

# Genitope Corporation

Delivering on the promise of personalized medicine<sup>SM</sup>



PROCESSED



MAY 09 2005

THOMSON  
FINANCIAL

---

## 2004 Annual Report

PE 12-31-04

TM



Delivering on the promise of personalized medicine<sup>SM</sup>

To Our Stockholders:

We are pleased to report that Genitope Corporation continued to make substantial progress in 2004. Our goal of bringing to market our lead product candidate, MyVax<sup>®</sup> Personalized Immunotherapy, continues to progress on schedule. Importantly, we have begun preparing our company for the next phase of growth, which is transitioning from a late-stage drug development company into a true commercial enterprise. As part of accomplishing this, we completed two additional successful financings and strengthened and expanded our management team.

Our lead product candidate, MyVax<sup>®</sup> Personalized Immunotherapy, continues to achieve milestones in its pivotal Phase 3 trial treating patients with previously untreated follicular non-Hodgkin's lymphoma. Patient registration is complete and we have initiated treatment on all patients in the trial. We anticipate initiating the first interim analysis of the data in our pivotal Phase 3 trial late in the second quarter of 2005 and announcing the outcome several weeks later. If we meet the trial's pre-defined efficacy endpoint, we will work with the Food & Drug Administration (FDA) to complete the final leg of the drug approval process.

As we work towards our goal of receiving FDA approval for MyVax<sup>®</sup> Personalized Immunotherapy, we have begun to put the pieces in place that will allow us to successfully manufacture each patient's drug at commercial scale and support a successful product launch upon approval. We successfully completed two rounds of financing this past year, which provided Genitope Corporation with an additional \$113 million in net proceeds. These proceeds will be used to fund costs related to the leasing and build out of a commercial scale manufacturing facility, to fund expenses related to manufacturing and potential commercialization, clinical trials and research and for the establishment of sales and marketing capabilities. We are currently in negotiations to lease a commercial manufacturing and corporate headquarters facility, which we hope to finalize by early May of 2005.

Part of our transition and launch strategy involves the expansion of our management team and the hiring of high caliber talent. As a result, we added several individuals to our management team. Michael Buckley, Ph.D. joined as vice president of manufacturing, and Steven Chamow, Ph.D. joined as Genitope Corporation's vice president of process sciences. In addition, we appointed Thomas P. Theriault, Ph.D. as vice president of research and development and Claude Miller as vice president of quality. In April 2004, we were also pleased to announce that John M. Vuko joined us as vice president of finance and chief financial officer. These individuals bring us essential biotech and financial experience that will benefit Genitope Corporation as it enters its next phase of development.

As we look to 2005 and beyond, we are excited about the prospects of our company. The clinical development of MyVax<sup>®</sup> Personalized Immunotherapy progresses on schedule. We expect to initiate new clinical trials that will examine the drug's safety and efficacy in treating lymphoma and other B-cell cancers. We have begun the process of transforming our company into a true commercial enterprise and eagerly await the first interim analysis of the data from our pivotal Phase 3 trial. With the continued help of our dedicated employees, we are confident that we can achieve our primary goal of bringing MyVax<sup>®</sup> Personalized Immunotherapy to the marketplace and give courageous patients and doctors another weapon in their fight against non-Hodgkin's lymphoma.

Sincerely,

A handwritten signature in black ink that reads "Dan W. Denney, Jr." with a stylized flourish at the end.

Dan W. Denney, Jr., Ph.D.  
Chairman and Chief Executive Officer

# **Genitope Corporate Overview**

## **Corporate Introduction**

Genitope Corporation is pioneering the application of personalized immunotherapy in the field of oncology. Appreciating the ability of the human immune system to effectively and safely fight disease, Genitope Corporation has chosen to utilize the immune system as a basis to combat cancer. Furthermore, Genitope Corporation also recognizes that every cancer patient is unique and, optimally, each therapy should be as well. The potential of personalized medicine to treat patients in a safer and more effective manner compared to current forms of cancer treatment is the motivation behind Genitope Corporation's lead product, MyVax® Personalized Immunotherapy. MyVax® Personalized Immunotherapy is currently being tested in a pivotal Phase 3 clinical trial as well as several Phase 2 clinical trials for the treatment of B-cell non-Hodgkin's lymphoma (B-cell NHL).

## **Harnessing the Immune System**

In general, immunotherapy uses a patient's own immune system to fight disease. Immunotherapies can be categorized as either passive or active.

