more than 1% of our common stock.

No selling shareholder has held a position as a director or executive officer nor has a material employment relationship with us or any of our affiliates within the past 3 years, other than Joseph V. Gulfo, M.D., Robert E. Humphreys, M.D., Minzhen Xu, M.D. and Mark A. Fletcher. Following the Merger, Dr. Gulfo has remained Chief Executive Officer and President of Antigen, our wholly-owned subsidiary. Following the Merger, Dr. Humphreys has the positions of Executive Vice President and Chief Operating Officer of Antigen, and following the Merger, Dr. Xu is the Vice President - Biology of Antigen. Mr. Fletcher has been our Vice President and General Counsel since March 19, 2003.

PLAN OF DISTRIBUTION

We are registering the shares of common stock covered by this prospectus on behalf of the selling shareholders. The selling shareholders may offer and sell shares from time to time. In addition, a selling shareholder's donees, pledgees, transferees and other successors in interest may sell shares received from a named selling shareholder after the date of this prospectus. In that case, the term "selling shareholders" as used in this prospectus includes such donees, pledgees, transferees and other successors in interest. The selling shareholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Sales may be made over the NASDAQ SmallCap Market or otherwise, at then prevailing market prices, at prices related to prevailing market prices or at negotiated prices. The shares may be sold by way of any legally available means, including in one or more of the following transactions:

- block trade in which a broker-dealer engaged by a selling shareholder attempts 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 pursuant to this prospectus;
- and ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers.

Transactions under this prospectus may or may not involve brokers or dealers. The selling shareholders may sell shares directly to purchasers or to or through broker-dealers, who may act as agents or principals. Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in selling shares. Broker-dealers or agents may receive compensation in the form of commissions, discounts or concessions from the selling shareholders in amounts

to be negotiated in connection with the sale. Broker-dealers or agents also may receive compensation in the form of discounts, concessions or commissions from the purchasers of shares for whom the broker-dealers may act as agents or to whom they sell as principal, or both. This compensation as to a particular broker-dealer might exceed customary commissions.

The selling shareholders have advised us that they have not, as of the date of this prospectus, entered into any agreements, understandings or arrangements with any underwriters or broker-dealers for the sale of shares, nor is there an underwriter or coordinating broker acting in connection with the proposed sale of shares by the selling shareholders. To our knowledge, the selling shareholders have not entered into any agreements, understandings or arrangements with any particular broker or market maker with respect to the sale of the shares covered by this prospectus.

In connection with distributions of the shares or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with these transactions, broker-dealers or financial institutions may engage in short sales of the shares in the course of hedging the positions they assume with selling shareholders. The selling shareholders may also:

- sell shares short and redeliver the shares to close out these short positions;
- enter into option or other transactions with broker-dealers or other financial institutions that require the delivery to the broker-dealer or financial institution of the shares, which the broker-dealer or financial institution may resell or otherwise transfer under this prospectus;
- loan or pledge the shares to a broker-dealer or other financial institution that may sell the shares so loaned or pledged under this prospectus upon a default; or
- sell shares covered by this prospectus that qualify for sale under Rule 144 under the Securities Act of 1933 pursuant to that Rule rather than under this prospectus.

The selling shareholders and any broker-dealers participating in the sale of shares covered by this prospectus may be deemed to be "underwriters" within the meaning of the Securities Act of 1933 in connection with sales of such shares. Any commission, discount or concession received by a broker-dealer and any profit on the resale of shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act of 1933.

We have agreed to pay the expenses of registering the shares under the Securities Act of 1933, including registration and filing fees, printing expenses, administrative expenses and certain legal and accounting fees. The selling shareholders will bear all discounts, commissions or other amounts payable to underwriters, dealers or agents, as well as fees and disbursements for legal counsel retained by any selling shareholder.

We have agreed with some of the selling shareholders to indemnify each other and other related parties against specified liabilities, including liabilities arising under the Securities Act of 1933. The selling shareholders also may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of shares against liabilities, including

liabilities arising under the Securities Act of 1933.

A supplement to this prospectus will be filed, if required, under Rule 424(b) under the Securities Act of 1933 to include additional disclosure before offers and sales of the securities in question are made.

The selling shareholders and any other persons participating in a distribution of the shares will be subject to applicable provisions of the Securities Exchange Act of 1934 and the rules and regulations thereunder, including Regulation M, which may restrict certain activities of, and limit the timing of purchases and sales of the shares by the selling shareholders and other persons participating in a distribution of the shares. Furthermore, under Regulation M, persons engaged in a distribution of the shares are prohibited from simultaneously engaging in market making and certain other activities with respect to the shares for a specified period of time prior to the commencement of such distributions subject to specified exceptions or exemptions. All of the foregoing may affect the marketability of the shares offered hereby. We have notified the selling stockholders that they will be subject to applicable provisions of the Securities Exchange Act of 1934 and its rules and regulations, including, among others, Rule 102 under Regulation M. These provisions may limit the timing of purchases and sales of any of the shares of common stock by the selling stockholders. Rule 102 under Regulation M provides, with some exceptions, that it is unlawful for the selling stockholders or their affiliated purchasers to, directly or indirectly, bid for or purchase, or attempt to induce any person to bid for or purchase, for an account in which the selling stockholders or affiliated purchasers have a beneficial interest, any securities that are the subject of the distribution during the applicable restricted period under Regulation M. All of the above may affect the marketability of the shares of common stock. To the extent required by law, we may require the selling stockholders, and their brokers, if applicable, to provide a letter that acknowledges compliance with Regulation M under the Securities Exchange Act of 1934 before authorizing the transfer of the selling stockholders' shares of common stock.

LEGAL MATTERS

The validity of the issuance of the shares of common stock offered in this prospectus will be passed upon for us by Eckert Seamans Cherin & Mellott, LLC, 1515 Market Street, 9th Floor, Philadelphia, PA 19102. The firm of Eckert Seamans Cherin & Mellott owns 128,172 shares of common stock which it received in payment of legal fees and expenses in 1998 (60,000 shares of which the firm currently owns 30,000 shares) and upon the exercise of warrants in June 1999 (98,172 shares). The firm also has been granted options exercisable for 30,000 shares at $7.56 per share under our 2000 Stock Option Plan. Members of the firm own additional shares (less than one percent in total) that they purchased from time to time for cash, either from us or in the public market.

EXPERTS

The consolidated financial statements incorporated by reference in this prospectus have been audited by BDO Dunwoody LLP, independent auditors, to the extent and for the periods set forth in their report incorporated herein by reference, and are incorporated herein in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.

The consolidated financial statements incorporated by reference in this prospectus have been audited by Deloitte & Touche LLP, independent auditors, to the extent and for the periods set forth in their report incorporated herein by

reference, and are incorporated herein in reliance upon such report given upon the authority of said firm as experts in auditing and accounting.