

PROTALEX INC

Form SB-2

January 27, 2006

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As filed with the Securities and Exchange Commission on January 27, 2006

REGISTRATION NO. 333-[ ]

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**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM SB-2  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**PROTALEX, INC.**

(Name of small business issuer in its charter)

**Delaware**

(State or other Jurisdiction of  
Incorporation or Organization)

**8731**

(Primary Standard Industrial  
Classification Code Number)

**91-2003490**

(I.R.S. Employer Identification  
No.)

**145 UNION SQUARE DRIVE  
NEW HOPE, PA 18938  
(215) 862-9720**

(Address and telephone number of principal executive offices and principal place of business)

**STEVEN H. KANE  
PRESIDENT AND CHIEF EXECUTIVE OFFICER  
145 UNION SQUARE DRIVE  
NEW HOPE, PA 18938  
(215) 862-9720**

(Name, address and telephone number of agent for service)

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Copies to:  
**DONALD C. REINKE, ESQ.  
REED SMITH LLP  
TWO EMBARCADERO CENTER  
SAN FRANCISCO, CA 94111  
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**Approximate date of proposed sale to the public:** From time to time after this Registration Statement becomes 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, please check the following box.  x

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

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.  o \_\_\_\_\_

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.  o \_\_\_\_\_

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.  o \_\_\_\_\_

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

**Calculation of Registration Fee**

Title of securities to be registered	Amount to be registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock	3,470,990	\$2.81	\$9,753,482	\$1,043.63

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Subject to Completion, dated January 27, 2006

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

**PROTALEX, INC.**

**3,470,990 Shares of**

**Common Stock**

This prospectus is part of a registration statement of Protalex, Inc. filed with the Securities and Exchange Commission. This prospectus relates to the resale by selling stockholders of up to 3,470,990 shares of our common stock, of which 2,595,132 shares are currently outstanding and 875,858 shares are issuable upon exercise of warrants granted to these selling stockholders and certain placement agents (collectively, the "Holders"). We will not receive any proceeds from the sale of the shares by these Holders. The Holders may sell common stock from time to time in the principal market on which the stock is traded at the prevailing market price or in negotiated transactions.

Our common stock is listed on the Over-the-Counter Bulletin Board, or OTCBB, under the symbol "PRTX.OB." The last reported sales price per share of our common stock, as reported by the OTCBB on January 23, 2006, was \$2.81.

**Investing in our common stock involves a high degree of risk. 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.**

The date of this prospectus is \_\_\_\_\_, 2006.

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**WE HAVE NOT AUTHORIZED ANY DEALER, SALESPERSON OR OTHER PERSON TO GIVE ANY INFORMATION OR REPRESENT ANYTHING NOT CONTAINED IN THIS PROSPECTUS. YOU SHOULD NOT RELY ON ANY UNAUTHORIZED INFORMATION. THIS PROSPECTUS DOES NOT OFFER TO SELL OR BUY ANY SHARES IN ANY JURISDICTION IN WHICH IT IS UNLAWFUL. THE INFORMATION IN THIS PROSPECTUS IS CURRENT AS OF THE DATE ON THE COVER AND MAY NOT BE CURRENT AS OF ANY SUBSEQUENT DATE.**

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### NOTICE ABOUT FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. To the extent that the information presented in this prospectus discusses financial projections, information or expectations about our business plans, results of operations, products or markets, or otherwise makes statements about future events, such statements are forward-looking. Words such as “may,” “will,” “should,” “could,” “would,” “predicts,” “potentially,” “could,” “may,” “anticipates,” “believes,” “estimates,” “projects,” “forecasts,” “expects,” “plans” and “proposes,” as well as statements in future tense, identify forward-looking statements. Forward looking statements include, without limitation:

- statements about our product development and commercialization goals and expectations;
  - potential market opportunities;
- our plans for and anticipated results of our clinical development activities;
  - the potential advantage of our product candidates;

• statements about our future capital requirements, the sufficiency of our capital resources to meet those requirements and the expected composition of our capital resources; and

- other statements that are not historical facts.

Forward-looking statements are based on the judgment of management at the time the statements are made. Inaccurate assumptions and known and unknown risks and uncertainties can affect the accuracy of forward-looking statements. These include, among others, the cautionary statements in the “Risk Factors” and “Management’s Discussion and Analysis or Plan of Operation” sections of this prospectus. These cautionary statements identify important factors that could cause actual results to differ materially from those described in the forward-looking statements. When considering forward-looking statements in this prospectus, you should keep in mind the cautionary statements in the “Risk Factors” and “Management’s Discussion and Analysis or Plan of Operation” sections, and other sections of this prospectus.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this prospectus. We undertake no obligation to publicly update any forward-looking statement to reflect new information, events or circumstances, whether anticipated or unanticipated, or to conform the statement to actual results or changes in our expectations.

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## PROSPECTUS SUMMARY

*The following summary highlights selected information contained in this prospectus. This summary does not contain all the information you should consider before investing in our securities. Before making an investment decision, you should read the entire prospectus carefully, including the “Risk Factors” section, the financial statements and the notes to the financial statements. Unless otherwise indicated or required by the context, as used in this prospectus, the terms “we,” “our,” “us” and “the Company” refer to Protalex, Inc.*

### Our Company

We are a development stage company engaged in developing a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases. Autoimmune diseases occur when the body’s immune system attacks itself. We are creating a class of human pharmaceuticals from organic molecules to regulate the immune system with persisting effects. Our initial autoimmune disease target is Idiopathic Thrombocytopenic Purpura, or ITP, followed by Rheumatoid Arthritis, or RA. We plan to bring to market our lead product, PRTX-100, a drug designed to combat the effects of ITP, RA and, potentially, other autoimmune diseases. We have completed pre-clinical studies on PRTX-100 and filed an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, on March 4, 2005. On March 31, 2005, the FDA verbally disclosed to the Company that it had placed the Company’s IND on clinical hold, pending additional product characterization. On August 10, 2005, the Company formally replied to the FDA. On September 9, 2005, the FDA notified the Company that it had lifted the clinical hold on the Company’s IND and that the Company’s proposed study could proceed. The Company commenced with the Phase I clinical trial on December 5, 2005. The Company anticipates that this clinical trial will be completed in the fourth fiscal quarter of 2006.

Our predecessor corporation was incorporated on April 23, 1958, as “Ideal Homes, Inc.,” which changed its name to Enerdyne Corporation (Enerdyne) and became a publicly traded company. We acquired Enerdyne through a reverse merger in November 1999. Since that time, our focus has been on the development of autoimmune drugs, as discussed above. Our corporate headquarters is located at 145 Union Square Drive, New Hope, Pennsylvania 18938, and our telephone number is (215) 862-9720.

Our continued existence and plans for future growth depend on our ability to obtain the capital necessary to develop a successful product through the issuance of additional debt or equity. As of November 30, 2005, our cumulative net loss was \$15,053,173. We currently do not have a product in the market, and we need to obtain additional financing and develop an approved drug to sustain our existence. We estimate it will require approximately \$43,000,000 to develop PRTX-100.

In September 2003, May 2005 and December 2005, we raised \$12,657,599, \$5,057,885 and \$5,839,059, respectively, through private placements of our common stock and warrants to various institutional and other accredited investors. This capital has been used to continue our operations from September 2003 to the present. The additional capital that would be required for us to continue our operations is discussed in the risk factor entitled “If we cannot raise additional capital on acceptable terms, we will be unable to complete planned clinical trials, obtain regulatory approvals or commercialize our product candidates” on page 5 of this prospectus. Details of our liquidity and capital resources are also discussed in “Management’s Discussion and Analysis or Plan of Operation” on page 20.

### Recent Developments

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On December 30, 2005, we raised \$5,839,059 through the sale of 2,595,132 shares of our common stock at \$2.25 per share, with warrants to purchase an additional 648,784 shares of our common stock, at an exercise price of \$2.99 per share. In addition, in connection with this financing, the Company issued warrants to purchase 227,074 shares of common stock, at an exercise price of \$2.99 per share, to its placement agents as partial commission compensation. All of the warrants expire on December 30, 2010. This registration statement is being filed to cover these securities.

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**The Offering**

Common stock offered by selling stockholders (including shares underlying warrants)	3,470,990 shares.
Common stock to be outstanding after the offering	26,208,069 shares (1).
Use of proceeds	We will not receive proceeds from the resale of shares by the selling stockholders. If all warrants held by the selling stockholders are exercised, our proceeds from the exercise of those warrants would be approximately \$2.6 million.
Over-the-Counter Bulletin Board symbol	PRTX.OB

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(1)Based on 22,038,353 shares of common stock outstanding as of January 23, 2006 and 5,045,574 shares issuable upon exercise of warrants relating to the financing transactions in September 2001, September 2003 and May 2005 but excludes: (i) up to 4,006,805 shares of common stock issuable upon exercise of employee and director stock options.



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## RISK FACTORS

*This investment involves a high degree of risk. Before you invest, you should carefully consider the risks and uncertainties described below and the other information in this prospectus. If any of the following risks are realized, our business, operating results and financial condition could be harmed and the value of our stock could go down. This means you could lose all or a part of your investment.*

### **Risks Related to Our Business**

#### **We have a history of significant losses, and we may never achieve or sustain profitability.**

We are focused on product development and have not generated any revenues to date. We have incurred operating losses each year of our operations and we expect to continue to incur operating losses for the next several years. We may never become profitable. The process of developing our products requires significant clinical development and laboratory testing and clinical trials, as well as regulatory approvals. In addition, commercialization of our targeted products will require the establishment of sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect our research and development and general and administrative expenses will increase over the next several years and, as a result, we expect our losses will increase. As of November 30, 2005, our cumulative net loss was \$15,053,173. Our net loss was \$5,567,729 for the fiscal year ended May 31, 2005 (\$12,307,203 cumulatively through May 31, 2005) and \$2,745,970 for the subsequent six months. Our continued operational loss may lower the value of our common stock and may jeopardize our ability to continue our operations.

#### **If we fail to obtain regulatory approvals for PRTX-100 or any other drug we develop, we will not be able to generate revenues from the commercialization or sale of those drugs.**

We must receive regulatory approval of each of our drugs before we can commercialize or sell that product. The pre-clinical laboratory testing, formulation development, manufacturing and clinical trials of any product we develop, as well as the distribution and marketing of these products, are regulated by numerous federal, state and local governmental authorities in the United States, principally the FDA, and by similar agencies in other countries. The development and regulatory approval process takes many years, requires the expenditure of substantial resources, is uncertain and subject to delays, and will thus delay our receipt of revenues, if any, from PRTX-100 or any other drug we develop. We cannot assure you that our clinical trials will demonstrate the safety and efficacy of PRTX-100 or any other drug we develop or will result in a marketable product.

No product can receive FDA approval unless human clinical trials show both safety and efficacy for each target indication in accordance with FDA standards. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in early stage development. We therefore cannot assure you that the results from our pre-clinical trials for PRTX-100 or any other drug we develop will be predictive of results obtained in future clinical trials. Further, data obtained from pre-clinical and clinical activities are subject to varying interpretations that could delay, limit or prevent regulatory agency approval. We cannot assure you that our trials will establish the safety and efficacy of PRTX-100 or any other drug we develop sufficiently for us to obtain regulatory approval.

#### **If we are unable to enroll enough patients to complete our clinical trials, regulatory agencies may delay their review of or reject our applications, which may result in increased costs and harm our ability to develop products.**

Regulatory agencies may delay reviewing our applications for approval, or may reject them, based on our inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. Delays in planned patient enrollment may result in increased costs and delays, which could have a harmful effect on our ability to develop products. We may also encounter delays or rejections based on changes in regulatory agency policies during the period in which we develop a drug or the period required for review of any application for regulatory agency approval of a particular compound. We also may encounter delays if we are unable to produce clinical trial material in sufficient quantities and of sufficient quality to meet the schedule for our planned clinical trials. In addition, we rely on a number of third-parties, such as clinical research organizations, to help support the clinical trials by performing independent clinical monitoring, data acquisition and data evaluations. Any failure on the part of these third-parties could delay the regulatory approval process.

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**Our products, if approved, may fail to achieve market acceptance.**

There can be no assurance that any products we successfully develop, if approved for marketing, will achieve market acceptance or generate significant revenues. We intend for our products, including PRTX-100, to replace or alter existing therapies or procedures, and hospitals, physicians or patients may conclude that these products are less safe or effective or otherwise less attractive than existing therapies or procedures. If our products do not receive market acceptance for any reason, it would adversely affect our business, financial condition and results of operations.

Further, our competitors may develop new technologies or products that are more effective or less costly, or that seem more cost-effective, than our products. We can give no assurance that hospitals, physicians, patients or the medical community in general will accept and use any products that we may develop.

**If we cannot raise additional capital on acceptable terms, we will be unable to complete planned clinical trials, obtain regulatory approvals or commercialize our product candidates.**

We will require substantial future capital in order to continue to conduct the research and development, clinical and regulatory activities necessary to bring our products to market and to establish commercial manufacturing, marketing and sales capabilities. Our future capital requirements will depend on many factors, including:

- the progress of pre-clinical development and laboratory testing and clinical trials;
- time and costs involved in obtaining regulatory approvals;
- the number of products we pursue;
- costs in filing and prosecuting patent applications and enforcing or defending patent claims; and
- the establishment of selected strategic alliances and activities required for product commercialization.

In order to raise additional capital, we would seek funding through private or public sales of our securities. This funding may significantly dilute existing stockholders and, if we are able to obtain this funding from one or more strategic partners, they may limit our rights to our technology. No assurance can be given that we will be able to obtain additional financing on favorable terms, if at all. If we were to encounter any future problems with our previously filed and approved IND application or otherwise advance in the FDA approval process, our ability to sustain our operations would be significantly jeopardized.

**If we are unable to protect, obtain and maintain our proprietary rights, we may not be able to compete effectively or operate profitably.**

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology covering our product candidates and avoiding infringement of the proprietary technology of others. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our industry are still evolving. However, we will be able to protect our proprietary rights from unauthorized use by third-parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.



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We have tried to protect our proprietary position by filing a U.S. patent application related to PRTX-100. Because the patent position of pharmaceutical companies involves complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own may not provide any protection against competitors. Our pending patent application or those we may file in the future or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed, or designed around any patents we may have issued to us. Moreover, the laws of foreign countries do not protect intellectual property rights to the same extent as the laws of the United States.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, licensors, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent was to be disclosed to or independently developed by a competitor, our business and financial condition could be adversely affected.

**If other companies claim that we infringe their proprietary technology, we may incur liability for damages or be forced to stop our development and commercialization efforts.**

Competitors and other third-parties may initiate patent litigation against us in the United States or in foreign countries based on existing patents or patents that may be granted in the future. These lawsuits can be expensive and would consume time and other resources even if unsuccessful or brought without merit. Our competitors may have sought or may seek patents that cover aspects of our technology.

We are aware that a third-party has a pending patent application for technologies generally related to ours, and more patents for similar technologies may be filed in the future. In the United States, patent applications may remain confidential after filing or publish 18 months after filing.

Owners or licensees of patents may file one or more infringement actions against us. Any such infringement action could cause us to incur substantial costs defending the lawsuit and could distract our management from our business, even if the allegations of infringement or misappropriation are unwarranted. The defense of multiple claims could have a disproportionately greater impact. Furthermore, an adverse outcome from this type of claim could have subject us to a judgment that requires us to pay substantial damages. A judgment could also include an injunction or other court order that could prevent us from making, using, selling, offering for sale or importing our products or prevent our customers from using our products. Alternatively, we could be required to license disputed rights from the third party. If a court determines, or if we independently discover, that any of our products or manufacturing processes violates third-party proprietary rights, we might not be able to reengineer the product or processes to avoid those rights, or obtain a license under those rights on commercially reasonable terms, if at all.

**We may become involved in lawsuits to protect or enforce our patents that would be expensive and time consuming.**

In order to protect or enforce our patent rights, we may initiate patent litigation against third-parties. In addition, we may become subject to interference or opposition proceedings conducted in patent and trademark offices to determine the priority of inventions. The defense of intellectual property rights, including patent rights through lawsuits,

interference or opposition proceedings, and other legal and administrative proceedings, would be costly and divert our technical and management personnel from their normal responsibilities. An adverse determination of any litigation or defense proceedings could put our patent application at risk of not issuing.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. For example, during the course of this kind of litigation, confidential information may be inadvertently disclosed in the form of documents or testimony in connection with discovery requests, depositions or trial testimony. This disclosure could negatively affect our business and financial results.

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**If third-party manufacturers of our products fail to devote sufficient time and resources to our concerns, or if their performance is substandard, our clinical trials and product introductions may be delayed and our costs may rise.**

We have relied on, and intend to rely in the future, in part, on third-party contract manufacturers to supply, store and distribute PRTX-100 and other potential products. Any products we develop may be in competition with other product candidates and products for access to these facilities. Thus, we may not be successful in contracting with third-party manufacturers, or they may not be able to manufacture these candidates and products in a cost-effective or timely manner. Additionally, our reliance on third-party manufacturers exposes us to the following risks, any of which could delay or prevent the completion of (x) our clinical trials, (y) the approval of our products by the FDA or (z) the commercialization of our products, resulting in higher costs or depriving us of potential product revenues:

- Contract manufacturers are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. Their failure to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the availability of material for clinical study and may delay or prevent filing or approval of marketing applications for our products. Additionally, failure to achieve and maintain high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously hurt our business.
- It may be difficult or impossible for us to find replacement manufacturers quickly on acceptable terms, or at all. For example, we have initially relied on a single contract manufacturer, Eurogentec S.A., to produce PRTX-100. Changing this manufacturer, or changing the manufacturer for any other products we develop, may be difficult. The number of potential manufacturers is limited, and changing manufacturers may require confirmation of the analytical methods of the manufacturing processes and procedures in accordance with FDA-mandated cGMPs. Such confirmation of the analytical methods may be costly and time-consuming.
- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to produce, store and distribute our products successfully.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Agency, and corresponding state and foreign agencies to ensure strict compliance with cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit the performance of third-party contractors, we do not have control over our third-party manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

Eurogentec S.A. has produced a sufficient inventory of PRTX-100 to conduct our Phase I and Phase II clinical trials. If these inventories are lost or damaged, or if Eurogentec cannot produce additional inventory to complete the remaining phases of clinical trials, the clinical development of our product candidate or its submission for regulatory approval could be delayed, and our ability to commercialize this product could be impaired or precluded.

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**We may not be able to manufacture our products in commercial quantities, which would prevent us from marketing our products.**

To date, PRTX-100 has been manufactured in enough quantities to conduct our Phase I and Phase II clinical trials. If this product were approved by the FDA for commercial sale, we would need to manufacture it in larger quantities. We have no manufacturing facilities at this time, and we have no experience in the commercial manufacturing of drugs and limited experience in designing drug manufacturing equipment. Thus, we would need to either develop the capability of manufacturing on a commercial scale or engage third-party manufacturers with this capability. Significant scale-up of manufacturing may require certain additional validation studies, which the FDA must review and approve. Moreover, contract manufacturers often encounter difficulties in achieving volume production, quality control and quality assurance, as well as shortages of qualified personnel. For these reasons, a third-party manufacturer might not be able to manufacture sufficient quantities of PRTX-100 to allow us to commercialize it. If we are unable to increase the manufacturing capacity for PRTX-100, or any other product we may develop, we may experience delays in or shortages in supply when launching them commercially.

**We have no experience selling, marketing or distributing our products and no internal capability to do so.**

If we receive regulatory approval to commence commercial sales of PRTX-100, we will face competition with respect to commercial sales, marketing and distribution. These are areas in which we have limited experience. To market our product directly, we must develop a direct marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. There can be no assurance that we will successfully establish sales and distribution capabilities either on our own or in collaboration with third-parties or gain market acceptance for our product. To the extent we enter co-promotion or other licensing arrangements, any revenues we receive will depend on the efforts of third-parties. Those efforts may not succeed.

**Competition in the pharmaceutical industry is intense; if we fail to compete effectively, our financial results will suffer.**

We engage in a business characterized by extensive research efforts, rapid developments and intense competition. We cannot assure you that our products will compete successfully or that research and development by others will not render our products obsolete or uneconomical. Our failure to compete effectively would negatively affect our business, financial condition and results of operations. We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price. Specifically, other factors we expect will impact our ability to compete include the relative speed with which we can develop products, complete the clinical, development and laboratory testing and regulatory approval processes and supply commercial quantities of the product to the market.

We expect competition to increase as technological advances are made and commercial applications broaden. In commercializing PRTX-100 and any additional products we develop using our technology, we will face substantial competition from large pharmaceutical, biotechnology and other companies, universities and research institutions.

Most of our competitors have substantially greater capital resources, research and development staffs, facilities and experience in conducting clinical trials and obtaining regulatory approvals than us. As well, some of our competitors have advantages over us in manufacturing and marketing pharmaceutical products. We are thus at a competitive disadvantage to those competitors who have greater capital resources and we may not be able to compete effectively.