Passive immunotherapy involves introducing pre-formed antibodies into a patient that are specific to a particular target. The antibodies attach to any cell displaying the target regardless of whether it is a healthy or diseased cell. The patient's immune system responds by eliminating the cells tagged by the antibody. Although the effect conferred by passive immunotherapies is immediate, it is also temporary.

Active immunotherapy involves introducing a target into a patient to induce the patient's immune system to then generate a specific, adaptive immune response. This type of immune response produces both target-specific antibodies made by B-cells (humoral immunity) and target-specific T-cells (cellular immunity). Active immunotherapies may also generate long-lived immunologic memory that could potentially confer long-term protection against disease. Genitope Corporation's MyVax® Personalized Immunotherapy uses a purified recombinant idiotype protein that is a unique target for each patient's B-cell tumor to elicit an active immune response directed against the patient's tumor cells.

## **A Personal Approach to Cancer Therapy**

Enabled by a proprietary gene amplification technology for producing these target proteins, our approach is to develop personalized, active immunotherapies that are both patient- and tumor-specific. The unique genetic make-up, or "fingerprint", of a patient's tumor is the basis of MyVax® Personalized Immunotherapy. Specifically, idiotype proteins on the surface of malignant B-cells are being investigated as a "fingerprint" to target each patient's cancer. The therapy is designed to elicit an active immune response involving both the humoral and cellular arms of the immune system. The specificity of the idiotype target and the immune response together may provide a means of destroying tumor cells without harming healthy cells or causing debilitating side effects.

## **Gene Expression Technology Platform**

Genitope Corporation develops personalized immunotherapies using a proprietary gene amplification technology, referred to as Hi-GET® technology. This recombinant protein production method offers several benefits. First, our personalized immunotherapy manufacturing process is efficient, reproducible and scalable. Further, this platform requires very little starting material and does not require live cells — frozen material can be used. So, biopsy samples from patients can be acquired, frozen and shipped to us for the production of each patient's drug. Using this platform, Genitope

Corporation has already created hundreds of personalized immunotherapies for use in clinical trials in the United States and Canada.

### **Clinical Development**

MyVax® Personalized Immunotherapy is currently in a pivotal Phase 3 clinical trial as well as additional Phase 2 clinical trials for the treatment of B-cell NHL. In our completed and ongoing clinical trials, MyVax® Personalized Immunotherapy has been found to be generally safe and well tolerated in the treatment of B-cell NHL.

In the United States, B-cell NHL represents approximately 85% to 90% of over 300,000 existing and approximately 55,000 newly diagnosed NHL patients each year. NHL is clinically classified as either slow-growing, referred to as indolent, or fast-growing, referred to as aggressive. There are approximately 25,000 patients diagnosed with indolent B-cell NHL in the United States each year.

Our pivotal Phase 3 clinical trial is for the treatment of follicular B-cell NHL, which represents approximately half of the cases of indolent B-cell NHL. We believe that patient-specific active immunotherapies can also be applied successfully to the treatment of other cancers.

### **Quick Facts**

- **Location:** Redwood City, California
- **Number of Employees:** 128
- **Stock Symbol:** NASDAQ: GTOP
- **Focus:** Research, development, and manufacture of personalized immunotherapies
- **Goal:** To commercialize novel, personalized immunotherapies for the treatment of cancer

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**Form 10-K**

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

OR

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: **000-50425**

**Genitope Corporation**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**77-0436313**

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

**525 Penobscot Drive**

**Redwood City, CA 94063**

*(Address of principal executive offices, including zip code)*

**(650) 482-2000**

*(Registrant's telephone number, including area code)*

**Securities registered pursuant to section 12(b) of the Act:**

**None**

**Securities registered pursuant to Section 12(g) of the Act:**

**Common Stock, \$0.001 par value per share**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Annual Report on Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes  No

The aggregate market value of Common Stock, \$0.001 per share par value, held by non-affiliates as of June 30, 2004 (based on the closing sale price of such stock as reported on the Nasdaq National Market on June 30, 2004) was approximately \$167.9 million. This excludes an aggregate of 6,862,233 shares of the registrant's common stock held by officers and directors and by each person known by the registrant to own 5% or more of the registrant's outstanding common stock as of June 30, 2004. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

As of February 28, 2005, there were 28,192,280 shares of Common Stock, \$0.001 per share par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Items 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after December 31, 2004 in connection with the solicitation of proxies for the registrant's 2005 Annual Meeting of Stockholders.