**If we are unable to retain key personnel and hire additional qualified scientific, sales and marketing, and other personnel, we may not be able to achieve our goals.**

We depend on the principal members of our scientific and management staff, including Steven H. Kane, our president and chief executive officer, Victor S. Sloan, M.D., our senior vice president and chief medical officer, and Marc L. Rose, CPA, our vice president of finance, chief financial officer, treasurer and corporate secretary. The loss of any of these individuals' services might significantly delay or prevent the achievement of research, development or business objectives and could negatively affect our business, financial condition and results of operations. We do not maintain key person life insurance on any of these individuals.

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Mr. Kane, who joined us in December 2002, Dr. Sloan, who joined us in August 2005 and Mr. Rose, who joined us in November 2004, are key additions to our management team and will be critical to directing and managing our growth and development in the future. We are not aware of any present intention of any of these individuals to leave our Company.

Our success depends, in large part, on our ability to attract and retain qualified scientific and management personnel such as these individuals. We face intense competition for such personnel and consultants. We cannot assure you that we will attract and retain qualified management and scientific personnel in the future.

Further, we expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, contract manufacturing and marketing, will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. The failure to attract and retain such personnel or to develop such expertise could reduce prospects for our success.

**Risks Relating to Our Industry**

**Even if we obtain marketing approval, PRTX-100 will be subject to ongoing regulatory review.**

If regulatory approval of PRTX-100 is granted, that approval may be subject to limitations on the indicated uses for which it may be marketed or contain requirements for costly post-marketing follow-up studies. As to products for which marketing approval is obtained, the manufacturer of the product and the manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other regulatory authorities. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product will remain subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or the manufacturer, including withdrawal of the product from the market. We may be slow to adapt, or we may never adapt, to changes in existing requirements or adoption of new requirements or policies.

If we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

**Market acceptance of PRTX-100 will be limited if users are unable to obtain adequate reimbursement from third-party payors.**

Government health administration authorities, private health insurers and other organizations generally provide reimbursement for products like PRTX-100, and our commercial success will depend in part on these third-party payors agreeing to reimburse patients for the costs of our product. Even if we succeed in bringing our proposed products to market, we cannot assure you that third-party payors will consider it cost-effective or provide reimbursement in whole or in part for its use.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. PRTX-100 is intended to replace or alter existing therapies or procedures. These third-party payors may conclude that our product is less safe, effective or cost-effective than existing therapies or procedures. Therefore, third-party payors may not approve our product for reimbursement.

If third-party payors do not approve our product for reimbursement or fail to reimburse them adequately, sales will suffer as some physicians or their patients will opt for a competing product that is approved for reimbursement or is adequately reimbursed. Even if third-party payors make reimbursement available, these payors' reimbursement policies may adversely affect our ability to sell our product on a profitable basis.

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Moreover, the trend toward managed healthcare 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 reduced demand for our product, which could adversely affect our business, financial condition and results of operations.

In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after the FDA or other regulatory agencies approve PRTX-100 for marketing. While we cannot predict the likelihood of any of these legislative or regulatory proposals, if any government or regulatory agencies adopt these proposals they could negatively affect our business, financial condition and results of operations.

**We may be required to defend lawsuits or pay damages in connection with the alleged or actual harm caused by our products.**

We face an inherent business risk of exposure to product liability claims in the event that the use of any of our products is alleged to have resulted in harm to others. This risk exists in clinical trials as well as in commercial distribution. In addition, the pharmaceutical and biotechnology industries in general have been subject to significant medical malpractice litigation. We may incur significant liability if product liability or malpractice lawsuits against us are successful. Furthermore, product liability claims, regardless of their merits, could be costly and divert our management's attention from other business concerns, or adversely affect our reputation and the demand for our product. We currently maintain a \$1,000,000 general liability insurance policy and a \$3,000,000 clinical liability insurance policy. We intend to expand our liability insurance coverage to any products for which we obtain marketing approval, however, such insurance may be unavailable, prohibitively expensive or may not fully cover our potential liabilities. If we are unable to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims or field actions, we may be unable to continue to market our products and develop new markets.

**Rapid technological change could make our products obsolete.**

Pharmaceutical technologies have undergone rapid and significant change. We expect that pharmaceutical technologies will continue to develop rapidly. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any compound, product or process we develop may become obsolete before we recover any expenses incurred in connection with their development. Rapid technological change could make our products obsolete, which could negatively affect our business, financial condition and results of operations.

**Risks Related to Our Common Stock**

**Our common stock has experienced in the past, and may experience in the future, significant price volatility, which substantially increases the risk of loss to persons owning our common stock.**

The stock market, particularly in recent years, has experienced significant volatility particularly with respect to pharmaceutical and biotechnology stocks. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause this volatility in the market price of our common stock include:

· announcements of the introduction of new products by us or our competitors;

· market conditions in the pharmaceutical and biotechnology sectors;

· rumors relating to us or our competitors;

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litigation or public concern about the safety of our potential products;

our quarterly operating results;

deviations in our operating results from the estimates of securities analysts; and

FDA or international regulatory actions.

Because of the limited trading market for our common stock, and because of the significant price volatility, you may not be able to sell your shares of common stock when you desire to do so. In the fiscal year ended May 31, 2005, our stock price ranged from a high of \$2.95 to a low of \$1.95 per share, and during the first two quarters of the current fiscal year, our stock price ranged from a high of \$3.10 to a low of \$2.00. The inability to sell your shares in a rapidly declining market may substantially increase your risk of loss as a result of such illiquidity and because the price for our common stock may suffer greater declines due to its price volatility.

**We may be the subject of securities class action litigation due to future stock price volatility.**

In the past, when the market price of a stock has been volatile, holders of that stock have periodically instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

**Future sales of common stock by our existing stockholders may cause our stock price to fall.**

We are registering for resale by selling stockholders up to 3,470,990 shares of our common stock. These shares represent approximately 15% of our total outstanding common stock assuming full exercise of the warrants issued in December 2005 and held by the selling stockholders. The market price of our common stock could decline as a result of sales by our existing stockholders of shares of common stock in the market after this offering or the perception that these sales could occur. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate and thus inhibit our ability to raise additional capital when it is needed.

**We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.**

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any future debt or credit facility may preclude us from paying these dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**Our common stock is subject to the penny stock rules.**

Our common stock is subject to Rules 15g-1 through 15g-9 under the Securities Exchange Act of 1934, as amended, which impose certain sales practice requirements on broker-dealers which sell our common stock to persons other than established customers and “accredited investors” (generally, individuals with a net worth in excess of \$1,000,000 or annual incomes exceeding \$200,000 (or \$300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser’s written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our

common stock and purchasers of our common stock to sell their shares of such common stock. Additionally, our common stock is subject to the SEC regulations for “penny stock.” Penny stock includes any non-Nasdaq equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock which disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

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**PREVIOUS FINANCINGS**

Effective December 30, 2005, the Company entered into the following material definitive agreements:

- (1) Warrant and Common Stock Purchase Agreement dated December 22, 2005, or the Purchase Agreement among the Company and the several purchasers listed on Exhibit A thereof, or the Purchasers.
- (2) Registration Rights Agreement dated December 22, 2005 by and among, the Company and the Purchasers, and Griffin Securities, Inc. and Mufson, Howe, Hunter and Company, LLC, or together the Placement Agents.
- (3) Warrant dated December 30, 2005 among the Company and each Purchaser and Placement Agent.

Pursuant to the Purchase Agreement, the Company commenced a financing transaction in which effective as of December 30, 2005 the Purchasers became obligated to purchase (x) 2,595,132 shares of common stock at \$2.25 per share, or the Shares, for an aggregate cash consideration of \$5,839,059 and (y) warrants to purchase 648,784 shares of common stock at an exercise price of \$2.99 per share, or the 2005 Warrants, for nominal consideration. The 2005 Warrants expire on December 30, 2010 and provide for a net issue exercise feature and antidilution protection for certain equity issued below the exercise price.

The Company issued warrants, or the Comp Warrants, to purchase common stock in the aggregate amount of 227,074 shares to the Placement Agents as partial commission compensation in connection with the financing transactions contemplated in the Purchase Agreement. The terms of the Comp Warrants are essentially identical to the 2005 Warrants.

Pursuant to the Registration Rights Agreement, the Company is also obligated to file a resale Registration Statement on Form SB-2 by January 29, 2006 which will register the Shares and the shares issuable upon exercise of the 2005 Warrants and Comp Warrants or together the Registrable Securities, with the Securities and Exchange Commission, or SEC. In addition, the Purchasers are entitled to certain demand and piggyback registration rights. In the event the Company has not filed the Registration Statement by January 29, 2006, (the "the Filing Default Date"), the Company has agreed to pay liquidated damages to each purchaser, from and including the day following such Filing Default Date until the date that the Registration Statement is filed with the SEC, at a rate per month (or portion thereof) equal to 0.50% of the total purchase price of the Shares purchased by such purchaser pursuant to the Purchase Agreement, (the "Default Rate"). In addition, if the Registration Statement is not declared effective by the SEC by June 22, 2006, (the "Registration Default Date"), the Company has agreed to pay liquidated damages to each purchaser, from and including the day following such Registration Default Date until the earlier of (i) the time that the Registration Statement is declared effective by the SEC, or (ii) the time as all remaining Registrable Securities held by such purchaser (assuming cashless exercise of the 2005 Warrants) may be sold without restriction under Rule 144(k) (or successor rule), at the Default Rate.

Included among the Purchasers were Company Directors Peter G. Tombros and Frank M. Dougherty and 10% or greater stockholder and former director John E. Doherty.

**USE OF PROCEEDS**

This prospectus relates to 2,595,132 shares of our common stock, which may be sold from time to time by the selling stockholders. We will not receive any part of the proceeds from the sale of common stock by the selling stockholders.





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If all warrants issued in December 2005 that are held by the selling stockholders are exercised, our proceeds from the exercise of those warrants would be approximately \$2.6 million. We intend to use any proceeds we receive from the exercise of those warrants for general corporate purposes.

**MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

The following table sets forth, for the fiscal periods indicated, the high and low sale prices for the common stock of Protalex for the last two fiscal years. Our common stock is traded on the OTCBB under the stock symbol "PRTX.OB." The market represented by the OTCBB is extremely limited and the price for our common stock quoted on the OTCBB is not necessarily a reliable indication of the value of our common stock. Quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	High	Low
<b>Fiscal Year Ended May 31, 2004</b>		
First Quarter	\$ 3.30	\$ 1.50
Second Quarter	5.70	2.40
Third Quarter	2.80	2.25
Fourth Quarter	2.55	1.45
<b>Fiscal Year Ended May 31, 2005</b>		
First Quarter	\$ 2.95	\$ 2.15
Second Quarter	2.95	2.25
Third Quarter	2.95	1.95
Fourth Quarter	2.95	1.95
<b>Fiscal Year Ended May 31, 2006</b>		
First Quarter	\$ 2.95	\$ 2.00
Second Quarter	3.10	2.20

Our common stock is subject to Rules 15g-1 through 15g-9 under the Exchange Act, which impose certain sales practice requirements on broker-dealers who sell our common stock to persons other than established customers and accredited investors (generally, individuals with net worth in excess of \$1,000,000 or annual incomes exceeding \$200,000 (or \$300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale.

As of January 23, 2006, we had 22,038,353 shares of common stock outstanding, which were held by approximately 480 stockholders of record. The transfer agent for our common stock is Wachovia Bank, 1525 West W.T. Harris Blvd., Bldg. 3C, 3rd Floor, Charlotte, NC 28262. In December 2005, Wachovia Bank sold its stock transfer business to American Stock Transfer & Trust Company or AST. At this time, no changes in personnel or location have been provided to the Company, and we anticipate normal business relations with AST.

**DIVIDEND POLICY**

Our board of directors determines any payment of dividends. We have never declared or paid cash dividends on our common stock. We do not expect to authorize the payment of cash dividends on our shares of common stock in the foreseeable future. Any future decision with respect to dividends will depend on future earnings, operations, capital requirements and availability, restrictions in future financing agreements and other business and financial

considerations.

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## BUSINESS

### Overview

In September 1999, Protalex acquired a majority of the issued and outstanding shares of common stock of Enerdyne from Don Hanosh, pursuant to a Stock Purchase Agreement between Protalex, Enerdyne and Mr. Hanosh. In November 1999, Protalex merged with and into Enerdyne pursuant to a Merger Agreement and Plan of Reorganization, and Enerdyne changed its name to Protalex, Inc. After the merger, Protalex's former stockholders held approximately 92% of the shares of common stock of the Company, and Enerdyne's former stockholders held approximately 8% of the shares of common stock of the Company. On December 1, 2004, Protalex, Inc., a New Mexico corporation, consummated a merger with and into its newly-formed, wholly-owned subsidiary, Protalex Delaware in order to reincorporate in the State of Delaware. Following our reincorporation, our authorized capital stock consists of 100,000,000 shares of \$0.00001 par value common stock.

We are a development stage company engaged in developing a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases. Our lead product, PRTX-100, has demonstrated effectiveness in pre-clinical studies in regulating the immune system with persisting effects. However, the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we will see in our clinical trials. We currently have no product on the market. The autoimmune diseases initially targeted by the Company are ITP and RA.

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. According to the Platelet Disorders Support Association, approximately 200,000 individuals are affected by ITP, with women affected approximately three times as often as men. It can affect all ages and ethnic groups, and about 50% of the new cases occur in children. Current treatment includes corticosteroids and removal of the spleen. Although most cases can be controlled with therapy, the treatments can have significant side effects and there is currently no broadly effective curative therapy.

RA is an autoimmune disease that causes the inflammation of the membrane lining multiple joints, resulting in pain, stiffness, warmth, redness and swelling. The inflamed joint lining, the synovium, can invade and damage bone and cartilage. Inflammatory cells release enzymes and cytokines that may damage bone and cartilage. The involved joint can lose its shape and alignment, resulting in pain and loss of movement. According to the National Institute of Health, scientists estimate that RA affects approximately 2.1 million Americans. According to the Merck Manual of Health & Aging, RA affects about 1% of the population worldwide.

Our bioregulatory compounds are based on the principle of normalizing the activities of immune cells at a more basic level than traditional pharmaceutical agents, which act upon the end products of complex body functions. In autoimmune disease models, PRTX-100, which is a natural compound, has reversed the pathologic process resulting in a restoration and maintenance of normal healthy tissue. We intend to bring this biotechnology to bear on a range of serious autoimmune diseases that affect millions of sufferers worldwide, for indications such as Pemphigus, Systemic Lupus Erythematosus, Psoriasis, Inflammatory Bowel Disease (Crohn's disease and Ulcerative colitis), Insulin-dependent Diabetes Mellitus, and Multiple Sclerosis. To date, however, we have not conducted any pre-clinical trials related to the treatment of these diseases which would require substantial additional capital infusions.

We are creating a class of human pharmaceuticals from organic molecules to regulate the immune system with persisting effects. We plan to bring to market our lead product, PRTX-100, a drug designed to combat the effects of ITP, RA and, potentially, other autoimmune diseases. We have completed pre-clinical studies on PRTX-100 and filed an Investigational New Drug, or IND, application with the FDA on March 4, 2005. On March 31, 2005, the FDA verbally disclosed to the Company that it had placed the Company's IND on clinical hold, pending additional product characterization. On August 10, 2005, the Company formally replied to the FDA. On September 9, 2005, the FDA notified the Company that it had lifted the clinical hold on the Company's IND and that the Company's proposed study could proceed. The Company commenced with the Phase I clinical trial on December 5, 2005. The Company anticipates that this clinical trial will be completed in the fourth fiscal quarter of 2006.

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We are also broadening our intellectual property and developing our management team, facilities and operational infrastructure for commercialization of our products. Our business and laboratory operations are located in New Hope, Pennsylvania. We also outsource some of our activities to premier contract organizations and facilities. For example, we have completed the manufacturing of PRTX-100 under Current Good Manufacturing Practices (cGMP) in quantities we believe are sufficient for upcoming human Phase I and Phase II clinical trials. We also plan to contract with a third-party site management organization to run our clinical trials in the United States and potentially in international locations.

Our in-house research includes demonstrating the efficacy of PRTX-100 in well established and characterized animal models of RA and other autoimmune diseases. For example, we have tested PRTX-100 in murine collagen induced arthritis, or CIA, model of human RA. This is the model that was used to test the efficacy of the FDA approved drug, etanercept, or Enbrel™. PRTX-100 has also demonstrated its efficacy in an animal model of Systemic Lupus Erythematosus. Our scientists are also investigating the mechanism of action and developing a second-generation class of compounds. Laboratory staff are also developing analytical methods to screen derivative compounds for bioactivity, measure drug concentrations in the blood, and measure systemic effects to be used in evaluating the efficacy and safety data in human clinical trials.

Pre-clinical safety studies for PRTX-100 have been conducted and so far no evidence of abnormal clinical reactions or toxicity has been observed. These studies and the pre-clinical efficacy studies were the foundation for the IND application. IND-related activities included manufacturing and formulation of PRTX-100 for animal toxicity testing and for Phase I and II human clinical trials, arranging for packaging and testing, designing clinical trial protocols, and planning the clinical trials with physicians who will be investigators in the trials.

We have concluded seven prior private placements of our common stock, raising a total of \$27.0 million in the aggregate and carrying us through early research, pre-clinical and early stage clinical trials. The most recent private placement in December 2005 raised approximately \$5.8 million. Since we have commenced with our Phase I clinical trial, we anticipate that we will need to raise additional capital in the second half of calendar year 2007 to fund the ongoing FDA approval process.

As our lead product moves closer to the marketing stage, we intend to look for opportunities to enter into collaborative arrangements with larger strategic partners to market and sell our products in the United States and in foreign markets. We also intend to seek out partners who would be responsible for funding or reimbursing all or a portion of the costs of pre-clinical and clinical trials required obtaining regulatory approval. In return for such payments, we could grant these partners' rights to market certain of our products in particular geographical regions. We are also evaluating the alternative approach of pursuing our programs independently with the intention of becoming a fully integrated biopharmaceutical company.

**About Bioregulation**

The immune system exists to protect the body from foreign agents such as bacteria and viruses. In a normal functioning system, a complex set of interactions results in the destruction of these outside bodies. An important aspect of this process is the ability to recognize self (normal tissue) from non-self (foreign agents). Autoimmune diseases such as ITP, RA and others result when this self-recognition goes awry and the immune system mistakenly identifies normal tissue as foreign. In RA, the dysregulation of the immune system causes the joint lining to form invasive tissue that degrades cartilage and bone. With the current treatments available, prevention of long-term damage in RA requires ongoing indefinite drug therapy. The vast majority of FDA approved drugs for the treatment of RA carry significant side effects such as potential infections and development of cancer. They generally target specific products of the immune response that are formed well after the system has lost its ability to self-regulate. We believe

our bioregulatory compound PRTX-100 has the potential to restore normal immune response by targeting the disease at its source.

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We have discovered a method of “restoring” the immune system through the use of a natural compound called PRTX-100, which has been shown to have no side effects at treatment dosages in animal studies. It also has been shown to work very early in the immune response to prevent the activation of lymphoid cells and the secretion of pathogenic cytokines. In the animal model specifically designed to evaluate the efficacy of anti-arthritic drugs, PRTX-100 has not only inhibited the development of inflammation, but also repaired and/or reversed the tissue damage caused by inflammatory response.

**Animal Studies**

Protalex’s lead candidate PRTX-100 has proven effective in two clinical standard mouse autoimmune models:

*Collagen-Induced Arthritis* -- PRTX-100 has demonstrated reproducible efficacy in a well-established animal model of RA. Mice received two injections of collagen in order to stimulate an inflammatory response. One group was treated with various doses of PRTX-100, a second group received Enbrel™, a leading commercially available treatment for RA, and the control group was injected with vehicle saline solution. The mice were observed for clinical symptoms, joint size and loss of function. The results showed that very low doses of PRTX-100 and standard doses of Enbrel™ suppressed clinical symptoms including joint swelling over the first two to three weeks of treatment, and slowed disease progression as compared with the control group. Thereafter, the PRTX-100-treated mice continued to remain disease-free whereas the mice treated with Enbrel™ showed a resumption of joint inflammation and tissue damage. This response to Enbrel™ was expected because the mice developed immune response to it because it is a foreign protein. Overall, these results indicate that PRTX-100 is a potential treatment for RA in humans. The data from these studies has been used to serve as a rationale for conducting clinical trials in human patients.

*BXSB Mice* -- These animals are genetically predisposed to autoimmune diseases. This model is used to evaluate drugs for autoimmune diseases such as Lupus, Crohn’s disease and other autoimmune diseases. This genetic model more closely approximates the human condition in that it is complex, multi-factorial and usually treated by multiple drug regimens. In these studies, mice were treated with PRTX-100 and sacrificed at regular intervals. Their organs were weighed and sectioned for histological analysis and their spleens were used for immunological assays. Spleen enlargement (splenomegaly) was significantly reduced in treated animals compared with the controls at almost every time point, demonstrating the ability of PRTX-100 to delay the onset and severity of this disease. Treatment with PRTX-100 also reduced non-specific immunoglobulin production and specific autoantibody production and restored the number and function of immune cells known as T and B lymphocytes. These results represent improvement in a whole animal setting in this complex disease syndrome.

Completed pre-clinical safety studies in animals have shown no drug-related toxicity. The studies were conducted in New Zealand white rabbits. New Zealand white rabbits are a very sensitive model to show any potential toxicity of immunomodulatory drugs such as PRTX-100. All animals survived to scheduled euthanasia. No differences were observed in body weight gain or food consumption, nor in hematology, clinical chemistry, urinalysis, or organ weight data in animals treated with PRTX-100 compared with controls treated with vehicle (same dilutive material less PRTX-100). These study results were a crucial component of our IND application with the FDA.

We have performed additional studies in non-human primates to determine the pharmacokinetics of PRTX-100. The results of those studies have indicated more favorable dosing schedules (longer half lives) than studies obtained from rodents. Since non-human primates are more closely related to humans, we decided to perform additional toxicology studies in monkeys to establish the toxicity and starting doses in humans. While these studies delayed the IND submission until March 4, 2005, we believe that this approach will ultimately accelerate the development path and maximize success of PRTX-100 in patients. Other IND-related activities included additional manufacturing and formulation of our drug for Phase I and II clinical trials, arranging for packaging and testing, designing clinical trial



protocols, and completing additional toxicology studies utilizing our manufactured drug. Additionally we intend to conduct research and pre-clinical activities with PRTX-100 and other compounds in ITP, Pemphigus and other related indications.

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**Manufacturing**

We have in the past contracted the manufacturing of our lead drug substance PRTX-100 to Eurogentec S.A. in Belgium. The formulation, stability testing and packaging of the final product for clinical supplies are conducted at another reputable FDA-approved company in the United States. These companies have provided the product for both toxicological testing and clinical supplies. The drug is produced under cGMP. The process is scalable to commercial production.

**Markets**

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. According to the Platelet Disorders Support Association, approximately 200,000 individuals are affected by ITP, with women affected approximately three times as often as men. It can affect all ages and ethnic groups, and about 50% of the new cases occur in children. Current treatment includes corticosteroids and removal of the spleen. Although most cases can be controlled with therapy, the treatments can have significant side effects and there is currently no broadly effective curative therapy.

RA will continue to be our long term focus. RA was chosen as a target disease because it represents a well-defined, rapidly growing market for which currently available treatments are expensive, and many patients may not benefit from the existing drugs which can also cause serious side effects. Therefore, there is a significant unmet need in the RA patients who need alternative treatments. If approved, we anticipate that PRTX-100 will provide these patients with a choice of therapy that is efficacious, cost-effective, and has little or no side effects.

According to the National Institute of Health and The Merck Manual of Health & Aging respectively, approximately 2.1 million Americans suffer from RA, with an estimated 1% of the world population suffering from RA. Navigant Consulting estimated that the RA market for 2004 would surpass \$6.2 billion and estimates that it will increase to \$14.8 billion by the end of 2009.

Currently, no uniformly effective treatment for RA exists. Current treatments are costly, and in most cases must be continued for decades. In contrast, we believe that bioregulator therapy such as PRTX-100 is potentially much more cost-effective and efficacious.

We anticipate that our products will initially be used to treat patients with severe cases of RA, particularly for those individuals for whom other treatments have failed. Additionally, we believe that our experience with this class of patients will prove the efficacy and safety of our products, and will encourage the use of our products in less severely affected individuals in earlier stages of the disease.

Another objective of the Company is the development of second-generation compounds to add to our pharmaceutical product portfolio. The characterization of the new compounds is underway while the patent application process is ongoing.

Additionally, our goal is to pursue FDA approval to treat other autoimmune diseases, where our drug's ability to decrease the inflammatory response will abrogate the underlying disease processes. The BXSb animal model is a generalized autoimmune model, so efficacy in pre-clinical trials shows promise in treating other diseases.



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**Competition**

We believe, based on our pre-clinical trials, that our compound, PRTX-100, has a potential competitive advantage, as it requires lower doses and is more convenient, safer and more efficacious than existing therapies. This potential advantage has not yet been, and may not ever be, validated in clinical trials. Current RA treatments are characterized by complex manufacturing methods and have resulted in an average annual retail cost of approximately \$15,600 to \$34,000 per patient, according to an article entitled “Adalimumab: The First Entirely Human Monoclonal Antibody for Rheumatoid Arthritis,” by pharmacists Alicia Mack and Jessica Neely, as well as Thompson Micromedix respectively. A number of pharmaceutical agents are currently being used, with varying degrees of success, to control the symptoms of RA and slow its progression. Available treatment options include:

- Analgesic/anti-inflammatory preparations, ranging from simple aspirin to the recently introduced COX-2 inhibitors;
- Immunosuppressive/antineoplastic drugs, including azathioprine and methotrexate;
- TNF (Tumor Necrosis Factor) inhibitors, also known as anti-TNF therapy, currently represented by etanercept (Enbrel™), infliximab (Remicade™), and adalimumab (Humira™);
- Soluble Interleukin-1 (IL-1) Receptor Therapy, Anakinra (Kineret™). Anakinra™, a human recombinant IL-1 receptor antagonist (hu rIL-1ra) is approved by the FDA for the treatment of RA; and
- “Immunoabsorption Therapy,” also known as ProSORBA®, now in limited use in Europe and the United States, entailing weekly sessions during which a patient’s blood is separated and passed through a molecular filter. The use of such extreme treatment modalities emphasizes the unmet need for a new treatment for patients who cannot respond to existing therapies.

In all, several dozen large and small pharmaceutical companies are active in this market, with Amgen Corporation and Johnson & Johnson, Inc. dominating the market with their respective products, Enbrel™ and Remicade™. According to Evaluate Pharma. as of December 16, 2005, Enbrel™, a soluble receptor construct that is administered subcutaneously, generated estimated revenue of \$2.6 billion in 2004. Remicade™, a chimeric monoclonal antibody administered by intravenous infusion, generated estimated revenue of \$3.0 billion in 2004, and Abbot’s Humira™, a recent entry into the RA market, and generated estimated revenue of \$852 million in 2004.

Another recent entrant into the RA market is a less well-known product by Amgen Corporation, Anakinra (Kineret™). Despite intense media attention and significant sales, the long-term efficacy of these compounds remains to be evaluated. Post-marketing experience has indicated an enhanced risk for serious and opportunistic infections in patients treated with Remicade™ or Enbrel™. Disseminated tuberculosis due to reactivation of latent disease was also seen commonly with TNF inhibitor treatment. In some of the clinical trials, lymphomas were more commonly observed in patients treated with TNF inhibitors compared to placebo controls. TNF inhibitors are not recommended in patients with demyelinating disease or with congestive heart failure. Transient neutropenia or other blood dyscrasias have been reported with Enbrel™ and the other TNF inhibitors. Findings such as these indicate that new and safe treatments for autoimmune diseases such as RA are needed. We anticipate that PRTX-100 and our other products will provide such opportunity, but there can be no assurance that such results will occur.

There are two companies that are developing thrombopietin aginists for treating ITP. GlaxoSmithKline’s drug #497115 is in Phase II clinical trials and Amgen’s AMG 531 is also in Phase II clinical trials.

Currently, there are no products on the market specifically for the treatment of Pemphigus, however CellCept™ by Hoffma-La Roche, Inc. a division of Roche Group is currently conducting pre-clinical trials for this indication.

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If a patent is issued under our U.S. patent application, that patent may be a potential barrier to entry that could prevent competitors from implementing the same procedures as ours. However, we may be unable to protect these proprietary rights. See the risk factor titled “If we are unable to protect our proprietary rights, we may not be able to compete effectively or to operate profitably” on page 5 of this prospectus.

**Government Regulation**

Our ongoing research and development activities, and our future manufacturing and marketing activities, are subject to extensive regulation by numerous governmental authorities, both in the United States and in other countries. In the United States, the FDA regulates the approval of our products under the authority of the Federal Food, Drug and Cosmetics Act.

In order to obtain FDA approval of our drugs, extensive pre-clinical and clinical tests must be conducted and a rigorous clearance process must be completed. Final approval by the FDA for safety and efficacy may take several years and require the expenditure of substantial resources.

Clinical studies are typically conducted in three sequential phases, although these phases may overlap. In Phase I trials, a drug is tested for safety in one or more doses in a small number of patients or volunteers. In Phase II trials, efficacy and safety are tested in up to several hundred patients. Phase III trials involve additional safety, dosage and efficacy testing in an expanded patient population at multiple test sites.

The results of the pre-clinical and clinical trials are submitted to the FDA in the form of a Biological License Application, or BLA. The approval of a BLA may take substantial time and effort. In addition, upon approval of a BLA, the FDA may require post marketing testing and surveillance of the approved product, or place other conditions on their approvals.

Sales of new drugs outside the United States are subject to foreign regulatory requirements that differ from country to country. Foreign regulatory approval of a product must generally be obtained before that product may be marketed in those countries.

We and any third-party manufacturers or suppliers must continually adhere to federal regulations setting forth requirements, known as current good manufacturing practices, or cGMP, and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. If our facilities, or the facilities of our manufacturers or suppliers, cannot pass a preapproval plant inspection, the FDA will not approve the marketing of our product candidates. In complying with cGMP and foreign regulatory requirements, we and any of our potential third-party manufacturers or suppliers will be obligated to expend time, money and effort in production, record-keeping and quality control to ensure that our products meet applicable specifications and other requirements.

**Patents, Trademarks, and Proprietary Technology**

Our success will depend on our ability to maintain trade secrets and proprietary technology in the United States and in other countries, and to obtain and maintain patents for our bioregulatory technology. We filed an initial usage patent application with the U.S. Patent and Trademark Office in April 2002 and prosecution of this patent application is ongoing. We have also filed for foreign protection relating to this patent in Canada, Japan and the European Union. Additional patent applications relating to the manufacturing process of PRTX-100 are being pursued.

Laboratory work has begun to characterize derivatives and develop synthetic analogs to PRTX-100, for which we will pursue additional patents as appropriate.

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**Employees**

We currently have eight full-time employees. None of our employees are represented by an organized labor union. We believe our relationship with our employees is very good, and we have never experienced an employee-related work stoppage. We will need to hire and retain highly-qualified experienced technical, management and sales personnel in order to execute our business plan, carry out product development and secure advantages over our competitors. No assurances can be given that we will be able to provide the overall compensation necessary to retain such skilled employees.

**Facilities**

Our office and laboratory is located in a space at 145 Union Square Drive, New Hope, Pennsylvania 18938. We lease this property pursuant to a lease agreement, which was amended in November 2005. The amended lease agreement expands the office space to include property located at 130 Union Square Drive and extended the lease termination date to January 31, 2008. Our facilities in New Hope cover approximately 5,873 square feet.

**LEGAL PROCEEDINGS**

We are not a party to any pending legal proceeding. We are not aware of threatened legal proceedings to which any person, officer, affiliate of ours or any owner of more than 10% of our stock is an adverse party to or has a material interest adverse to us.

**MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and related notes beginning at page F-1. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors," "Business" and elsewhere in this document. See "Notice About Forward-Looking Statements."

**Plan of Operation**

Favorable pre-clinical safety and efficacy studies for the Company's lead compound, PRTX-100, laid the foundation for the IND for treating RA. The Company submitted its IND application to the FDA on March 4, 2005. On March 31, 2005, the FDA verbally disclosed to the Company that it had placed the Company's IND on clinical hold, pending additional product characterization. On August 10, 2005, the Company formally replied to the FDA. On September 9, 2005, the FDA notified the Company that it had lifted the clinical hold on its IND and that its proposed study can proceed. The Company commenced with the Phase I clinical trial on December 5, 2005. The Company anticipates that this clinical trial will be completed in the fourth fiscal quarter of 2006. The Company also expects that other clinical trial-related activities will occur during the next fiscal year, including designing clinical trial protocols for additional clinical trials, arranging for packaging and testing, and completing additional toxicology studies utilizing its manufactured drug.

In the area of intellectual property and derivative drug development, the Company's patent application was filed in April 2002. Additional patent applications relating to the manufacturing process of PRTX-100 is being pursued.



Staffing plans for fiscal 2006 include hiring a Clinical Project Manager, and additional clinical and laboratory support personnel. Continued growth in staffing is anticipated in the Company's business plan. Specialized staffing requirements in the areas of scientific and FDA regulatory affairs will require competitive salaries to attract and retain qualified personnel. On July 26, 2005, the Company announced the hiring of Victor S. Sloan, M.D., as Senior Vice President and Chief Medical Officer. On October 19, 2005, Anissa M. Leh, MS started as the Director of Clinical Operations. Effective January 31, 2006, Hector Alila D.V.M. Ph.D. will no longer be employed as the Company's senior vice president of drug development. The Company anticipates hiring Dr. Alila's replacement within the next six months.

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Research and Development Expenses - Research and Development expenses were \$1,687,014 and \$994,739 for the six and three months ended November 30, 2005, respectively, compared with \$1,639,264 and \$919,718 for the six and three months ended November 30, 2004, respectively. The increase in this quarter of \$75,021 or 8% was primarily due to an increase in clinical personnel when compared to the same period in 2004.

Administrative Expenses - Administrative expenses were \$965,384 and \$569,268 for the six and three months ended November 30, 2005, respectively, compared with \$605,854 and \$386,079 for the six and three months ended November 30, 2004, respectively. The increase in this quarter of \$183,189 or 47% was due to hiring of additional personnel, wage increases for existing personnel and stock based compensation, which increased in this quarter by \$106,129 when compared to the same period in 2004.

Professional Fees - Professional fees were \$226,294 and \$91,133 for the six and three months ended November 30, 2005, respectively, compared with \$267,192 and \$178,991 for the six and three months ended November 30, 2004, respectively. The decrease of \$87,858 or 49% was due to a decrease in activity in the areas of legal, audit, tax, employee recruitment, investment banking fees, investor relations and the Scientific Advisory Board when compared to the same period in 2004.

**Liquidity and Capital Resources**

Since 1999, the Company has incurred significant losses. The Company expects to continue experiencing operating losses and negative cash flow for the foreseeable future. The Company's primary source of cash to meet short-term and long-term liquidity needs is the sale of shares of its common stock. The Company issues shares in private placements at a discount to the then-current market price (as resales of privately-placed shares are restricted under the Securities Act, which reduces their liquidity and, accordingly, their value as compared to freely-tradable shares on the open market).

On September 19, 2003, the Company raised \$12,657,599 through the sale of 7,445,654 shares of its common stock at \$1.70 per share, with warrants to purchase an additional 3,164,395 shares of its common stock, at an exercise price of \$2.40 per share. The warrants expire on September 19, 2008. Net of transaction costs of \$1,301,536, the Company's proceeds were \$11,356,063.

On May 25, 2005, the Company raised \$5,057,885 through the sale of 2,593,788 shares of its common stock at \$1.95 per share, with warrants to purchase an additional 920,121 shares of its common stock, at an exercise price of \$2.25 per share. The warrants expire on May 25, 2010. As part of this transaction, the exercise price for the warrants from the September 2003 transaction were lowered from \$2.40 per share to \$2.25 per share. Net of transaction costs of \$206,691, the Company's proceeds were \$4,851,194.

On December 30, 2005, the Company raised \$5,839,059 through the sale of 2,595,132 shares of its common stock at \$2.25 per share, with warrants to purchase an additional 648,784 shares of its common stock, at an exercise price of \$2.99 per share. The warrants expire on December 30, 2010. Net of transaction costs of approximately \$300,000, the Company's proceeds were \$5,539,059.

As of November 30, 2005, the Company's net working capital was \$6,035,029 and its total cash and cash equivalents were \$6,760,832. The Company has no planned material capital expenditures, significant payments due on long-term obligations, or other demands or commitments to be incurred beyond the next 12 months. However, the Company anticipates entering into significant contracts to perform clinical trials in calendar year 2006 that will extend into calendar year 2007. With the completion of the December 30, 2005 transaction, the Company anticipates that it will need to raise additional capital in the second half of calendar year 2007 to fund the ongoing FDA approval process.



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### Off-Balance Sheet Arrangements

We have entered into the following off-balance sheet arrangements:

- *Employee Agreements-Officers.* To attract and retain qualified management personnel, the Company has entered into employment agreements with three executive officers: Steven H. Kane, President and Chief Executive Officer, Victor S. Sloan, MD, Senior Vice President and Chief Medical Officer, and Marc L. Rose, Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary.
- *Directors Agreements.* To attract and retain qualified candidates to serve on the Board of Directors, the Company has entered into agreements with G. Kirk Raab, Chairman of the Board, Carleton A. Holstrom, Chairman of the Audit Committee, Eugene A. Bauer, MD and Peter G. Tombros, under which Messrs. Raab, Holstrom, Dr. Bauer and Mr. Tombros receive aggregate annual cash payments aggregating \$150,000, \$20,000, \$20,000 and \$20,000, respectively, as directors' fees.
- *Operating Lease - Office Space.* The Company has entered into a three year operating lease in New Hope, PA for 3,795 square feet of office and laboratory space. The lease commenced on January 9, 2004 and was originally to expire on February 28, 2007. On November 18, 2005, the company modified the existing lease which added an additional 2,147 square feet and extended the lease term to January 31, 2008.
- *Operating Lease - Copier.* The Company has entered into a sixty-three month operating lease with Ricoh Customer Finance Corporation for a multi-function copier. The lease commenced on December 16, 2004 and will expire on March 16, 2010.
- *Capital Lease - Lab Equipment.* The Company has entered into a thirty-six month capital lease with Waters Corporation for an HPLC protein separator. The lease commenced on April 13, 2003 and will expire May 1, 2006.

Contractual Obligations	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Employment Agreements-Officers	1,001,320	1,001,320	0	0	0
Directors Agreements	210,000	210,000	0	0	0
Operating Lease - Office Space	349,051	9,076	339,975	0	0
Operating Lease - Copier	12,946	249	8,963	3,735	0
Capital Lease - Lab Equipment	9,425	9,425	0	0	0

Total	1,582,743	1,230,070	348,938	3,735	0
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### Critical Accounting Policies and Estimates

The Company's significant accounting policies are more fully described in Note B to the financial statements included in this Registration Statement and in Note B to the financial statements included in the Company's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2005 filed with the Securities and Exchange Commission. Certain accounting policies are particularly important to the portrayal of the Company's financial position and results of operations and require the application of significant judgment by management. As a result, these policies are subject to an inherent degree of uncertainty. In applying these policies, management makes estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and related disclosures. The Company bases its estimates and judgments on historical experience, terms of existing contracts, observance of trends in the industry, information received from outside sources, and on various other assumptions that management believes to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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The Company has reviewed and determined that those policies remain the Company's critical accounting policies as of and for the three months ended November 30, 2005. The Company did not make any changes to those policies during the period.

### MANAGEMENT

The following table sets forth certain information with respect to each of our directors and executive officers as of January 23, 2005:

Name	Age	Position and Offices Held with the Company
G. Kirk Raab(1)(2)	70	Chairman of the Board
Steven H. Kane(1)	53	President, Chief Executive Officer and Director
Victor S. Sloan M.D.	46	Senior Vice President and Chief Medical Officer
Marc L. Rose, CPA	40	Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary
Dinesh Patel, Ph.D.(3)	55	Director
Frank M. Dougherty(1)(2)	57	Director
Carleton A. Holstrom(3)	70	Director
Thomas P. Stagnaro(3)	62	Director
Eugene A. Bauer, M.D.(2)	64	Director
Peter G. Tombros	62	Director

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- (1) Member of the Nominating Committee.  
(2) Member of Compensation Committee.  
(3) Member of the Audit Committee.

Set forth below is biographical information for each of the above:

**G. Kirk Raab** has served on the Company's Board of Directors since August 22, 2003. Mr. Raab is also the Chairman of the Board. Mr. Raab currently sits on the Boards and serves as Chairman of Applied Imaging Inc. and BiPar Sciences, Inc. Mr. Raab is a member of the Board of Directors of Connetics Corporation, TransOral Pharmaceuticals and Velos Medical Informatics, Inc. Connetics and Applied Imaging are publicly traded companies. Mr. Raab also serves on the board of The National Foundation for Science and Technology Medals. From February 1990 to July 1995, Mr. Raab served as the President and Chief Executive Officer of Genentech. He originally joined Genentech in February 1985, as President and Chief Operating Officer. Prior to joining Genentech, Mr. Raab worked for Abbott Laboratories for 10 years, most recently as President, Chief Operating Officer and a director. Mr. Raab served as the first Chairman of the Biotechnology Industry Organization and the California Health Care Institute. Mr. Raab graduated from Colgate University in 1959, and is a Trustee Emeritus. He is a former trustee of KQED, the San Francisco Ballet, the San Francisco Symphony, UCSF Foundation and Golden Gate Planned Parenthood.

**Steven H. Kane** has served on the Company's Board of Directors since December 16, 2002. He is currently the President and Chief Executive Officer of the Company. He has over 25 years experience in the health care industry. Most recently, he was Vice President of North American Sales & Field Operations for Aspect Medical. While at Aspect, he helped guide the company to a successful initial public offering in January 2000. Prior to Aspect, Mr. Kane was Eastern Area Vice President for Pyxis Corporation, where he was instrumental in positioning the company for its successful initial public offering in 1992. Pyxis later was acquired by Cardinal Health for \$1 billion. Prior to that Mr. Kane worked in sales management with Eli-Lilly and Becton Dickinson.