**GENITOPE CORPORATION**  
**FORM 10-K**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business .....	1
Item 2. Properties .....	38
Item 3. Legal Proceedings .....	38
Item 4. Submission of Matters to a Vote of Security Holders .....	38
<b>PART II</b>	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Repurchases of Equity Securities .....	38
Item 6. Selected Financial Data .....	40
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations .....	41
Item 7A. Quantitative and Qualitative Disclosures About Market Risk .....	51
Item 8. Financial Statements and Supplementary Data .....	52
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure .....	79
Item 9A. Controls and Procedures .....	79
Item 9B. Other Information .....	79
<b>PART III</b>	
Item 10. Directors and Executive Officers of the Registrant .....	79
Item 11. Executive Compensation .....	80
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters .....	80
Item 13. Certain Relationships and Related Transactions .....	80
Item 14. Principal Accountant Fees and Services .....	80
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules .....	81
<b>SIGNATURES</b> .....	82
<b>INDEX TO EXHIBITS</b> .....	83

The terms "Genitope," "we," "us" and "our" as used in this annual report refer to Genitope Corporation.

Genitope® Corporation, Hi-GET® gene amplification technology, our logo and MyVax® personalized immunotherapy are our registered house mark and trademarks. This report includes other service marks, trademarks and trade names of other companies such as Rituxan® anti-CD20 antibody.

## PART I

### Forward-Looking Statements

*This annual report on Form 10-K contains "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These forward looking statements include, but are not limited to, statements about the progress of our clinical trials and research programs, the sufficiency of our cash resources, the timing of the immunization of the last patient registered in the Phase 3 clinical trial and the timing of the initiation of the first and second interim analyses of the data from our Phase 3 clinical trial. These forward-looking statements are generally identified by words such as "believes," "anticipates," "plans," "expects," "will," "intends" and other similar words and expressions. Discussions containing these forward-looking statements may be found in "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in the forward-looking statements. The risks discussed in "Risk Factors," among other things, should be considered in evaluating our prospects and future financial performance. Genitope undertakes no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this report.*

### ITEM 1. BUSINESS

#### BUSINESS

##### Overview

We are a biotechnology company focused on the research and development of novel immunotherapies for the treatment of cancer. Immunotherapies are treatments that utilize the immune system to combat diseases. Our lead product candidate, MyVax personalized immunotherapy, is a patient-specific active immunotherapy that is based on the unique genetic makeup of a patient's tumor and is designed to activate a patient's immune system to identify and attack cancer cells. MyVax is currently in a pivotal Phase 3 clinical trial and additional Phase 2 clinical trials for the treatment of B-cell non-Hodgkin's lymphoma, or B-cell NHL. B-cells, also called B lymphocytes, are one of the two major classes of lymphocytes, which are types of white blood cells. In the United States, B-cell NHL represents approximately 85% to 90% of over 300,000 existing and approximately 55,000 newly diagnosed NHL patients each year. NHL is clinically classified as either slow-growing, referred to as indolent, or fast-growing, referred to as aggressive. There are approximately 25,000 patients diagnosed with indolent B-cell NHL in the United States each year. Our pivotal Phase 3 clinical trial is for the treatment of follicular B-cell NHL, which represents approximately half of the cases of indolent B-cell NHL. We believe that patient-specific active immunotherapies can also be applied successfully to the treatment of other cancers. As a result, we are also developing MyVax for the treatment of chronic lymphocytic leukemia, or CLL.

In November 2000, based on positive interim Phase 2 clinical trial results from our 9901 trial, we initiated a pivotal, double-blind, controlled Phase 3 clinical trial, our 2000#03 trial, to treat patients with follicular B-cell NHL. We believe that, if successful, the results of the trial will support our application for regulatory approval of MyVax for the treatment of follicular B-cell NHL. We completed patient registration, the process during which a patient is screened and a biopsy is taken to determine whether the patient is eligible to participate in the clinical trial, in April 2004. Our independent Data Safety Monitoring Board, or DSMB, met on November 15, 2004 to review data in the clinical trial. After reviewing data for the entire Phase 3 clinical trial and blinded, preliminary immune response data for more than 100 of the initial patients immunized in the clinical trial, the DSMB noted no concerns and recommended that the trial continue as planned. We currently anticipate that the two planned interim analyses will be initiated in approximately the second quarter of 2005 and the second quarter of 2006, with the detailed follow-up period of the clinical trial scheduled to conclude in approximately the fourth quarter of 2007.