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**Victor S. Sloan, M.D.** has served as the Senior Vice President and Chief Medical Officer of Protalex since July 2005. Prior to joining Protalex, from 1998 to 2005 Dr. Sloan was Senior Director and Disease Area Section Head, Arthritis at Novartis Pharmaceuticals Corporation. While at Novartis, Dr. Sloan oversaw numerous clinical trials ranging from proof of concept through Phase III, as well as several regulatory submissions in arthritis. Additionally, he worked closely with research and clinical development teams in conducting due diligence of potential in-licensed compounds. In addition to his industry experience, Dr. Sloan holds an appointment as Clinical Associate Professor of Medicine, Robert Wood Johnson Medical School, and serves on the Board of Directors of both the Arthritis Foundation, NJ Chapter, and the Lupus Foundation of America, NJ Chapter. Dr. Sloan is a board certified rheumatologist with extensive experience in designing and managing all phases of the clinical trial process. Dr. Sloan received his A.B. from University of Chicago, M.D. from New York Medical College and attended the Belfer Institute for Advanced Biomedical Studies, Albert Einstein College of Medicine.

**Marc L. Rose, CPA**, has served as the Company's Vice President of Finance, Chief Financial Officer and Treasurer since November 2004 and in April 2005 Mr. Rose was elected Corporate Secretary. From March 2001 to November 2004, Mr. Rose served as Vice President and Chief Financial Officer of the DentalEZ Group, a privately held manufacturer of dental equipment and dental handpieces located in Malvern, PA. From January 1998 to March 2001, Mr. Rose was Practice Manager of Oracle Consulting Services for Oracle Corporation responsible for designing and implementing Oracle financial and project applications. From September 1990 to January 1998, Mr. Rose held several positions with the controllership organization of Waste Management, Inc and from June 1988 to September 1990, was an auditor with Ernst & Young in Philadelphia.

**Dinesh Patel, Ph.D.**, has served on the Company's Board of Directors since September 18, 2003. Dr. Patel is a Managing Director and Founding Partner of vSpring Capital, an early stage venture capital fund with \$125 million under management. Dr. Patel is also the Founder, Chairman, President & CEO of Ashni Naturaceuticals, Inc. a company that specializes in the research, development and marketing of clinically tested and patent-protected naturaceutical products. In 1999, Dr. Patel co-founded and was the Chairman of Salus Therapeutics, Inc., a biotechnology company focused on the research and development of nucleic acid-based therapeutics, including antisense and gene therapy drugs. In August 2003 publicly traded Genta, Inc acquired Salus for \$30 million. From 1985 through 1999, Dr. Patel served as Co-founder, Chairman of the Board of Directors, President & CEO, of Thera Tech, Inc., a Salt Lake City, Utah based company, that has been a pioneer in the development and manufacture of innovative drug delivery products. Under Dr. Patel's guidance, TheraTech established strategic alliances with major pharmaceutical companies including Eli Lilly, Pfizer, Proctor & Gamble, Roche, and SmithKline Beecham. TheraTech went public in 1992 and became profitable in 1997. In January 1999, TheraTech was acquired for approximately \$350 million by Watson Pharmaceuticals, a California based company. Dr. Patel has been the recipient of numerous awards, including the US Small Business Administration's Business Achiever Award, and Scientific and Technology Award (State of Utah) and Entrepreneur of the Year Award (Mountain West venture Group). Dr. Patel received his bachelor's degree in Pharmacy at Gujarat University located in Ahmedabad, Gujarat, India. He received a master's degree from the Philadelphia College of Pharmacy and his Ph.D. in Physical Pharmacy from the University of Michigan. Dr. Patel is active in the Indian and local community serving on several boards and as an active donor for various charitable causes.

**Frank M. Dougherty** has served on the Company's Board of Directors since October 16, 2001, and served as the Company's Corporate Secretary from June 21, 2002 to December 16, 2002. From January 22, 2004 to April 13, 2005, Mr. Dougherty served as the Corporate Secretary and Treasurer of the Company. Mr. Dougherty is a practicing attorney and founder and owner of Frank M. Dougherty P.C., a law firm in Albuquerque, New Mexico. Mr. Dougherty has practiced law since 1982, and founded his current law firm in November 2001. Prior to becoming a lawyer, Mr. Dougherty practiced as a CPA in Santa Fe, New Mexico. Mr. Dougherty has an undergraduate degree in economics from the University of Colorado, a graduate degree in accounting from the University of Arizona and a law



degree from Texas Tech University.

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**Carleton A. Holstrom** has been a director of Protalex since October 2004. From 1977 through 1987, Mr. Holstrom was the Chief Financial Officer of Bear, Stearns & Co. and its successor, the Bear Stearns Companies, Inc., and from 1987 to the present, he has been a Managing Director Emeritus. From 1996 to 1997, Mr. Holstrom was the Chief Financial Officer of Scientific Learning Corporation. From 1983 to the present, Mr. Holstrom has served on the Board of Directors of Custodial Trust Company of Princeton, New Jersey, and Scientific Learning Corporation of Oakland, California. From 1989 through 1995, Mr. Holstrom served on the Board of Governors of Rutgers University and was the Chair of the Board of Governors from 1994 through 1995. From 1983 through 1985, Mr. Holstrom served on the Board of Trustees of Rutgers University and was the Chair of that Board from 1998 through 1999. From 1995 through the present date, he has been an Emeritus Member of the Rutgers University Board of Trustees. From 1997 through 2000, Mr. Holstrom served on the Rutgers University Foundation Board of Overseers. He was the Chair of the Board of Overseers from 1979 through 1981. From 2000 to the present, he has served on the Rutgers University Foundation Board of Overseers in an emeritus capacity. From 1994 through 2005, Mr. Holstrom has served on the University of Wisconsin at Madison College of Letters and Sciences Board of Overseers. From 1989 through the present, he served on the University of Wisconsin Foundation Board of Directors and was the Vice Chair of that Foundation from 2000 through 2003. Mr. Holstrom has been a Director of the Woodrow Wilson National Fellowship Foundation from 2002 through the present date.

**Thomas P. Stagnaro** has served on the Company's Board of Directors since July 8, 2002. He is President and Chief Executive Officer of Americas Biotech Distributor (ABD), which he founded in June 2004. Previously, Mr. Stagnaro was President and Chief Executive Officer of Agile Therapeutics, a private company focused on developing women's healthcare products from September 2000 to August 2004. Mr. Stagnaro also serves as a director on the board of INKINE Pharmaceutical and Life Science Research Organization. Mr. Stagnaro formerly was President and Chief Executive Officer of 3-Dimensional Pharmaceuticals and Univax Biologics. Mr. Stagnaro began his career with Searle Laboratories and held increasingly important positions during his 30 years in the pharmaceutical industry. Mr. Stagnaro has raised over \$200 million for three development stage companies and took Univax Biologics public in 1972. Mr. Stagnaro holds three patents and has published numerous articles.

**Eugene A. Bauer, M.D.** has served on the Company's Board of Directors since February 15, 2005. Dr. Bauer is Chief Executive Officer and board member of Neosil Incorporated, a privately held biotechnology company. From 2002 to 2004 Dr. Bauer was a Senior Client Partner with Korn/ Ferry International. Dr. Bauer served as Vice President for the Stanford University Medical Center from 1997 to 2001, and as Dean of the Stanford University School of Medicine from 1995 through 2001. Dr. Bauer was a founder of Connetics. Since 1988 he has been Professor, Department of Dermatology, Stanford University School of Medicine, and was Chief of the Dermatology Service at Stanford University Hospital from 1988 to 1995. From 1982 to 1988, he was a professor at Washington University School of Medicine. Dr. Bauer has served as Chairman of two National Institutes of Health study sections of the National Institute of Arthritis and Musculoskeletal and Skin Diseases and has served on a board of scientific counselors for the National Cancer Institute. Dr. Bauer also serves as a director of three private companies and one non-profit Dermatological Organization. Dr. Bauer holds B.S. and M.D. degrees from Northwestern University.

**Peter G. Tombros** has served as a director of Protalex since November 2005. Mr. Tombros is currently the Chairman and Chief Executive Officer of VivoQuest, Inc., a drug discovery company based in New York. Mr. Tombros served as President and CEO of Enzon from 1994 to 2001. Before Enzon, Mr. Tombros spent 25 years with Pfizer as Vice President of Marketing, Sr. Vice President and General Manager of the Roerig Pharmaceutical Division, and Executive Vice President of Pfizer Pharmaceuticals, Inc. Mr. Tombros also served as Vice President Corporate Strategic Planning where he was responsible for mergers and acquisitions and oversight of the Pfizer Venture Capital investments. Mr. Tombros is also a director of Alpharma, Inc., Cambrex Corporation, Dendrite International, Inc., NPS Pharmaceuticals and Icoria, Inc. Mr. Tombros received B.S. and M.S. degrees from the Pennsylvania State University and an M.B.A. from the University of Pennsylvania, Wharton Graduate School of Business.



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**Executive Compensation**

Our compensation and benefits program is designed to attract, retain and motivate employees to operate and manage us for the best interests of our constituents. Executive compensation is designed to provide incentives for those senior members of management who bear responsibility for our goals and achievements. The compensation philosophy is based on a base salary, with opportunity for significant bonuses to reward outstanding performance, and a stock option program.

The following table sets forth the compensation we paid for services rendered in all capacities during the last three fiscal years to our Chief Executive Officer and our other highly compensated executive officers who served as such at the end of the fiscal year ended May 31, 2005. In accordance with the rules of the SEC, the compensation described in this table does not include medical, group life insurance or other benefits which are available generally to our salaried employees.

**SUMMARY COMPENSATION TABLE**

Name & Principal Position	Year	Annual Compensation			Restricted Stock Awards \$
		Salary \$	Bonus \$	Other Annual Compensation	
Steven H. Kane, President,	2005	\$ 281,350	\$ 0	\$ 0	\$ 0
Chief Executive Officer, and	2004	\$ 179,165	\$ 176,576	\$ 0	\$ 20,835(2)
Director	2003(1)	\$ 0	\$ 0	\$ 0	\$ 104,107(2)
Hector W. Alila, DVM, Ph.D,	2005	\$ 180,417	\$ 0	\$ 0	\$ 0
Senior Vice President, Drug	2004(3)	\$ 42,500	\$ 0	\$ 0	\$ 107,500
Development					
Marc L. Rose, Vice President	2005	\$ 89,818	\$ 0	\$ 0	\$ 38,250
and Chief Financial Officer,	2004(4)	\$ 0	\$ 0	\$ 0	\$ 0
Treasurer and Corporate					
Secretary					

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- (1) Mr. Kane was hired as the Company's President effective as of December 16, 2002. Prior to that date, he was not employed, in any capacity, by the Company.
- (2) Mr. Kane received 41,668 shares of restricted stock from December 16, 2002 through May 31, 2003. The value of this restricted stock received by Mr. Kane was computed using the closing price of Protalex's common stock on May 31, 2003, which was \$2.25. Mr. Kane received 8,334 shares of restricted stock on June 15, 2003. The value of this stock was also computed using the closing price of Protalex's common stock on May 31, 2003.
- (3) Dr. Alila was hired as the Company's Senior Vice President, Drug Development effective as of March 1, 2004. Prior to that date, he was not employed, in any capacity, by the Company. Effective January 31, 2006, the employment of Dr. Alila will cease.
- (4) Mr. Rose was hired as the Company's Vice President, Chief Financial Officer, Treasurer and Corporate Secretary effective as of November 15, 2004. Prior to that date, he was not employed, in any capacity, by the Company.



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### Option Grants in the Fiscal Year Ended May 31, 2005

The following table sets forth information concerning the stock options granted to each person named in the above "Summary Compensation Table" during our fiscal year ended May 31, 2005, and the exercise price of all such options:

#### OPTION/SAR GRANTS IN LAST FISCAL YEAR INDIVIDUAL GRANTS

	Number of Securities Underlying Options/SARs Granted (#)	Percent of Total Options/SARs Granted to Employees in Fiscal Year (%)	Exercise or Base Price (\$/Share)	Market Price on Date of Grant
Steven H. Kane	175,000	23%	\$ 2.55	\$ 2.55
Victor S. Sloan	0	0%	—	—
Hector W. Alila	50,000	7%	\$ 2.55	\$ 2.55
Marc L. Rose	100,000	13%	\$ 2.55	\$ 2.55

#### AGGREGATED OPTION EXERCISES IN THE FISCAL YEAR ENDED MAY 31, 2005 AND YEAR END OPTION VALUES.

The following table sets forth information concerning the exercise of stock options by each person named in the "Summary Compensation Table" during our fiscal year ended May 31, 2005, and the value of all exercisable and unexercisable options at May 31, 2005:

Name	Number of Securities Underlying Unexercised Options at Year End		Value of Unexercised In The Money Options at Year End	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Steven H. Kane	682,163	531,079	\$ 284,832	\$ 196,789
Victor S. Sloan	0	0	\$ 0	\$ 0
Hector W. Alila	47,915	152,085	\$ 0	\$ 0
Marc L. Rose	12,500	87,500	\$ 0	\$ 0

The values of unexercised in-the-money options at year-end in the table above were determined based on the fair market value as of May 31, 2005 minus the per share exercise price multiplied by the number of shares.

#### Employment Agreements

Effective as of October 25, 2005, we have an employment agreement with our current President and Chief Executive Officer, Steven H. Kane. Effective January 1, 2006, Mr. Kane is paid at a rate of \$33,333.33 per month. Mr. Kane is eligible to participate in the Company's annual executive bonus plan, as well as in any life, health, accident, disability, or hospitalization insurance plans, pension plans, or retirement plans as the Company's Board of Directors makes available to the Company's executives as a group. Either the Company or Mr. Kane can terminate Mr. Kane's employment at any time, with or without cause, upon notice. If the Company terminates Mr. Kane without cause, Protalex will continue to pay Mr. Kane his monthly salary for a period of 18 months and will accelerate vesting of any of Mr. Kane's outstanding unvested options that would have vested over the next 18 months. During Mr. Kane's

employment and for two (2) years thereafter, Mr. Kane must obtain Protalex's prior written approval before soliciting, inducing or attempting to persuade any employee or independent contractor of Protalex to terminate their relationship with Protalex to work for any other person or entity.

Effective as of November 15, 2004, we entered into a letter agreement with Marc L. Rose, which provides for a grant of options to acquire 100,000 shares of our common stock. These options are subject to the Company's 2003 Stock Option Plan, as amended, vest over four years at a rate of 1/48 per month starting on May 15, 2005, retroactive to November 15, 2004 and have a 10-year term. The letter agreement also provides for an award of 15,000 restricted shares of our common stock. Mr. Rose is eligible to participate in our annual executive bonus plan, as well as in any life, health, accident, disability, or hospitalization insurance plans, pension plans, or retirement plans as our board of directors makes available to our executives as a group. Effective January 1, 2006, Mr. Rose is paid at a rate of \$16,666.67 per month. The agreement also provides for payment to Mr. Rose of up to 12 payments equal to his monthly base salary in the event Mr. Rose is terminated without cause

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Effective August 23, 2005, we entered into a letter agreement with Victor S. Sloan, M.D., which provides for a grant of options to acquire 250,000 shares of our common stock. These options are subject to the Company's 2003 Stock Option Plan, as amended, vest over four years at a rate of 1/48 per month starting on February 23, 2006, retroactive to August 23, 2005 and have a 10-year term. The letter agreement also provides for an award of 40,000 restricted shares of our common stock. Dr. Sloan is eligible to participate in our annual executive bonus plan, as well as in any life, health, accident, disability, or hospitalization insurance plans, pension plans, or retirement plans as our board of directors makes available to our executives as a group. Effective January 1, 2006, Dr. Sloan is paid at a rate of \$23,333.33 per month. Either the Company or Dr. Sloan can terminate Dr. Sloan's employment at any time, with or without cause, upon notice. If the Company terminates Dr. Sloan without cause, he is entitled to one lump sum payment equal to his annual base salary at the time of such termination

**Director Compensation**

Directors received stock-based compensation for their services as directors during the fiscal year ended May 31, 2005. We issued 325,000 stock options to directors during such fiscal year, at exercise prices ranging from \$2.30 to \$2.80 per share based on the closing price of our Common Stock on the date of issuance. In addition we have an agreement with G. Kirk Raab, the Chairman of the Board, Carleton A. Holstrom, Chairman of the Audit Committee, Eugene A. Bauer, M.D. and Peter G. Tombros, to make aggregate annual cash payments to each aggregating \$150,000, \$20,000, \$20,000 and \$20,000, respectively, as directors' fees payable as disclosed below. Directors do not receive separate meeting fees, but are reimbursed for out-of-pocket expenses. We do not provide a retirement plan for our non-employee directors.

**CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS**

For the six and three month period ended November 30, 2005, the Company incurred \$20,717 and \$17,240, respectively, of expenses related to air travel for business purposes only, to a partnership principally owned by the Chief Executive Officer of the Company. For the six and three month period ended November 30, 2004, the Company incurred \$4,932 and \$1,138, respectively, of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company.

The Company has an agreement with its Chairman to pay \$12,500 per month as a director fee. For the six and three month period ended November 30, 2005, the Company incurred \$75,000 and \$37,500 respectively, for this director's fee. For the six and three month period ended November 30, 2004, the Company incurred \$75,000 and \$37,500 respectively, for this director's fee.

The Company has agreements with Carleton A. Holstrom, Eugene A. Bauer, M.D. and Peter G. Tombros to pay each of them \$1,667 per month on a quarterly basis payable in arrears as a director fee. For the six and three month period ended November 30, 2005, the Company incurred \$20,000 and \$10,000, respectively, for these directors' fees. For the six and three month period ended November 30, 2004, the Company incurred \$0 and \$0, respectively, for these directors' fees.



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

Set forth in the following table is the beneficial ownership of common stock as of January 23, 2006, for our directors, the named executive officers listed in the Summary Compensation Table, our directors and executive officers as a group and each person or entity known by us to beneficially own more than five percent of the outstanding shares of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person or a group and the percentage ownership of that person or group, shares of our common stock issuable currently or within 60 days of January 23, 2006, upon exercise of options or warrants held by that person or group are deemed outstanding. These shares, however, are not deemed outstanding for computing the percentage ownership of any other person. Except as indicated by footnote, and subject to community property laws where applicable, the stockholders named in the table below have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them. Percentage ownership is based on 22,038,353 shares of common stock outstanding as of January 23, 2006, together with applicable options and warrants for each stockholder. Unless otherwise indicated, the address of each person listed below is in the care of Protalex, Inc., 145 Union Square Drive, New Hope, PA 18938.

Name and Title	Shares Beneficially Owned	
	Number	Percent
G. Kirk Raab, Chairman of the Board and Director	492,798(1)	2.2%
Steven H. Kane, President and Director	1,218,538(2)	5.5%
Victor S. Sloan, M.D., Senior Vice President and Chief Medical Officer	98,907(3)	*
Hector W. Alila D.V.M, Ph.D, former Senior Vice President, Drug Development	137,500(4)	*
Marc L. Rose, CPA, Vice President, Chief Financial Officer, Treasurer and Corporate Secretary	49,762(5)	*
Peter G. Tombros, Director	125,000(6)	*
John E. Doherty, Former Director	3,201,549(7)	14.4%
Frank M. Dougherty, Director	445,581(8)	2.0%
Eugene A. Bauer, M.D., Director	125,000(9)	*
Thomas Stagnaro, Director	269,500(10)	1.4%
vSpring SBIC, L.P. Attn: Dinesh Patel 2795 E. Cottonwood Pkwy, Suite 360 Salt Lake City, UT 84121	13,140,340(11)	59.6%
Integral Capital Partners VI, L.P. Attn: Pamela K. Hagenah 3000 Sand Hill Road Big 3, Suite 240 Menlo Park, CA 94025	1,687,500(12)	7.7%
SF Capital Partners Ltd. Attn: Daniel McNally 3600 South Lake Drive St. Francis, WI 53235	1,588,235(13)	7.2%
All officers and directors as a group (11 persons)	13,751,747(14)	62.4%

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\* Indicates less than 1%.

- (1) Includes options to purchase 492,798 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (2) Includes options to purchase 1,135,117 shares of Protalex common stock and warrants to purchase 7,778 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (3) Includes options to purchase 58,907, shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (4) Includes options to purchase 87,500 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (5) Includes options to purchase 34,762 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (6) Includes options to purchase 100,000 shares of Protalex common stock and warrants to purchase 5,000 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (7) Includes options to purchase 110,000 shares of Protalex common stock and warrants to purchase 27,778 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (8) Includes options to purchase 90,000 shares of Protalex common stock and warrants to purchase 2,778 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (9) Includes options to purchase 125,000 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (10) Includes options to purchase 269,500 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (11) Includes warrants to purchase 1,047,255 shares of Protalex common stock exercisable within 60 days of January 23, 2006, and 8,957,338 shares of Protalex common stock (including options and warrants to purchase 3,027,151 shares of Protalex common stock exercisable within 60 days of January 23, 2006) held by Steven H. Kane, John E. Doherty, Frank M. Dougherty, G. Kirk Raab, Thomas P. Stagnaro, Marc L. Rose, Integral Capital Partners VI, L.P. and SF Capital Partners Ltd. for which vSpring SBIC, L.P. shares voting power as described in the following sentence. vSpring SBIC, L.P. has entered into a Shareholder Agreement dated September 18, 2003, as amended on May 25, 2005, with Steven H. Kane, John E. Doherty, Frank M. Dougherty, G. Kirk Raab, Thomas P. Stagnaro, Marc L. Rose, Integral Capital Partners VI, L.P. and SF Capital Partners Ltd., pursuant to which each such party executed proxies appointing vSpring SPEC, L.P. as their proxy to vote all of such party's respective shares (i) to fix and maintain the number of directors at seven unless a greater or lesser number is approved by vSpring and the Company and (ii) to cause and maintain the election of a candidate designated by vSpring SBIC, L.P. on the Protalex board of directors. The proxy may not be exercised on any other matter, and each party may vote their shares on all other matters.  
vSpring SBIC Management LLC, a Delaware limited liability company, is the general partner of vSpring SBIC, LP Management of the business affairs of vSpring SBIC, LP, including decisions respecting disposition and/or voting of the shares of Protalex common stock held by vSpring SBIC, LP., resides in a majority of the managing members of vSpring SBIC Management, LLC., such that no single managing member of vSpring Management has voting and/or dispositive power of such shares. The managing members of vSpring SBIC Management, LLC are Paul Ahlstrom, Ed Ekstrom, Dr. Dinesh Patel, Scott Petty and Greg Warnock. In furnishing information relating to the beneficial ownership of vSpring SBIC, LP's shares, Protalex is relying solely on information provided by vSpring SBIC, L.P. and vSpring Management LLC. As noted above, Dinesh Patel, a member of our board of directors, is a managing member of vSpring Management, LLC, shares voting power in respect to vSpring SBIC Management LLC's shares and may be deemed to beneficially own the shares owned by vSpring SBIC Management LLC.
- (12) Includes warrants to purchase 437,500 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (13) Includes warrants to purchase 411,765 shares of Protalex common stock exercisable within 60 days of January 23, 2006.
- (14) Includes options to purchase 496,407 shares of Protalex common stock and warrants to purchase 1,052,255 shares of Protalex common stock exercisable within 60 days of January 23, 2006.



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## DESCRIPTION OF SECURITIES

The following description of our common stock is a summary and is qualified in its entirety by the provisions of our certificate of incorporation, which has been filed with the SEC.

On December 1, 2004, Protalex, Inc., a New Mexico corporation, consummated a merger with and into its newly-formed, wholly-owned subsidiary, Protalex Delaware in order to reincorporate in the State of Delaware. Our authorized capital stock consists of 100,000,000 shares of \$0.00001 par value common stock, of which 22,038,353 shares were issued and outstanding as of January 23, 2006. We have reserved 11,756,829 shares of common stock for issuance pursuant to outstanding options and warrants, including 6,711,255 shares reserved for issuance under existing stock option agreements and our 2003 Stock Option Plan, as amended. Each issued and outstanding share is fully paid and non-assessable. No pre-emptive rights under our Certificate of Incorporation exist with respect to any of our common stock. Holders of shares of our common stock are entitled to one vote for each share on all matters to be voted on by the stockholders. Holders of shares of our common stock have no cumulative voting rights. Holders of shares of our common stock are entitled to share ratably in dividends, if any, as may be declared, from time to time by our board of directors in its discretion, from funds legally available therefor. In the event of a liquidation, dissolution or winding up of Protalex, the holders of shares of our common stock are entitled to their pro rata share of all assets remaining after payment in full of all liabilities.

## INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

The General Corporation Law of the State of Delaware and our bylaws provide for indemnification of our directors for liabilities and expenses that they may incur in such capacities. In general, our directors and officers are indemnified with respect to actions taken in good faith and in a manner such person believed to be in our best interests, and with respect to any criminal action or proceedings, actions that such person has no reasonable cause to believe were unlawful. Furthermore, the personal liability of our directors is limited as provided in our articles of incorporation.

We maintain directors and officers liability insurance with an aggregate coverage limit of \$3,000,000.

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

## PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, assignees and successors-in-interest 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 the purchaser;
- 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;
- 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.

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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 pledge their shares to their brokers under the margin provisions of customer agreements. If a selling stockholder defaults on a margin loan, the broker may, from time to time, offer and sell the pledged shares.

The selling stockholders may pledge their shares of common stock to their brokers under the margin provisions of customer agreements. If a selling stockholder defaults on a margin loan, the broker may, from time to time, offer and sell the pledged shares.

Broker-dealers engaged by the selling stockholders may arrange for other broker-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.

Each selling stockholder may be deemed to be an “underwriter” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares 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, but excluding brokerage commissions or underwriter discounts. We and the selling stockholders have agreed to indemnify each other against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

### **SELLING STOCKHOLDERS**

Certain of the selling stockholders purchased an aggregate of 2,595,132 shares of common stock in a December 2005 private placement offering under Section 4(2) and Section 506 of Regulation D under the Securities Act. These selling stockholders also received warrants to purchase an aggregate of 875,858 shares of common stock upon exercise of warrants. The warrants have an exercise price of \$2.99 per share.

We have registered for resale the shares sold in the private placement and issuable on exercise of the warrants to permit the selling stockholders and transferees to resell the shares when they deem appropriate. Except with respect to John E. Doherty, a greater than 10% stockholder and former director, current directors Frank M. Dougherty and Peter G. Tombros (as to each of which additional information is provided previously under the section of this prospectus entitled “Security Ownership of Certain Beneficial Owners and Management”) and William Hitchcock, who served as our Chairman of the Board from October 2001 to October 2003, none of the selling stockholders or their respective affiliates has, or within the past three years has had, any position, office or other material relationship with us or any of our predecessor or affiliates, nor is in a position where it should be able to control us.

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Twelve selling shareholders have affiliations with broker-dealers as follows:

- Terral Jordan employer's wholly-owned subsidiary is a member of the NASD.
- William M. Hitchcock is a registered representative of Pembroke Financial Partners LLC, which is a NASD member firm.
- John C. Lipman is the managing member of Carter Management Group LLC. Mr. Lipman is the chairman and sole owner of Carter Securities LLC, which is a NASD member firm.
- Seymour Rose is a registered representative of AXA Advisors, LLC, which is a NASD member firm.
- Paramount BioCapital Asset Management, Inc. is the general partner and investment manager of the following selling stockholders: (i) Aries Master Fund II, LP (ii) Aries Domestic Fund, LP and (iii) Aries Domestic Fund II, LP. Lindsay A. Rosenwald is the chief executive officer, chairman and sole stockholder of Paramount BioCapital Asset Management, Inc. and is the chief executive officer, chairman and sole stockholder of Paramount Biocapital, Inc, an NASD member firm.
- Larry Gellman is a managing director of, and owns equity securities in, Robert W. Baird & Co. Incorporated, which is a NASD member firm.
- Anthony Cantone is the President of Cantone Research, Inc., which is a NASD member firm.
- Cantone Partners, L.P. is a fund, in which Anthony Cantone is the General Manager. Anthony Cantone is President of Cantone Research, Inc., which is a NASD member firm.
- Griffin Securities, Inc. acted a placement agent for this transaction and is a NASD member firm.
- Salvatore Saraceno is an employee of Griffin Securities, Inc, which is a NASD member firm.
- Mark Zizzamia is an employee of Griffin Securities, Inc, which is a NASD member firm.
- Mufson, Howe, Hunter and Partners, LLC is wholly-owned by Mufson, Howe, Hunter and Company, LLC, acted as placement agent for this transaction and is a NASD member firm.

In the purchase agreement, each of the selling stockholders, including those selling stockholders with broker-dealer affiliations, represented that it had acquired the shares for investment purposes only and with no present intention of distributing those shares, except in compliance with all applicable securities laws. In addition, each of the selling stockholders purchased the shares in the ordinary course of business and represented that it qualifies as an "accredited investor" as such term is defined in Rule 501 under the Securities Act.

The table below sets forth the name of each person who is offering the resale of shares of common stock by this prospectus, the number of shares of common stock beneficially owned by each person, the number of shares of common stock that may be sold in this offering and the number of shares of common stock each person will own after the offering, assuming they sell all of the shares offered. We will not receive any proceeds from the resale of the common stock by the selling stockholders, except is a selling stockholder exercises his, her or its warrants with cash.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person or a group and the percentage ownership of that person or group, shares of our common stock issuable currently or within 60 days of January 23, 2006, upon exercise of options or warrants held by that person or group are deemed outstanding. These shares, however, are not deemed outstanding for computing the percentage ownership of any other person. Percentage ownership is based on 22,038,353 shares of common stock outstanding as of January 23, 2006, together with applicable options and warrants for each stockholder.

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	NO. OF SHARES OFFERED (INCLUDES STOCK UNDERLYING WARRANTS)	SHARES OWNED PRIOR TO THE OFFERING		SHARES OWNED AFTER THE OFFERING	
		NUMBER	PERCENTAGE	NUMBER	PERCENTAGE
Larry Gellman	250,000(1)	250,000	1.1%	0	*
Christoph Henkel	196,005(2)	943,794	4.1%	747,789	3.4%
Mosaix Ventures, LP	194,445(3)	194,445	*	0	*
Anthony J. Cantone	187,500(4)	187,500	*	0	*
Cordillera Fund, LP	167,500(5)	167,500	*	0	*
Hauck-Aufhaeueer Banquiers Luxembourg S.A.	166,666(6)	166,666	0	0	*
Sandra F. Pessin	166,666(7)	362,166	1.6%	195,500	*
Aries Master Fund II	158,334(8)	158,334	*	0	*
John E. Doherty	138,889(9)	3,091,549	12.4%	2,952,660	13.3%
Griffin Securities, Inc	114,764(10)	114,764	*	0	*
Jean Robert Bourgeois	112,500(11)	112,500	*	0	*
The Lincoln Fund, L.P.	111,111(12)	384,809	1.7%	273,698	1.2%
Carter Management Group, LLP	93,750(13)	93,750	*	0	*
Aries Domestic Fund, LP	86,111(14)	86,111	*	0	*
Investment Strategies Fund, L.P.	83,750(15)	83,750	*	0	*
Richard L. Braeux	62,500(16)	141,912	*	79,412	*
PAM Investments, LTD-I	62,500(17)	62,500	*	0	*
Larry S. Kopp	56,250(18)	56,250	*	0	*
William M. Hitchcock	55,555(19)	325,850	1.5%	270,295	1.2%
Kinloch & Company, LLC, SC	55,555(20)	530,392	2.4%	474,837	2.1%
Lance, Malvin & Partners, Inc.	55,555(21)	55,555	*	0	*
NITE Capital, LP	55,555(22)	55,555	*	0	*
Maud Tilghman Walker	55,555(23)	165,641	*	110,086	*
Thomas Veasey Zug, Jr.	55,555(24)	211,222	1.0%	155,667	*
Cantone Partners, L.P.	52,369(25)	52,369	*	0	*
Mufson, Hunter, Howe and Partners LLC	43,691(26)	43,691	*	0	*
Boris Volman	37,505(27)	37,505	*	0	*
Aries Domestic Fund II, LP	33,333(28)	33,333	*	0	*
David A. Dent	31,250(29)	31,250	*	0	*
Philip Isaacson	31,250(30)	31,250	*	0	*
N. Dean Meyer	31,250(31)	31,250	*	0	*
Richard Molinsky	31,250(32)	31,250	*	0	*
PAM Investments, Ltd. II	31,250(33)	31,250	*	0	*
Salvatore Saraceno	30,000(34)	30,000	*	0	*

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Mark Zizzamia	30,000(35)	30,000	*	0	*
Ranjan Lal	27,780(36)	27,780	*	0	*
Clancy Douglas McKenzie, MD	27,778(37)	27,778	*	0	*
Sterling Securities International Ltd.	27,766(38)	27,766	*	0	*
Daniel A. Bachtle	25,000(39)	25,000	*	0	*
Ben & Sophie Reuben	25,000(40)	25,000	*	0	*
Peter G. Tombros	25,000(41)	125,000	*	100,000	*
Craig William Lunsman	22,500(42)	48,567	*	26,067	*
Jack & Sharon Benoff	22,250(43)	30,271	*	8,021	*
David S. Hannes	20,000(44)	20,000	*	0	*
Tony Nikolich	18,750(45)	18,750	*	0	*
Victor Polakoff	15,000(46)	15,000	*	0	*
Frank Dougherty Rev. Trust UAD 9-30-05	13,889(47)	217,485	1.0%	203,596	*
Philip & Cheryl McDonald	13,889(48)	13,889	*	0	*
Mark S. Robinow	13,889(48)	13,889	*	0	*
Terral Jordan	13,875(50)	120,667	*	106,792	*
Mai N. Pogue	12,500(51)	12,500	*	0	*
DCB Enterprises Inc.	6,250(52)	6,250	*	0	*
Howard Allen LeVaux	6,250(53)	6,250	*	0	*
Seymour Rose	5,555(54)	5,555	*	0	*
Joe Jude Dervan & Elena Lisk	1,875(55)	6,875	*	5,000	*
David Dervan	475(56)	475	*	0	*

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\* Indicates less than 1%.

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- (1) Includes stock underlying a warrant to purchase 50,000 shares of common stock at an exercise price of \$2.99 per share.
- (2) Includes stock underlying a warrant to purchase 39,201 shares of common stock at an exercise price of \$2.99 per share.
- (3) Includes stock underlying a warrant to purchase 38,889 shares of common stock at an exercise price of \$2.99 per share.
- (4) Includes stock underlying a warrant to purchase 37,500 shares of common stock at an exercise price of \$2.99 per share.
- (5) Includes stock underlying a warrant to purchase 33,500 shares of common stock at an exercise price of \$2.99 per share.
- (6) Includes stock underlying a warrant to purchase 33,333 shares of common stock at an exercise price of \$2.99 per share.
- (7) Includes stock underlying a warrant to purchase 33,333 shares of common stock at an exercise price of \$2.99 per share.
- (8) Includes stock underlying a warrant to purchase 31,667 shares of common stock at an exercise price of \$2.99 per share.
- (9) Includes stock underlying a warrant to purchase 27,778 shares of common stock at an exercise price of \$2.99 per share. Mr. Doherty previously served a member of the Company's Board of Directors from September 1999 to October 2005 and as the Company's President and Chief Executive Officer from September 1999 to December 2002.
- (10) Includes stock underlying a warrant to purchase 114,764 shares of common stock at an exercise price of \$2.99 per share. Griffin Securities, Inc. acted as placement agents for the December 2005 financing transaction.
- (11) Includes stock underlying a warrant to purchase 22,500 shares of common stock at an exercise price of \$2.99 per share.
- (12) Includes stock underlying a warrant to purchase 22,222 shares of common stock at an exercise price of \$2.99 per share.
- (13) Includes stock underlying a warrant to purchase 18,750 shares of common stock at an exercise price of \$2.99 per share.
- (14) Includes stock underlying a warrant to purchase 17,222 shares of common stock at an exercise price of \$2.99 per share.
- (15) Includes stock underlying a warrant to purchase 16,750 shares of common stock at an exercise price of \$2.99 per share.
- (16) Includes stock underlying a warrant to purchase 12,500 shares of common stock at an exercise price of \$2.99 per share.
- (17) Includes stock underlying a warrant to purchase 12,500 shares of common stock at an exercise price of \$2.99 per share.
- (18) Includes stock underlying a warrant to purchase 11,250 shares of common stock at an exercise price of \$2.99 per share.
- (19) Includes stock underlying a warrant to purchase 11,111 shares of common stock at an exercise price of \$2.99 per share. Mr. Hitchcock previously served as the Company's Chairman of the Board from October 2001 to October 2003.
- (20) Includes stock underlying a warrant to purchase 11,111 shares of common stock at an exercise price of \$2.99 per share.
- (21) Includes stock underlying a warrant to purchase 11,111 shares of common stock at an exercise price of \$2.99 per share.
- (22) Includes stock underlying a warrant to purchase 11,111 shares of common stock at an exercise price of \$2.99 per share.
- (23)

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- Includes stock underlying a warrant to purchase 11,111 shares of common stock at an exercise price of \$2.99 per share.
- (24) Includes stock underlying a warrant to purchase 11,111 shares of common stock at an exercise price of \$2.99 per share.
- (25) Includes stock underlying a warrant to purchase 8,750 shares of common stock at an exercise price of \$2.99 per share. Cantone Partners, L.P. was compensated for a finders' fee in connection with the December 2005 financing transaction.
- (26) Includes stock underlying a warrant to purchase 43,691 shares of common stock at an exercise price of \$2.99 per share. Mufson, Howe, Hunter and Partners, LLC acted as placement agents for the December 2005 financing transaction.
- (27) Includes stock underlying a warrant to purchase 7,501 shares of common stock at an exercise price of \$2.99 per share.
- (28) Includes stock underlying a warrant to purchase 6,667 shares of common stock at an exercise price of \$2.99 per share.
- (29) Includes stock underlying a warrant to purchase 6,250 shares of common stock at an exercise price of \$2.99 per share.
- (30) Includes stock underlying a warrant to purchase 6,250 shares of common stock at an exercise price of \$2.99 per share.
- (31) Includes stock underlying a warrant to purchase 6,250 shares of common stock at an exercise price of \$2.99 per share.
- (32) Includes stock underlying a warrant to purchase 6,250 shares of common stock at an exercise price of \$2.99 per share.
- (33) Includes stock underlying a warrant to purchase 6,250 shares of common stock at an exercise price of \$2.99 per share.
- (34) Includes stock underlying a warrant to purchase 30,000 shares of common stock at an exercise price of \$2.99 per share. Mr. Saraceno, an employee of Griffin Securities, Inc. acted as placement agents for the December 2005 financing transaction.
- (35) Includes stock underlying a warrant to purchase 30,000 shares of common stock at an exercise price of \$2.99 per share. Mr. Zizzamia, an employee of Griffin Securities, Inc. acted as placement agents for the December 2005 financing transaction.
- (36) Includes stock underlying a warrant to purchase 5,556 shares of common stock at an exercise price of \$2.99 per share.
- (37) Includes stock underlying a warrant to purchase 5,556 shares of common stock at an exercise price of \$2.99 per share.
- (38) Includes stock underlying a warrant to purchase 5,553 shares of common stock at an exercise price of \$2.99 per share.
- (39) Includes stock underlying a warrant to purchase 5,000 shares of common stock at an exercise price of \$2.99 per share.
- (40) Includes stock underlying a warrant to purchase 5,000 shares of common stock at an exercise price of \$2.99 per share.
- (41) Includes stock underlying a warrant to purchase 5,000 shares of common stock at an exercise price of \$2.99 per share. Mr. Tombros has served on the Company's board of directors since November 2005.
- (42) Includes stock underlying a warrant to purchase 4,500 shares of common stock at an exercise price of \$2.99 per share.
- (43) Includes stock underlying a warrant to purchase 4,450 shares of common stock at an exercise price of \$2.99 per share.
- (44) Includes stock underlying a warrant to purchase 4,000 shares of common stock at an exercise price of \$2.99 per share.
- (45) Includes stock underlying a warrant to purchase 3,750 shares of common stock at an exercise price of \$2.99 per share.
- (46)

- Includes stock underlying a warrant to purchase 3,000 shares of common stock at an exercise price of \$2.99 per share.
- (47) Includes stock underlying a warrant to purchase 2,778 shares of common stock at an exercise price of \$2.99 per share. Mr. Dougherty has served on the Company's board of directors since October 2001.
- (48) Includes stock underlying a warrant to purchase 2,778 shares of common stock at an exercise price of \$2.99 per share.
- (49) Includes stock underlying a warrant to purchase 2,778 shares of common stock at an exercise price of \$2.99 per share.
- (50) Includes stock underlying a warrant to purchase 2,775 shares of common stock at an exercise price of \$2.99 per share.
- (51) Includes stock underlying a warrant to purchase 2,500 shares of common stock at an exercise price of \$2.99 per share.
- (52) Includes stock underlying a warrant to purchase 1,250 shares of common stock at an exercise price of \$2.99 per share.
- (53) Includes stock underlying a warrant to purchase 1,250 shares of common stock at an exercise price of \$2.99 per share.
- (54) Includes stock underlying a warrant to purchase 1,111 shares of common stock at an exercise price of \$2.99 per share. Mr. Rose is the father of the Company's Vice President and Chief Financial Officer, Marc L. Rose.
- (55) Includes stock underlying a warrant to purchase 375 shares of common stock at an exercise price of \$2.99 per share. Mr. Dervan is an employee of the Company.
- (56) Includes stock underlying a warrant to purchase 95 shares of common stock at an exercise price of \$2.99 per share. Mr. Dervan is the brother of Joe Jude Dervan, an employee of the Company.

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## LEGAL MATTERS

The validity of the shares of common stock being offered hereby will be passed upon for us by Reed Smith LLP, San Francisco, California.

## EXPERTS

Our financial statements, as of and for the two years ended May 31, 2005 appearing in this prospectus and registration statement have been audited by Grant Thornton LLP, independent registered public accounting firm, as set forth on their report thereon appearing elsewhere in this prospectus, and are included in reliance upon such report given upon the authority of such firm as experts in accounting and auditing.

## AVAILABLE INFORMATION

We have filed a registration statement on Form SB-2 under the Securities Act of 1933, as amended, relating to the shares of common stock being offered by this prospectus, and reference is made to such registration statement. This prospectus constitutes the prospectus of Protalex, Inc., filed as part of the registration statement, and it does not contain all information in the registration statement, as certain portions have been omitted in accordance with the rules and regulations of the SEC.

We are subject to the informational requirements of the Securities Exchange Act of 1934, which requires us to file reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information may be inspected at public reference room of the SEC at Judiciary Plaza, 450 Fifth Street N.W., Washington D.C. 20549. Copies of such material can be obtained from the facility at prescribed rates. Please call the SEC toll free at 1-800-SEC-0330 for information about its public reference room. Because we file documents electronically with the SEC, you may also obtain this information by visiting the SEC's Internet website at <http://www.sec.gov> or our website at <http://www.protalex.com>. Information contained in our web site is not part of this prospectus.

Our statements in this prospectus about the contents of any contract or other document are not necessarily complete. You should refer to the copy of our contract or other document we have filed as an exhibit to the registration statement for complete information.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. The selling stockholders are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document. We furnish our stockholders with annual reports containing audited financial statements.

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## INDEX TO FINANCIAL STATEMENTS

Protalex, Inc.  
(A Company in the Development Stage)

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors  
Protalex, Inc.

We have audited the accompanying balance sheets of Protalex, Inc. (a Delaware Corporation in the development stage) as of May 31, 2005 and 2004, and the related statements of operations, changes in stockholders' equity, and cash flows for the years then ended and for the cumulative period from inception through May 31, 2005, as it relates to the fiscal years ended May 31, 2005 and 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Protalex, Inc. as of May 31, 2005 and 2004, and the results of its operations and its cash flows for the years then ended, and for the cumulative period from inception through May 31, 2005, as it relates to the fiscal years ended May 31, 2005 and 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/Grant Thornton LLP

Philadelphia, Pennsylvania  
July 29, 2005

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Protalex, Inc.  
(A Company in the Development Stage)

**BALANCE SHEETS**

May 31,

**ASSETS**

	2005	2004
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 9,453,367	\$ 9,292,783
Prepaid expenses and employee advances	9,281	22,041
Total current assets	9,462,648	9,314,824
<b>PROPERTY &amp; EQUIPMENT:</b>		
Lab equipment	313,613	260,425
Office and computer equipment	157,787	153,266
Furniture & fixtures	25,556	25,556
Leasehold improvements	27,060	5,540
	524,016	444,787
Less accumulated depreciation and amortization	(400,387)	(342,723)
	123,629	102,064
<b>OTHER ASSETS:</b>		
Deposits	7,590	7,590
Intellectual technology property, net of accumulated amortization of \$5,673 in 2005 and \$4,653 in 2004	14,627	15,647
Total other assets	22,217	23,237
	\$ 9,608,494	\$ 9,440,125

**LIABILITIES AND STOCKHOLDERS' EQUITY**

<b>CURRENT LIABILITIES:</b>		
Current maturities of capital lease obligation	\$ 20,046	\$ 20,487
Accounts payable	866,628	377,100
Payroll and related liabilities	28,835	24,560
Accrued expenses	81,517	—
Total current liabilities	997,026	422,147
Capital lease obligation, less current portion	—	20,046
Other	4,655	1,544
Total liabilities	1,001,681	443,737

**STOCKHOLDERS' EQUITY:**

Common stock, par value \$0.00001, 40,000,000 shares authorized, 19,393,221 and 16,784,433 shares issued and outstanding as of May 31, 2005 and 2004, respectively	194	14,683,854
Additional paid in capital	20,913,822	1,052,008
Deficit accumulated during the development stage	(12,307,203)	(6,739,474)

Total stockholders' equity	8,606,813	8,996,388
	\$ 9,608,494	\$ 9,440,125

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

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Protalex, Inc.  
(A Company in the Development Stage)

**STATEMENTS OF OPERATIONS**

For the years ended May 31, 2005 and 2004, and From  
Inception (September 17, 1999) through May 31, 2005

	Year Ended May 31, 2005	Year Ended May 31, 2004	From Inception Through May 31, 2005
REVENUES	\$ —	\$ —	\$ —
OPERATING EXPENSES:			
Research and development	(3,519,910)	(1,399,190)	(7,202,816)
Administrative	(1,457,694)	(1,393,347)	(3,814,440)
Professional fees	(714,665)	(288,077)	(1,279,958)
Depreciation and amortization	(5,111)	(5,486)	(146,106)
Operating Loss	(5,697,380)	(3,026,100)	(12,443,320)
Other income (expense)			
Interest income	132,181	44,618	216,466
Interest expense	(2,530)	(6,321)	(69,769)
Loss on disposal of equipment	—	(1,561)	(10,580)
Net Loss	\$ (5,567,729)	\$ (2,989,364)	\$ (12,307,203)
Weighted average number of common shares outstanding	16,832,643	15,384,933	12,737,901
Loss per common share - basic and diluted	\$ (.33)	\$ (.19)	\$ (.97)

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

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Protalex, Inc.  
(A Company in the Development Stage)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

From Inception (September 17, 1999) through May 31, 2005

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated In The Development Stage	Total
September 17, 1999 — initial issuance of 10,000 shares for intellectual technology license at \$.03 per share	10,000	\$ 300	\$ —	—	—	300
September 30, 1999 — cost of public shell acquisition over net assets acquired to be accounted for as a Recapitalization	—	—	—	(250,000)	—	(250,000)
October 27, 1999 — issuance of 84 shares to individual for \$25,000	84	25,000	—	—	—	25,000
November 15, 1999 — reverse merger transaction with Enerdyne Corporation, net transaction amounts	8,972,463	118,547	—	(118,547)	—	—
November 18, 1999 — February 7, 2000 — issuance of 459,444 shares to various investors at \$0.36 per share	459,444	165,400	—	—	—	165,400
January 1, 2000 — issuance of 100,000 shares in exchange for legal services	100,000	15,000	—	—	—	15,000
May 1 - 27, 2000 — issuance of 640,000 shares to various investors at \$1.00 per share	640,000	640,000	—	—	—	640,000
May 27, 2000 — issuance of 1,644 shares to individual in exchange for interest Due	1,644	1,644	—	—	—	1,644
Net loss for the year ended May 31, 2000	—	—	—	—	(250,689)	(250,689)
Balance, May 31, 2000	10,183,635	965,891	—	(368,547)	(250,689)	346,655



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	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated In The Development Stage	Total
December 7, 2000 — issuance of 425,000 shares to various investors at \$1.00 per share	425,000	425,000	—	—	—	425,000
May 31, 2001 — Forgiveness of debt owed to shareholder	—	—	40,000	—	—	40,000
Net loss for the year ended May 31, 2001	—	—	—	—	(553,866)	(553,866)
Balance, May 31, 2001	10,608,635	1,390,891	40,000	(368,547)	(804,555)	257,789
August 13, 2001 — Contribution by Shareholders	—	—	143,569	—	—	143,569
November 7, 2001 — issuance of 881,600 Shares at \$1.25 per share	881,600	1,102,000	—	—	—	1,102,000
November 26, 2001 — options issued to board member	—	—	133,000	—	—	133,000
Net loss for the year ended May 31, 2002	—	—	—	—	(1,280,465)	(1,280,465)
Balance, May 31, 2002	11,490,235	2,492,891	316,569	(368,547)	(2,085,020)	355,893
July 5, 2002 — issuance of 842,000 shares at \$1.50 per share	842,000	1,263,000	—	—	—	1,263,000
July 1, 2002 - May 1, 2003 - purchase of common stock from shareholder at \$.70 per share	(130,955)	(91,667)	—	—	—	(91,667)
January 15, 2003 - May 15, 2003 — common stock issued to Company president	41,670	82,841	—	—	—	82,841
May 14, 2003 — common stock issued to employee	5,000	11,250	—	—	—	11,250
June 1, 2002 - May 31, 2003 — options issued to board members and employees	—	—	287,343	—	—	287,343
Net loss for the year ended May 31, 2003	—	—	—	—	(1,665,090)	(1,665,090)
Balance, May 31, 2003	12,247,950	3,758,315	603,912	(368,547)	(3,750,110)	243,570
June 15, 2003, common stock issued to Company president	8,334	16,418	—	—	—	16,418
June 15, 2003, purchase of common stock from shareholder	(12,093)	(8,333)	—	—	—	(8,333)

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	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated In The Development Stage	Total
September 18, 2003 - issuance of 7,445,646 of common stock issued in private placement At \$1.70 per share, net of transaction costs	7,445,646	11,356,063	—	—	—	11,356,063
September 19, 2003 - repurchase and retired 2,994,803 shares for \$300,000	(2,994,803)	(300,000)	—	—	—	(300,000)
December 12, 2003 - issuance of 39,399 shares to terminated employees at \$2.60 per share	39,399	102,438	—	—	—	102,438
March 1, 2004 - common stock issued to employee at \$2.55 per share	50,000	127,500	—	—	—	127,500
May 31, 2004 - reclassify common stock contra to common stock	—	(368,547)	—	368,547	—	—
December 12, 2003 - issuance of 39,399 shares to terminated employees at \$2.60 per share	39,399	102,438	—	—	—	102,438
June 1, 2003 - May 31, 2004 - options issued to board members, employees and consultants	—	—	448,096	—	—	448,096
Net loss for the year ended May 31, 2004	—	—	—	—	(2,989,364)	(2,989,364)
Balance, May 31, 2004	16,784,433	\$ 14,683,854	\$ 1,052,008	—	—\$(6,739,474)	\$ 8,996,388
November 30, 2004 - adjust March 1, 2004 common stock issued to employee	—	(20,000)	—	—	—	(20,000)
January 13, 2005 - common stock issued to employee at \$2.55 per share	15,000	38,250	—	—	—	38,250
February 28, 2005 - Reclass Par Value for Reincorporation into DE as of 12/1/04	—	(14,701,935)	14,701,935	—	—	0
May 25, 2005 - issuance of 2,593,788 of common stock issued in private placement At \$1.95 per share, net of transaction costs	2,593,788	25	4,851,168	—	—	4,851,193





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	Common Stock		Additional	Common	Deficit	
	Shares	Amount	Paid in	Stock-	Accumulated	Total
			Capital	Contra	In The	
					Development	
					Stage	
June 1 , 2004 - May 31, 2005 - options issued to board members, employees and consultants			308,711			308,711
Net loss for the year ended May 31, 2005		—	—	—	(5,567,729)	(5,567,729)
Balance, May 31, 2005	19,393,221	\$ 194	\$ 20,913,822		→ \$(12,307,203)	\$ 8,606,813

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

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Protalex, Inc.  
(A Company in the Development Stage)

**STATEMENTS OF CASH FLOWS**

For the years ended May 31, 2005 and 2004, and From Inception  
(September 17, 1999) through May 31, 2005

	Year Ended May 31, 2005	Year Ended May 31, 2004	From Inception Through May 31, 2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (5,567,729)	\$ (2,989,364)	\$ (12,307,203)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:			
Loss on disposal of equipment	—	1,561	10,580
Depreciation and amortization	58,684	64,631	428,581
Non cash compensation expense	326,960	694,452	1,535,846
Non cash expenses	—	—	16,644
(Increase)/Decrease in advances, prepaid expenses and deposits	12,760	(22,759)	(16,871)
Increase in accounts payable and accrued expenses	571,045	261,606	948,145
Increase in payroll and related liabilities	4,275	15,744	28,835
Increase in other liabilities	3,111	1,529	4,655
Net cash and cash equivalents used in operating activities	(4,590,894)	(1,972,600)	(9,350,788)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Acquisition of intellectual technology license - fee portion	—	—	(20,000)
Acquisition of property and equipment	(79,229)	(40,426)	(410,536)
Excess of amounts paid for Public Shell over assets acquired to be accounted for as a recapitalization	—	—	(250,000)
Proceeds from disposal of equipment	—	—	6,000
Net cash and cash equivalents used in investing activities	(79,229)	(40,426)	(674,536)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from stock issuance	4,851,194	11,356,063	19,827,658
Principal payment on capital leases and installment purchase payable	(20,487)	(21,973)	(275,365)
Contribution by shareholders	—	—	183,569
Principal payment on note payable individual	—	—	(225,717)
Issuance of note payable to individual	—	—	368,546
Acquisition of common stock	—	(308,333)	(400,000)
Net cash and cash equivalents provided by financing activities	4,830,707	11,025,757	19,478,691

NET INCREASE IN CASH AND CASH EQUIVALENTS	160,584	9,012,731	9,453,367
Cash and cash equivalents, beginning	9,292,783	280,052	—
Cash and cash equivalents, ending	\$ 9,453,367	\$ 9,292,783	\$ 9,453,367
Supplemental disclosures of cash flow information:			
Interest paid	\$ 2,128	\$ 6,336	\$ 66,156
Taxes paid	\$ 50	\$ —	\$ 100

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

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Protalex, Inc.  
(A Company in the Development Stage)

**NOTES TO FINANCIAL STATEMENTS**

From Inception (September 17, 1999) through May 31, 2005

**NOTE A - DESCRIPTION OF OPERATIONS AND DEVELOPMENT STAGE STATUS**

The Company is a development stage enterprise incorporated on September 17, 1999 in Albuquerque, New Mexico and reincorporated in the State of Delaware in December 2004. The Company's headquarters are located in New Hope, Pennsylvania. The Company was formed to take all necessary steps to fully develop and bring to commercial realization certain bioregulatory technology for the treatment of human diseases. The Company has no operating revenue.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. The Company is a development stage enterprise and does not anticipate generating operating revenue for the foreseeable future. The ability of the Company to continue as a going concern is dependent upon developing products that are regulatory approved and market accepted. There is no assurance that these plans will be realized in whole or in part. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

On December 1, 2004, the Company reincorporated from New Mexico to Delaware. Additional information regarding the Company's reincorporation can be found in the Company's Current Report on Form 8-K dated December 1, 2004 and filed with the Securities and Exchange Commission on December 6, 2004. The impact to the Stockholders' Equity as of May 31, 2005 as a result of the reincorporation was to adjust Common Stock to its legal par value and is reflected in the accompanying Statement of Changes in Stockholders' Equity.

**NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

1. Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues and expense, and the disclosure of contingent assets and liabilities. Estimated amounts could differ from actual results.

2. Loss per Common Share

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 128 "Earnings Per Share" (SFAS No. 128) which is effective for periods ending after December 15, 1997. SFAS No. 128 provides for the calculation of "Basic" and "Diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing loss to common shareholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities have been excluded from the computations since they would be antidilutive. However, these dilutive securities could potentially dilute earnings per share in the future. As of May 31, 2005, the Company had a total of 7,570,971 potentially dilutive securities.

3. Stock Based Compensation

The Company adopted the disclosure provisions of Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." The Company accounts for options granted to employees using the intrinsic value recognition and measurement principles of APB Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations. In accordance with APB 25, the Company records compensation cost as the difference between the exercise price of the options and the fair market value of the Company stock on the measurement (grant) date. These costs are amortized to expense over the options' vesting period (see Recent Accounting Pronouncements pertaining to SFAS No. 123-Revised). Options to non-employees are accounted for using the fair value method, which recognizes the value of the option as an expense over the related service period with a corresponding increase to additional paid-in capital.

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The following table illustrates the effect on net loss and earnings per share if the Company applied the fair value recognition provision of SFAS No. 123 to stock-based employee compensation.

	<b>Year Ended May 31, 2005</b>	<b>Year Ended May 31, 2004</b>	<b>From Inception Through May 31, 2005</b>
Net loss, as reported	\$ (5,567,729)	\$ (2,989,364)	\$ (12,307,203)
Add: stock-based employee compensation expense included in reported net loss	288,710	306,969	883,022
Deduct: stock-based employee compensation Expense determined under fair-value method for all awards	(1,384,715)	(1,087,701)	(3,289,649)
Pro forma net loss	\$ (6,663,734)	\$ (3,770,096)	\$ (14,713,830)
Loss per common share, as reported - basic and diluted	\$ (.33)	\$ (.19)	\$ (.97)
Proforma loss per common share - basic and diluted	\$ (.40)	\$ (.25)	\$ (1.16)

The fair value of the options are estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions:

	<b>Year Ended May 31, 2005</b>	<b>Year Ended May 31, 2005</b>	<b>From Inception Through May 31, 2005</b>
Dividends per year	0	0	0
Volatility percentage	102-107%	95%-102%	90%-131%
Risk free interest rate	2.57-3.52%	2.07%-4.78%	2.07%-5.11%
Expected life (years)	4	4	3-5

#### 4. Cash and Cash Equivalents

For the purposes of reporting cash flows, the Company considers all cash accounts, which are not subject to withdrawal restrictions or penalties, and highly liquid investments with original maturities of 90 days or less to be cash and cash equivalents.

#### 5. Property, Equipment, Intellectual Technology Property, Depreciation and Amortization

Equipment is carried at cost. Depreciation and amortization has been provided by the Company in order to amortize the cost of property and equipment over their estimated useful lives, which are estimated to be over three to five years. The Company uses the straight-line method for all classes of assets for book purposes and accelerated methods for tax purposes. Depreciation and amortization expense is \$57,664, \$63,616, and \$422,908 for the years ended May 31, 2005, 2004 and from inception through May 31, 2005, respectively. Depreciation included in research and development expense totaled \$53,575, \$59,145 and \$282,475 for the years ended May 31, 2005 and 2004 and from inception to May 31, 2005, respectively.

The Company's intellectual technology property was originally licensed from a former related party. This intellectual technology property was then assigned to the Company upon the dissolution of the related party. The cost of the intellectual technology property is being amortized over a 20-year period. Amortization expense is \$1,020, \$1,015 and \$5,673 for the years ended May 31, 2005, 2004 and from inception through May 31, 2005, respectively. The Company reviews the intellectual property for impairment on at least an annual basis in accordance with SFAS No. 142 "Goodwill and Other Intangible Assets". Amortization expense for the intellectual property will be \$1,020 for each of the next five years.

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6. Income Taxes

Income taxes are recognized using enacted tax rates, and are composed of taxes on financial accounting income that is adjusted for the requirement of current tax law and deferred taxes. Deferred taxes are accounted for using the asset and liability method. Under this method, deferred tax assets and liabilities are recognized based on the difference between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The Company does not expect to have current income taxes payable or deferred tax asset balances for the foreseeable future.

7. Other Comprehensive Income

From September 17, 1999 (inception) through May 31, 2005, the Company had no changes in equity which constitute components of other comprehensive income.

8. Research and Development

Research and development costs are expensed as incurred and also include depreciation as reported above.

9. Fair Value of Financial Instruments

The fair value of the Company's financial instruments, principally cash and debt, approximates their carrying value.

10. Recent Accounting Pronouncements

In December 2004, the FASB revised SFAS No. 123. SFAS No. 123-Revised supersedes APB 25 and related interpretations, and will require all companies to estimate the fair value of all share-based awards granted and then amortize that estimated fair value to expense over the requisite service period. SFAS No. 123-Revised is effective for the Company for all annual periods beginning after June 15, 2005. The Company currently accounts for options issued to its employees under the recognition and measurement principles of APB 25 and related interpretations. The Company is required to adopt SFAS No. 123-Revised by the first quarter of fiscal year 2007. See Note B. 3, "Stock Based Compensation," for pro forma information if the Company had elected to adopt the requirements of the previously issued SFAS No. 123 for options issued to employees.

11. Reclassifications

Certain amounts in the 2004 financial statements have been reclassified to conform to the 2005 presentation.

**NOTE C - REVERSE MERGER**

On November 15, 1999, Enerdyne Corporation (Enerdyne or Public Shell) acquired all of the outstanding common stock of Protalex, Inc. (Protalex) in exchange for the issuance of additional shares of Enerdyne stock. The ratio of exchange was 822 shares of Enerdyne stock issued for each share of Protalex stock received. For accounting purposes, the acquisition has been treated as an acquisition of Enerdyne by Protalex and as a recapitalization of Protalex (Reverse Merger). The historical financial statement of operations presented herein include only those of the accounting acquirer and the retained earnings (deficit) of only the accounting acquirer carries over consistent with the requirements of reverse merger accounting. Concurrently with the share exchange, Enerdyne changed its name to Protalex, Inc.





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The details of the reverse merger transaction are as follows:

Account Description	Protalex, Inc.	Enerdyne Corporation	Transaction Adjustments	Balance Sheet at November 16, 1999
Cash	\$ 23,531	\$ —	\$ —	23,531
Note receivable shareholder	—	118,547	—	118,547
License	20,300	—	—	20,300
Investment in Enerdyne	368,547	—	(368,547)	—
Other current assets	8,212	—	—	8,212
Other current liabilities	(17,555)	—	—	(17,555)
Accounts payable Alex	(40,000)	—	—	(40,000)
Note payable	(368,546)	—	—	(368,546)
Common stock	(25,300)	(833,459)	714,912	(143,847)
Additional paid in capital	—	(1,105,014)	1,105,014	—
Treasury stock	—	430,424	(430,424)	—
Accumulated deficit	30,811	1,389,502	(1,389,502)	30,811
Common stock - contra	—	—	368,547	368,547
	\$ —	\$ —	\$ —	\$ —

**NOTE D - INCOME TAXES**

The provision for income taxes for the years ended May 31, 2005 and 2004 consist of the following. Total income tax benefit differs from the amounts computed by applying the statutory tax rate to loss before income taxes due to the increase in the Company's valuation allowance.

	Year Ended May 31, 2005	Year Ended May 31, 2004
Statutory federal and state rates of 40%	\$ 2,227,000	\$ 1,196,000
Increase in valuation allowance	(2,227,000)	(1,196,000)
Actual tax benefit	\$ —	\$ —

For the years ended May 31, 2005 and 2004, the components of income tax benefit (expense) consist of the following:

	Year Ended May 31, 2005	Year Ended May 31, 2004
Current:		
Federal	\$ —	\$ —
State	—	—
Deferred:		
Federal	1,858,000	926,000
State	369,000	163,000
Valuation allowance	(2,227,000)	(1,089,000)

Income tax benefit	\$	—\$	—
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The components of the net deferred tax asset as of May 31, 2005 and 2004 are as follows:

	Year Ended May 31, 2005	Year Ended May 31, 2004
Assets:		
Net operating losses	\$ 3,818,000	\$ 2,311,000
Vacation accrual	12,000	6,000
Stock based compensation	613,000	411,000
General business credit	506,000	—
Deferred tax assets	4,949,000	2,728,000
Liability, Equipment	(26,000)	(32,000)
Gross deferred tax asset	4,923,000	2,696,000
Less valuation allowance	(4,923,000)	(2,696,000)
Deferred tax asset, net of valuation allowance	\$	—\$

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The gross deferred taxes have been fully offset by a valuation allowance since the Company cannot currently conclude that it is more likely than not that the benefits will be realized. The net operating loss carryforward for income tax purposes of approximately \$10,000,000 as of May 31, 2005 expires beginning in 2014 through 2020. Internal Revenue Code Section 382 places a limitation on the amount of taxable income that can be offset by carryforwards after a change in control (generally greater than a 50% change in ownership). As a result of these provisions, utilization of the NOL and tax credit carryforwards may be limited.

**NOTE E - RELATED PARTIES**

During the years ended May 31, 2005 and May 31, 2004, the Company incurred \$12,098 and \$10,505 respectively, of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company.

During the years ended May 31, 2005 and May 31, 2004, the Company incurred \$12,515 and \$15,238 respectively, of expenses related to legal services to a firm, which employs one of the Company's board members.

The Company has an agreement with its Chairman to pay \$12,500 per month as a director fee. During the years ended May 31, 2005 and May 31, 2004, the Company incurred \$150,000 and \$122,177 respectively for this director's fee.

The Company has an agreement with Carleton A. Holstrom and Dr. Eugene Bauer to pay each \$1,667 per month payable on a quarterly in arrears as a director fee. During the years ended May 31, 2005 and May 31, 2004, the Company incurred \$16,667 and \$0 respectively for these directors' fees. As of May 31, 2005, \$1,667, is included within Accounts Payable and was subsequently paid on July 15, 2005.

**NOTE F - CAPITAL LEASE OBLIGATIONS**

Protalex leases certain equipment under a capital lease. As of May 31, 2005 and 2004, the recorded amount of assets, net of related accumulated depreciation was \$20,383 and \$40,767, respectively.

Future minimum lease payments and the related present value of the future obligation under the capital lease at May 31, 2005 are as follows:

Year	
2006	20,736
Total minimum obligations	20,736
Interest	(690)
Present value of minimum capital lease obligations	20,046
Current portion	(20,046)
Long-term capital lease obligations	\$ 0

**NOTE G - STOCK OPTIONS**

Prior to January 22, 2004, all options were issued as "stand alone" options. On January 22, 2004, the board of directors of the Company approved the Protalex, Inc. 2003 Stock Option Plan., which provides for incentive and non-qualified stock options to purchase a total of 1,500,000 shares of the Company's Common Stock. Under the terms of the plan, incentive options may not be granted for less than the fair market value of the Common Stock at the date of the grant and non-qualified options shall not be granted for less than 85% of the fair market value of the Common Stock at the date of the grant. Beginning January 1, 2005, all stock options are granted at fair market value. Vesting generally occurs ratably over forty eight months and is exercisable over a period no longer than ten years after the grant date. As

of May 31, 2005, options to purchase 3,401,255 shares of the Company's Common Stock were granted, of which 1,115,000 were issued under the Company's 2003 Stock Option Plan and the remaining 2,285,255 were issued as stand alone options. As of May 31, 2005, 2,100,342 are exercisable.

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A summary of the common stock option activity for employees, directors and officers as of May 31, 2005 is as follows:

	Weighted Average Exercise		Exercisable
	Options	Prices	
Balance, September 17, 1999	—	\$ —	—
Granted, April 28, 2000	40,000	0.36	—
Granted, November 26, 2001	100,000	1.25	100,000
Expired, April 28, 2002	(40,000)	.036	—
Granted, June 1, 2002	125,000	1.50	125,000
Granted, July 18, 2002	233,680	1.50	233,680
Granted, October 24, 2002	100,000	1.45	100,000
Granted, December 16, 2002	863,242	1.50	469,664
Granted, December 16, 2002	50,000	1.70	40,000
Granted, March 15, 2003	130,000	1.50	—
Granted, April 1, 2003	40,000	1.50	20,833
Granted, July 1, 2003	40,000	1.50	18,333
Granted, August 13, 2003	100,000	1.50	100,000
Granted, September 19, 2003	584,333	1.50	301,802
Granted, October 28, 2003	60,000	1.50	60,000
Granted, January 22, 2004	75,000	2.13	75,000
Granted, January 22, 2004	100,000	2.13	29,997
Granted, January 22, 2004	50,000	2.75	16,666
Forfeited, January 22, 2004	(130,000)	1.50	—
Granted, March 1, 2004	150,000	2.17	43,749
Granted, July 22, 2004	15,000	2.60	3,124
Granted, October 26, 2004	30,000	2.70	4,790
Granted, October 26, 2004	100,000	2.30	100,000
Granted, January 13, 2005	330,000	2.55	31,663
Granted, January 13, 2005	125,000	2.55	125,000
Forfeited, January 26, 2005	(10,000)	1.70	—
Forfeited, January 26, 2005	(10,000)	2.13	—
Granted, February 15, 2005	100,000	2.80	100,000
Granted, April 13, 2005	50,000	2.60	1,041
	3,401,255		2,100,342

The following summarizes certain information regarding stock options at May 31, 2005:

Exercise Price Range	Number	Total Weighted Average Exercise Price	Weighted Average Remaining Life (yrs)	Exercisable		Weighted Average Remaining Life
				Number	Weighted Average Exercise Price	
\$1.25 - 1.75	2,286,255	\$ 1.49	7.1	1,569,312	\$ 1.49	7.1
\$1.76 - 2.25	315,000	\$ 2.15	8.8	148,746	\$ 2.14	8.8
	700,000	\$ 2.54	9.5	282,284	\$ 2.48	9.5

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\$2.26 -									
2.75									
\$2.76 -									
3.25	100,000	\$	2.80	9.7	100,000	\$	2.80	9.7	
	3,401,255				2,100,342				

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**NOTE H - DESCRIPTION OF LEASING ARRANGEMENTS**

The Company leases its office space under a non-cancelable operating lease. The lease term is for three years, with an option to extend for one or two years beyond the initial term. Rent expense for the years ended May 31, 2005 and 2004 was \$98,498 and \$37,571, respectively.

In December 2004, the Company entered into a non-cancelable operating lease for a multi-function copier. The lease term is for sixty three months. Rent expense for the years ended May 31, 2005 and 2004 was \$1,245 and \$0, respectively.

Future minimum lease payments are as follows:

<b>Year ending May 31,</b>	
2006	\$ 113,500
2007	78,752
2008	2,988
2009	2,988
2010	2,241
<b>Total</b>	<b>\$ 200,469</b>

**NOTE I - SALE AND REPURCHASE OF COMMON STOCK**

On September 18, 2003, the Company closed a private placement, raising a total of \$11,356,063, net of transaction costs in exchange for 7,445,646 shares of common stock and 2,605,976 warrants exercisable at \$2.40 per share, expiring on September 18, 2008. In addition, 558,423 warrants, exercisable at \$2.40 per share, were issued to Merriman and Company, as part of their fee for acting as placement agent.

On September 19, 2003, the Company repurchased and retired 2,994,803 shares of common stock from former Chief Scientific Officer Paul Mann and family members for \$300,000.

On May 25, 2005, the Company closed a private placement, raising a total of \$4,851,194, net of transaction costs in exchange for 2,593,788 shares of common stock at \$1.95 per share and 920,121 warrants exercisable at \$2.25 per share, expiring on May 25, 2010. Included in this warrant amount were 100,000 warrants for Pacific Growth Equities, LLC. As part of this transaction, the warrants issued on September 18, 2003, were repriced from \$2.40 per share to \$2.25 per share.



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Protalex, Inc.  
(A Company in the Development Stage)

**BALANCE SHEETS**

	November 30, 2005 (Unaudited)	May 31, 2005
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 6,760,832	\$ 9,453,367
Prepaid expenses and employee advances	45,041	9,281
Total current assets	6,805,873	9,462,648
<b>PROPERTY &amp; EQUIPMENT:</b>		
Lab equipment	327,287	313,613
Office and computer equipment	157,787	157,787
Furniture & fixtures	25,556	25,556
Leasehold improvements and amortization	27,060	27,060
	537,690	524,016
Less accumulated depreciation	(435,379)	(400,387)
	102,311	123,629
<b>OTHER ASSETS:</b>		
Deposits	7,590	7,590
Intellectual technology property, net of accumulated amortization of \$6,183 and \$5,673 as of November 30, 2005 and May 31, 2005, respectively	14,117	14,627
Total other assets	21,707	22,217
	\$ 6,929,891	\$ 9,608,494
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current maturities of capital lease obligation	\$ 9,267	\$ 20,046
Accounts payable	613,799	866,628
Payroll and related liabilities	40,770	28,835
Accrued expenses	107,008	81,517
Total current liabilities	770,844	997,026
<b>OTHER LIABILITIES</b>		
Total liabilities	4,693	4,655
	775,537	1,001,681
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, par value \$0.00001, 100,000,000 and 40,000,000 shares authorized as of November 30, 2005 and May 31, 2005 respectively, 19,443,221 and 19,393,221 shares issued and outstanding as of November 30, 2005 and May 31, 2005, respectively		
	194	194
Additional paid in capital	21,207,333	20,913,822
Deficit accumulated during the development stage	(15,053,173)	(12,307,203)
Total stockholders' equity	6,154,354	8,606,813

\$ 6,929,891 \$ 9,608,494

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

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Protalex, Inc.  
(A Company in the Development Stage)

**STATEMENTS OF OPERATIONS**

For the three and six month periods ended November 30, 2005 and 2004, and From  
Inception (September 17, 1999) through November 30, 2005  
(Unaudited)

	Six Months Ended November 30, 2005	Six Months Ended November 30, 2004	Three Months Ended November 30, 2005	Three Months Ended November 30, 2004	From Inception Through November 30, 2005
Revenues	\$	\$	\$	\$	\$
<b>Operating Expenses</b>					
Research and development	(1,687,014)	(1,639,264)	(994,739)	(919,718)	(8,889,830)
Administrative	(965,384)	(605,854)	(569,268)	(386,079)	(4,779,824)
Professional fees	(226,294)	(267,192)	(91,133)	(178,991)	(1,506,252)
Depreciation and amortization	(2,105)	(2,733)	(1,050)	(1,337)	(148,211)
Operating Loss	(2,880,797)	(2,515,043)	(1,656,190)	(1,486,125)	(15,324,117)
<b>Other income (expense)</b>					
Interest income	135,441	46,637	67,107	21,042	351,907
Interest expense	(614)	(1,637)	(302)	(973)	(70,383)
Loss on disposal	—	—	—	—	(10,580)
Net Loss	\$ (2,745,970)	\$ (2,470,043)	\$ (1,589,385)	\$ (1,466,056)	\$ (15,053,173)
<b>Weighted average number of common shares outstanding</b>					
	19,435,516	16,784,433	19,437,836	16,784,433	13,276,836
Loss per common share - basic and diluted	\$ (.14)	\$ (.15)	\$ (.08)	\$ (.09)	\$ (1.13)

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

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Protalex, Inc.  
(A Company in the Development Stage)

**STATEMENTS OF CASH FLOWS**

For the six month periods ended November 30, 2005 and 2004 and From  
Inception (September 17, 1999) through November 30, 2005  
(Unaudited)

	Six Months Ended November 30, 2005	Six Months Ended November 30, 2004	From Inception Through November 30, 2005
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (2,745,970)	\$ (2,470,043)	\$ (15,053,173)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities			
Loss on disposal of equipment	—	—	10,580
Depreciation and amortization	35,502	24,686	464,083
Non cash compensation expense	293,511	151,515	1,829,357
Non cash expenses	—	—	16,644
(Increase) in:			
Prepaid expense and employee advances	(35,760)	(8,556)	(52,631)
Increase (decrease) in:			
Accounts payable and accrued expenses	(227,338)	40,328	720,807
Payroll and related liabilities	11,935	7,601	40,770
Other liabilities	38	2,316	4,693
Net cash and cash equivalents used in operating activities	(2,668,082)	(2,252,153)	(12,018,870)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Acquisition of intellectual technology license - fee portion	—	—	(20,000)
Acquisition of equipment	(13,674)	(19,539)	(424,210)
Excess of amounts paid for public shell over assets acquired to be accounted for as a recapitalization	—	—	(250,000)
Proceeds from disposal of equipment	—	—	6,000
Net cash and cash equivalents used in investing activities	(13,674)	(19,539)	(688,210)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from stock issuance	—	—	19,827,658
Principal payment on equipment notes payable and capital leases	(10,779)	(10,070)	(286,144)
Contribution by shareholders	—	—	183,569
Principal payment on note payable to individuals	—	—	(225,717)
Issuance of note payable to individuals	—	—	368,546

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Acquisition of common stock	—	—	(400,000)
Net cash and cash equivalents (used in) provided by financing activities	(10,779)	(10,070)	19,467,912
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(2,692,535)</b>	<b>(2,281,762)</b>	<b>6,760,832</b>
Cash and cash equivalents, beginning	9,453,367	9,292,783	—
Cash and cash equivalents, end	\$ 6,760,832	\$ 7,011,021	\$ 6,760,832
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:</b>			
Interest paid	\$ 614	\$ 1,637	\$ 66,770
Taxes paid	\$ 4,625	\$ —	\$ 4,725

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

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**NOTE A - NOTES TO INTERIM FINANCIAL STATEMENTS (Unaudited)**

The interim financial data is unaudited; however in the opinion of management, the interim data includes all adjustments, consisting of normal recurring adjustments, necessary for a fair statement of the results for the interim period. The financial statements included herein have been prepared by Protalex, Inc. (the "Company") pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been omitted pursuant to such rules and regulations, although the Company believes that the disclosures included herein are adequate to make the information presented not misleading.

Information regarding the organization and business of the Company, accounting policies followed by the Company and other important information are contained in the notes to the Company's financial statements filed as part of the Company's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2005. This quarterly report should be read in conjunction with such annual report.

**NOTE B - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**1. Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions affecting the reported amounts of assets, liabilities, revenues and expense, and the disclosure of contingent assets and liabilities. Estimated amounts could differ from actual results.

**2. Loss per Common Share**

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 128, "Earnings Per Share" (SFAS No. 128) which provides for the calculation of "Basic" and "Diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing net loss to common shareholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities have been excluded from the computations since they would be antidilutive. However, these dilutive securities could potentially dilute earnings per share in the future. As of November 30, 2005, the Company had a total of 8,058,521 potentially dilutive securities.

**3. Stock Based Compensation**

The Company adopted the disclosure provisions of Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." The Company accounts for options granted to employees using the intrinsic value recognition and measurement principles of APB Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations. In accordance with APB 25, the Company records compensation cost as the difference between the exercise price of the options and the fair market value of the Company stock on the measurement (grant) date. These costs are amortized to expense over the options' vesting period (see Note C - Recent Accounting Pronouncements pertaining to SFAS No. 123-Revised). Options to non-employees are accounted for using the fair value method, which recognizes the value of the option as an expense over the related service period with a corresponding increase to additional paid-in capital.

The following table illustrates the effect on net loss and earnings per share if the Company applied the fair value recognition provision of SFAS No. 123 to stock-based employee compensation.



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**Unaudited**

	Six Months Ended November 30, 2005	Six Months Ended November 30, 2004	Three Months Ended November 30, 2005	Three Months Ended November 30, 2004	From Inception Through November 30, 2005
Net loss, as reported	\$ (2,745,970)	\$ (2,470,043)	\$ (1,589,385)	\$ (1,466,056)	\$ (15,053,173)
Add: stock-based employee Compensation expense included in reported Net loss	293,511	151,515	199,048	92,919	1,176,533
Deduct: Stock-based employee Compensation expense determined under fair-value method for all Awards	(818,866)	(548,485)	(562,376)	(388,311)	(4,108,516)
Pro forma net loss	\$ (3,271,325)	\$ (2,867,013)	\$ (1,952,713)	\$ (1,761,447)	\$ (17,985,156)
Loss per share, as reported basic and diluted	\$ (.14)	\$ (.15)	\$ (.08)	\$ (.09)	\$ (1.13)
Pro forma loss per share basic and Diluted	\$ (.17)	\$ (.17)	\$ (.11)	\$ (.11)	\$ (1.36)

The fair value of the options is estimated on the date of the grant using the Black-Scholes option pricing model with the following assumptions:

	Six Months Ended November 30, 2005	Six Months Ended November 30, 2004	Three Months Ended November 30, 2005	Three Months Ended November 30, 2004	From Inception Through November 30, 2005
Dividends per year	0	0	0	0	0
Volatility percentage	107%	103%	103%	103%	90%-131%
Risk free interest rate	3.85%	2.57%	2.25%	2.57%	2.07%-5.11%
Expected life (years)	4	4	4	4	3-5

On August 23, 2005, the Company issued options to purchase up to 250,000 shares of common stock of the Company to an employee, as part of an agreement for his employment, at an exercise price of \$2.50 per share. The options were issued pursuant to stand-alone option agreements and under the Company's 2003 Stock Option Plan, amended and restated as of July 29, 2005. These options vest over a forty-eight month period based on the date of employment. The options will expire August 2015.

On August 23, 2005, the Company issued 40,000 shares of restricted common stock to the same employee, as part of his agreement for employment.



On October 25, 2005, the Company issued 10,000 shares of restricted common stock to an employee, as part of her agreement for employment.

**NOTE C - RECENT ACCOUNTING PRONOUNCEMENTS**

In December 2004, the FASB revised SFAS No. 123. SFAS No. 123-Revised supersedes APB 25 and related interpretations, and will require all companies to estimate the fair value of all share-based awards granted and then amortize that estimated fair value to expense over the requisite service period. SFAS No. 123-Revised is effective for the Company for all annual periods beginning after June 15, 2005. The Company currently accounts for options issued to its employees under the recognition and measurement principles of APB 25 and related interpretations. The Company is required to adopt SFAS No. 123-Revised by the first quarter of fiscal year 2007. See Note B. 3, "Stock Based Compensation," for pro forma information if the Company had elected to adopt the requirements of the previously issued SFAS No. 123 for options issued to employees.

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Unaudited

**NOTE D - RELATED PARTIES**

For the six and three month period ended November 30, 2005 the Company incurred \$20,717 and \$17,240, respectively, of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company. For the six and three month period ended November 30, 2004 the Company incurred \$4,932 and \$1,138, respectively, of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company.

The Company has an agreement with its Chairman to pay \$12,500 per month as a director fee. For the six and three month period ended November 30, 2005, the Company incurred \$75,000 and \$37,500 respectively, for this director's fee. For the six and three month period ended November 30, 2004, the Company incurred \$75,000 and \$37,500 respectively, for this director's fee.

The Company has agreements with Carleton A. Holstrom, Dr. Eugene A. Bauer and Peter G. Tombros to pay each of them \$1,667 per month on a quarterly basis payable in arrears as a director fee. For the six and three month period ended November 30, 2005, the Company incurred \$20,000 and \$10,000, respectively, for these directors' fees. For the six and three month period ended November 30, 2004, the Company incurred \$0 and \$0, respectively, for these directors' fees.

**NOTE E - SUBSEQUENT EVENT**

On December 30, 2005, the Company raised \$5,839,059 through the sale of 2,595,132 shares of its common stock at \$2.25 per share, with warrants to purchase an additional 648,784 shares of its common stock, at an exercise price of \$2.99 per share. The warrants expire on December 30, 2010. Net of transaction costs of approximately \$300,000, the Company's proceeds were \$5,539,059.

**ITEM 2 - MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION**

The following discussion should be read in conjunction with the Company's unaudited financial statements and related notes included in Item 1, "Financial Statements," of this Quarterly Report on Form 10-QSB, as well as the Company's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2005. This discussion, as well as the remainder of this Quarterly Report on Form 10-QSB, may contain forward-looking statements that are not historical facts and that are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward looking statements can be identified by the use of words such as "believe," "expect," "may," "will," "should," "intend", "anticipate" or the negative thereof or comparable terminology, and include discussions of matters such as anticipated financial performance, liquidity and capital resources, business prospects, technological developments, new and existing products, regulatory approvals and research and development activities. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. Please see the Company's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2005 and other documents filed with the Securities and Exchange Commission for additional disclosures regarding potential risk factors that may cause the Company's actual results and experience to differ materially from those contained in such forward-looking statements.

**Plan of Operations**

Favorable pre-clinical safety and efficacy studies for the Company's lead compound, PRTX-100, laid the foundation for the Investigational New Drug Application (IND) for treating Rheumatoid Arthritis (RA). The Company submitted its IND application to the United States Food and Drug Administration (FDA) on March 4, 2005; On March 31, 2005 the FDA verbally disclosed to the Company that it had placed the Company's IND on clinical hold, pending additional product characterization. On August 10, 2005, the Company formally replied to the FDA. On September 9, 2005, the FDA notified the Company that it lifted the clinical hold on its IND and that its proposed study can proceed. The Company commenced with the Phase I clinical trial on December 5, 2005 and the Company anticipates that this clinical trial will be completed in the fourth fiscal quarter of 2006. The Company also expects that other clinical trial-related activities will occur during the next fiscal year, including designing clinical trial protocols for additional clinical trials, arranging for packaging and testing, and completing additional toxicology studies utilizing its manufactured drug. Additionally, the Company intends to conduct research and pre-clinical activities with PRTX-100 in Idiopathic Thrombocytopenic Purpura (ITP), Pemphigus and other autoimmune indications.

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In the area of intellectual property and derivative drug development, the Company's patent application was filed in April 2002, and additional patent applications relating to the manufacturing process of PRTX-100 and new compounds are currently in process.

Staffing plans for fiscal 2006 include hiring a Clinical Project Manager, and additional clinical and laboratory support personnel. Continued growth in staffing is anticipated in the Company's business plan, and specialized staffing requirements in the areas of scientific and FDA regulatory affairs will require competitive salaries to attract and retain qualified personnel. On July 26, 2005, the Company announced the hiring of Victor S. Sloan, M.D., as Senior Vice President and Chief Medical Officer and on October 19, 2005, Anissa M. Leh, MS started as the Director of Clinical Operations.

Research and Development Expenses - Research and Development expenses were \$1,687,014 and \$994,739 for the six and three months ended November 30, 2005, compared with \$1,639,264 and \$919,718 for the six and three months ended November 30, 2004. The increase in this quarter of \$75,021 or 8.2% was primarily due to an increase in clinical personnel when compared to the same period in 2004.

Administrative Expenses - Administrative expenses were \$965,384 and \$569,268 for the six and three months ended November 30, 2005, compared with \$605,854 and \$386,079 for the six and three months ended November 30, 2004. The increase in this quarter of \$183,189 or 47% was due to hiring of additional personnel, wage increases for existing personnel and stock based compensation, which increased in this quarter by \$106,129 when compared to the same period in 2004.

Professional Fees - Professional fees were \$226,294 and \$91,133 for the six and three months ended November 30, 2005, compared with \$267,192 and \$178,991 for the six and three months ended November 30, 2004. The decrease of \$87,858 or 49% was due to a decrease in activity in the areas of legal, audit, tax, employee recruitment, investment banking fees, investor relations and the Scientific Advisory Board when compared to the same period in 2004.

**Liquidity and Capital Resources**

Since 1999, the Company has incurred significant losses, and the Company expects to experience operating losses and negative cash flow for the foreseeable future. The Company's primary source of cash to meet short-term and long-term liquidity needs is the sale of shares of its common stock. The Company issues shares in private placements at a discount to the then-current market price (as resales of privately-placed shares are restricted under the Securities Act, which reduces their liquidity and, accordingly, their value as compared to freely-tradable shares on the open market).

On September 19, 2003, the Company raised \$12,657,599 through the sale of 7,445,654 shares of its common stock at \$1.70 per share, with warrants to purchase an additional 3,164,395 shares of its common stock, at an exercise price of \$2.40 per share. The warrants expire on September 19, 2008. Net of transaction costs of \$1,301,536, the Company's proceeds were \$11,356,063.

On May 25, 2005, the Company raised \$5,057,885 through the sale of 2,593,788 shares of its common stock at \$1.95 per share, with warrants to purchase an additional 920,121 shares of its common stock, at an exercise price of \$2.25 per share. The warrants expire on May 25, 2010. As part of this transaction, the exercise price for the warrants from the September 2003 transaction were lowered from \$2.40 per share to \$2.25 per share. Net of transaction costs of \$206,691, the Company's proceeds were \$4,851,194.



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On December 30, 2005, the Company raised \$5,839,059 through the sale of 2,595,132 shares of its common stock at \$2.25 per share, with warrants to purchase an additional 648,784 shares of its common stock, at an exercise price of \$2.99 per share. The warrants expire on December 30, 2010. Net of transaction costs of approximately \$300,000, the Company's proceeds were \$5,539,059.

As of November 30, 2005, the Company's net working capital was \$6,035,029 and its total cash and cash equivalents were \$6,760,832. The Company has no planned material capital expenditures, significant payments due on long-term obligations, or other demands or commitments to be incurred beyond the next 12 months. However, the Company anticipates entering into significant contracts to perform clinical trials in calendar year 2006 that will extend into calendar year 2007. With the completion of the December 30, 2005 transaction, the Company anticipates that it will need to raise additional capital in the second half of calendar year 2007 to fund the ongoing FDA approval process.

**Off-Balance Sheet Arrangements**

We have entered into the following off-balance sheet arrangements:

- *Employee Agreements-Officers.* To attract and retain qualified management personnel, the Company has entered into employment agreements with four executive officers: Steven H. Kane, President and Chief Executive Officer, Victor S. Sloan, MD, Senior Vice President and Chief Medical Officer, Hector W. Alila, DVM, Ph.D., Senior Vice President of Drug Development, and Marc L. Rose, Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary.
- *Directors Agreements.* To attract and retain qualified candidates to serve on the Board of Directors, the Company has entered into agreements with G. Kirk Raab, Chairman of the Board, Carleton A. Holstrom, Chairman of the Audit Committee, and Eugene A. Bauer, MD and Peter G. Tombros, under which Messrs. Raab, Holstrom, Dr. Bauer and Mr. Tombros receive aggregate annual cash payments aggregating \$150,000, \$20,000, \$20,000 and \$20,000, respectively, as directors' fees.
- *Operating Lease - Office Space.* The Company has entered into a three year operating lease in New Hope, PA for 3,795 square feet of office and laboratory space. The lease commenced on January 9, 2004 and was originally to expire on February 28, 2007. On November 18, 2005, the company modified the existing lease which added an additional 2,147 square feet and extended the lease term to January 31, 2008.
- *Operating Lease - Copier.* The Company has entered into a sixty-three month operating lease with Ricoh Customer Finance Corporation for a multi-function copier. The lease commenced on December 16, 2004 and will expire on March 16, 2010.
- *Capital Lease - Lab Equipment.* The Company has entered into a thirty-six month capital lease with Waters Corporation for an HPLC protein separator. The lease commenced on April 13, 2003 and will expire May 1, 2006.

	<b>Payments due by period</b>				
<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than 5 years</b>

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Employment Agreements-Officers	1,090,369	1,090,369	0	0	0
Directors Agreements	210,000	210,000	0	0	0
Operating Lease - Office Space	349,051	9,076	339,975	0	0
Operating Lease - Copier	12,946	249	8,963	3,735	0
Capital Lease - Lab Equipment	9,425	9,425	0	0	0
Total	1,671,792	1,319,119	348,938	3,735	0

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**Unaudited**

**Critical Accounting Policies and Estimates**

The Company's significant accounting policies are more fully described in Note B to the financial statements included in this Quarterly Report and in Note B to the financial statements included in the Company's Annual Report on Form 10-KSB for the fiscal year ended May 31, 2005 filed with the Securities and Exchange Commission. Certain accounting policies are particularly important to the portrayal of the Company's financial position and results of operations and require the application of significant judgment by management. As a result, these policies are subject to an inherent degree of uncertainty. In applying these policies, management makes estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and related disclosures. The Company bases its estimates and judgments on historical experience, terms of existing contracts, observance of trends in the industry, information received from outside sources, and on various other assumptions that management believes to be reasonable and appropriate under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The Company has reviewed and determined that those policies remain the Company's critical accounting policies as of and for the three months ended November 30, 2005. The Company did not make any changes to those policies during the period.

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 24. Indemnification of Directors and Officers.

The General Corporation Law of the State of Delaware and our Bylaws provide for indemnification of our directors for liabilities and expenses that they may incur in such capacities. In general, our directors and officers are indemnified with respect to actions taken in good faith and in a manner such person believed to be in our best interests, and with respect to any criminal action or proceedings, actions that such person has no reasonable cause to believe were unlawful. Furthermore, the personal liability of our directors is limited as provided in our Articles of Incorporation.

We maintain directors and officers liability insurance with an aggregate coverage limit of \$3,000,000.

#### Item 25. Other Expenses of Issuance and Distribution.

The following table sets forth an itemization of all estimated expenses, all of which we will pay, in connection with the issuance and distribution of the securities being registered:

Nature of Expense	Amount
SEC registration fee	\$ 1,085
Accounting fees and expenses	\$ 8,000
Legal fees and expenses	\$ 25,000
Printing and related expenses	\$ 1,000
Total	\$ 35,085

#### Item 26. Recent Sales of Unregistered Securities.

Pursuant to a Warrant and Common Stock Purchase Agreement dated December 22, 2005, or the December Purchase Agreement, the Company commenced a financing transaction in which, effective as of December 30, 2005, the purchasers became obligated to purchase (x) 2,595,132 shares of common stock at \$2.25 per share for an aggregate cash consideration of \$5,839,059 and (y) warrants to purchase 648,784 shares of common stock at an exercise price of \$2.99 per share, or the December Warrants, for nominal consideration. The December Warrants expire on December 30, 2010 and provide for a net issue exercise feature and antidilution protection for certain equity issued below the exercise price.

The Company issued warrants to purchase common stock in the aggregate amount of 227,074 shares to Griffin Securities, Inc. and Mufson, Howe, Hunter and Company, LLC as partial commission compensation in connection with the financing transactions contemplated in the purchase agreement. The terms of these warrants are essentially identical to the December Warrants.

Pursuant to a Warrant and Common Stock Purchase Agreement dated May 25, 2005, or the May Purchase Agreement, the Company commenced a financing transaction in which the Company issued (x) 2,593,788 shares of common stock at \$1.95 per share for an aggregate cash consideration of \$5,057,885 and (y) warrants to purchase 786,788 shares of common stock at an exercise price of \$2.25 per share, or the May Warrants, for nominal consideration. The May Warrants expire on May 25, 2010 and provide for a net issue exercise feature and antidilution protection for certain equity issued below the exercise price.

On May 25, 2005, the Company issued warrants to purchase common stock in the amounts of 33,333 shares and 100,000 shares to the Jane Smith Turner Revocable Trust DTD 10/28/98 and Pacific Growth Equities, respectively, as consulting or finder's fee compensation in connection with the financing transactions contemplated in the Purchase Agreement. The terms of these warrants are essentially identical to the May Warrants.

On September 18, 2003, the Company sold 7,445,654 shares of common stock of the Company and warrants to purchase an additional 2,605,972 shares of common stock of the Company to institutional and individual investors for an aggregate purchase price of \$12,657,599. The Company also issued warrants to purchase 558,423 shares of Company common stock to Merriman Curhan Ford & Co., a registered broker-dealer, in connection with this financing. Each of the warrants has an exercise price of \$2.25 per share, as amended during the May 2005 transaction from the original exercise price of \$2.40, and expires on September 18, 2008.

The securities described above were issued to "accredited" investors only as such term is promulgated by the SEC. In reliance upon such investor suitability standards, the issuance of the securities described above were exempt from the registration requirements under the Securities Act of 1933 pursuant Section 4(2) thereof and in reliance upon Rule 506 of Regulation D promulgated by the SEC.

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**Item 27. Exhibits**

The following exhibits are included as part of this Form SB-2. References to “the Company” in this Exhibit List means Protalex, Inc., a Delaware corporation or prior to the reincorporation, Protalex, Inc., a New Mexico corporation.

Exhibit No. Description

2.1	Stock Purchase Agreement among the Company, Don Hanosh and Enerdyne Corporation (Incorporated by reference, to Exhibit 2.1 to the Company’s 10-SB filing on December 6, 1999)
2.2	Merger Agreement and Plan of Re-organization between the Company and Enerdyne Corporation (Incorporated by reference, to Exhibit 2.2 to the Company’s 10-SB filing on December 6, 1999)
2.3	Plan of Merger and Agreement between Protalex, Inc., a New Mexico corporation and Protalex, Inc. a Delaware Corporation (Incorporated by reference, to Exhibit 2.1 to the Company’s 8K filing on December 6, 2004)
3.1	Certificate of Incorporation of the Company (Incorporated by reference, to Exhibit 3.1 to the Company’s 8-K filing on December 6, 2004)
3.2	Bylaws of the Company (Incorporated by reference, to Exhibit 3.2 to the Company’s 8-K filing on December 6, 2004)
3.3	State of Delaware, Certificate of Amendment of Certificate of Incorporation (Incorporated by reference, to Exhibit 3.3 to the Company 10-QSB filed on January 13, 2006)
4.1	Letter Agreement with Pembroke Financial Ltd. dated July 9, 2001 (Incorporated by reference, to Exhibit 10.9 to the Company’s 10-KSB/A filed on September 24, 2003)
4.2	Securities Purchase Agreement dated September 18, 2003 between the Company and certain of the Selling Stockholders (Incorporated by reference, to Exhibit 4.2 to the Company’s SB-2 filed on October 20, 2003)
4.3	Investor Rights Agreement dated September 18, 2003 between the Company and certain of the Selling Stockholders (Incorporated by reference, to Exhibit 4.3 to the Company’s SB-2 filed on October 20, 2003)
4.4	Form of Common Stock Purchase Warrant issued by the Company to the Selling Stockholders (Incorporated by reference, to Exhibit 4.4 to Company’s SB-2 filed on October 20, 2003)
<u>4.5*</u>	<u>Warrant and Common Stock Purchase Agreement dated December 22, 2005 among the Company and the several purchasers thereunder</u>
<u>4.6*</u>	<u>Registration Rights Agreement dated December 22, 2005 among the purchasers under the Warrant and Common Stock Purchase Agreement of even date therewith</u>
<u>4.7*</u>	<u>Form of Warrant issued by the Company to the Selling Stockholders dated December 22, 2005 of even date therewith</u>
<u>5.1*</u>	<u>Opinion of Reed Smith LLP</u>
9.1	First Amended and Restated Shareholders Agreement dated May 25, 2005, between the Company and various common stock holders (Incorporated by reference, to Exhibit 9.1 to Company’s Pre-Effective Amendment No. 1 to Form SB-2 filed on July 13, 2005)
10.1	Employment offer letter executed by Steven H. Kane (Incorporated by reference to Exhibit 10.1 to the Company’s 10-QSB filed on January 13, 2006).
10.2	Board appointment executed by G. Kirk Raab (Incorporated by reference, to Exhibit 10.4 to the Company’s 10-KSB/A filed on September 24, 2003)
10.3	Form of Option Agreement (Incorporated by reference, to Exhibit 10.6 to the Company’s 10-KSB/A filed on September 24, 2003)
10.4	Equipment Lease Agreement between the Company and Waters Technologies Corporation (Incorporated by reference, to Exhibit 10.5 to the Company’s 10-KSB/A filed on September 24, 2003)

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- 10.5 Real Estate Lease between the Company and Kleinfeld Commercial Brokerage, LLC (Incorporated by reference, to Exhibit 10.5 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.6 Frame Contract between the Company and Eurogentec S.A. (Incorporated by reference, to Exhibit 10.5 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.7 Project Assignment 2 between the Company and Eurogentec S.A. (Incorporated by reference, to Exhibit 10.5 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.8 Assignment of Intellectual Property from Alex LLC to the Company (Incorporated by reference, to Exhibit 10.8 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.9 Assignment of Intellectual Property from Dr. Paul Mann to the Company (Incorporated by reference, to Exhibit 10.8 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.10 Project Assignment 1 between the Company and Eurogentec, S.A. (Incorporated by reference, to Exhibit 10.5 to the Company's 10-KSB/A filed September 24, 2003)
- 10.11 Stock Redemption Agreement dated August 15, 2003, by and between the Company, Paul L. Mann, Leslie A. McCament-Mann, Gail Stewe and Elizabeth Sarah Anne Wiley (Incorporated by reference, to Exhibit 10.10 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.12 Letter dated August 21, 2003 from Paul L. Mann to the Company (Incorporated by reference, to Exhibit 10.11 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.13 Promissory Note dated August 15, 2003, issued by the Company in favor of John E. Doherty (Incorporated by reference, to Exhibit 10.7 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.14 Promissory Note dated August 15, 2003, issued by the Company in favor of Steven H. Kane (Incorporated by reference, to Exhibit 10.7 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.15 Continuing and Unconditional Guaranty executed by John E. Doherty (Incorporated by reference, to Exhibit 10.2 to the Company's 10-SB filed on December 6, 1999)
- 10.16 Continuing and Unconditional Guaranty executed by James K. Strattman (Incorporated by reference, to Exhibit 10.3 to the Company's 10-SB filed on December 6, 1999)
- 10.17 Form of Confidential Disclosure Agreement (Incorporated by reference, to Exhibit 10.5 to the Company's 10-SB filed on December 6, 1999)
- 10.18 Technology License Agreement dated November 17, 1999, between the Company and Alex, LLC (Incorporated by reference, to Exhibit 10.4 to the Company's 10-SB filed on December 6, 1999)
- 10.19 Offer of Employment to Joseph Dervan dated January 20, 2003 (Incorporated by reference, to Exhibit 10.4 to the Company's 10-KSB/A filed on September 24, 2003)
- 10.20 Modified lease agreement with Union Square LP, dated November 18, 2005 (Incorporate by reference to Exhibit 99.1 to the Form 8-K filed and filed with the Securities and Exchange Commission on November 22, 2005).
- 10.21 Employment offer letter executed by Hector W. Alila (Incorporated by reference, to Exhibit 10.1 to the Company's 10-QSB filed on January 14, 2005)
- 10.22 Employment offer letter executed by Marc L. Rose (Incorporated by reference, to Exhibit 10.2 to the Company's 10-QSB filed on January 14, 2005)
- 10.23 Employment off letter executed by Victor S. Sloan (Incorporated by reference, to Exhibit 10.1 to the Company's Form 10-QSB filed on October 14, 2005)
- 10.24 Clinical Study Agreement executed October 19, 2005 between the Company and PAREXEL International LLC (Incorporated by reference to Exhibit 10.2 to the Company's 10-QSB filed on January 13, 2006).
- 23.1\* Consent of Grant Thornton LLP
- 23.2\* Consent of Reed Smith LLP (Contained in Exhibit 5.1 to this Registration Statement)
- 24.1\* Power of Attorney (Contained on the signature page to this Registration Statement)

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Filed herewith



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**Item 28. Undertakings.**

The undersigned registrant hereby undertakes to:

1. File, during any period in which offers or sales are being made, a post-effective amendment to this registration statement to:
  - (i) Include any prospectus required by Section 10(a)(3) of the Securities Act;
  - (ii) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of the 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) under the Securities Act 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, and
  - (iii) Include any additional or changed material information on the plan of distribution.
2. For determining liability under the Securities Act, 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.
3. File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.
4. For determining liability of the Company under the Securities Act to any purchaser in the initial distribution of the securities, the Company undertakes that in a primary offering of securities of the Company pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the Company will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the Company relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the Company or used or referred to by the Company;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the Company or its securities provided by or on behalf of the Company; and
  - (iv) Any other communication that is an offer in the offering made by the Company to the purchaser.

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

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

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**SIGNATURES**

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements of filing on Form SB-2 and authorizes this registration statement on Form SB-2 to be signed on its behalf by the undersigned, in the Borough of New Hope, Commonwealth of Pennsylvania.

**PROTALEX, INC.**  
**a Delaware corporation**

Date: January 27, 2006

By: /s/ STEVEN H. KANE

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Name: Steven H. Kane  
 Title: President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below hereby constitutes and appoints Steven H. Kane as his true and lawful attorney-in-fact and agent, with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do them in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of them, or their or his substitute or substitutes, shall do or cause to be done by virtue hereof.

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

/s/ G. Kirk Raab G. Kirk Raab	Chairman of the Board and Director	January 27, 2006
/s/ Steven H. Kane Steven H. Kane	President, Chief Executive Officer and Director (Principal Executive Officer)	January 27, 2006
/s/ Marc L. Rose Marc L. Rose	Vice President of Finance, Chief Financial Officer, Treasurer and Corporate Secretary (Principal Financial and Accounting Officer)	January 27, 2006
/s/ Dinesh Patel, Ph.D Dinesh Patel, Ph.D.	Director	January 27, 2006
/s/ Peter G. Tombros Peter G. Tombros	Director	January 27, 2006
/s/ Frank M. Dougherty Frank M. Dougherty	Director	January 27, 2006



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/s/ Thomas P. Stagnaro      Director      January 27, 2006  
Thomas P. Stagnaro

/s/ Carleton A. Holstrom      Director      January 27, 2006  
Carleton A. Holstrom

/s/ Eugene A. Bauer, M.D.      Director      January 27, 2006  
Eugene A. Bauer, M.D.

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