We have exclusive worldwide sales and marketing rights for MyVax. Subject to regulatory approval, we intend to manufacture and commercialize MyVax and to establish a North American sales force to market and sell MyVax. Due to the concentrated nature of the oncology market, we believe that we can sell MyVax in North America with a small sales force. Results from our completed and ongoing clinical trials of MyVax for the treatment of B-cell NHL indicate that MyVax is generally safe and well tolerated. To date, we have successfully manufactured MyVax in a timely manner to support our clinical trials.

Active immunotherapies similar to MyVax have been studied in clinical trials for over 16 years. Results from clinical trials at Stanford University Medical Center and the National Cancer Institute, or NCI, suggest that active immunotherapies may induce long-term remission and may improve survival in indolent B-cell NHL patients.

Remission is the period of time during which patients have a partial or complete reduction in the amount or severity of the symptoms of their disease. Despite the results of the Stanford and NCI clinical trials, further development of an active immunotherapeutic approach to the treatment of NHL historically has been limited by significant manufacturing difficulties. We have developed a proprietary manufacturing process, which includes our patented Hi-GET® gene amplification technology that is designed to overcome many of these historical manufacturing limitations. As compared to other existing manufacturing methods for active immunotherapies, we believe that our process is efficient, modular and reproducible, which we believe will enable us to manufacture and commercialize patient-specific active immunotherapies for the treatment of NHL and potentially other cancers.

We were incorporated in the State of Delaware on August 15, 1996.

### **The Immune System and Cancer**

The immune system is the body's natural defense mechanism to prevent and combat disease. The primary disease fighting functions of the immune system are carried out by white blood cells. In response to the presence of disease, white blood cells can mediate two types of immune responses, referred to as innate immunity and adaptive immunity. Together the innate and adaptive arms of the immune system generally provide an effective defense against a broad spectrum of diseases.

Innate immunity is mediated by the white blood cells that engulf and digest infecting microorganisms known as pathogens. These white blood cells are the first line of defense against many common infections because they do not require that the body be previously exposed to the pathogens. The role of the innate immune system is to control infections while adaptive immunity is being established for that pathogen.

Adaptive immunity is generated by the immune system throughout a person's lifetime as he or she is exposed to particular pathogens. As a person is exposed to a pathogen, the adaptive immune response will, in many cases, confer life-long protection from re-infection by the same pathogen. This adaptive immune response is the basis for preventative vaccines that protect against viral and bacterial infections such as measles, polio, diphtheria and tetanus.

Adaptive immunity is mediated by a subset of white blood cells called lymphocytes, which are divided into two types, B-cells and T-cells. B-cells and T-cells recognize molecules, usually proteins, known as antigens. An antigen is a molecule or substance that reacts with an antibody or a receptor on a T-cell. When a B-cell recognizes a specific antigen, it secretes proteins, known as antibodies, which in turn bind to a target containing that antigen and tag it for destruction by other white blood cells. When a T-cell recognizes an antigen, it either promotes the activation of other white blood cells or initiates destruction of the target cells directly. The collective group of B-cells and T-cells can recognize a wide array of antigens, but each individual B-cell or T-cell will recognize only one specific antigen. Because of this specificity, few lymphocytes will recognize the same antigen.

Despite the effectiveness of the immune system in defending the body against infectious disease, it is generally ineffective in defending the body against a cancer once it has appeared. The immune system has developed numerous immune suppression mechanisms to prevent it from destroying a person's normal tissue, and these same mechanisms are believed to prevent an immune response from being mounted against cancer

cells. In addition, the cancer cells themselves can make changes that reduce the ability of the immune system to attack the tumor.

### **Immunotherapy and Cancer**

Immunotherapies utilize a person's immune system in an attempt to combat diseases, including cancer. There are two forms of immunotherapy used to treat various diseases: passive and active. Both types of immunotherapy have been used with success to treat a number of different diseases. For example, active immunotherapies in the form of preventative vaccines have enabled the complete or virtual elimination of viral diseases such as smallpox and polio.

Passive immunotherapy is characterized by the introduction into a patient of antibodies specific to a particular antigen. When antibodies are infused into a cancer patient, they attach to any cell that displays the antigen. The patient's immune system then responds to eliminate those specific cells tagged by the antibody. Alternatively, radioactive molecules or toxins can be attached to an antibody before it is infused into the patient to kill the tagged cells directly. Although the protection that is provided by a passive immunotherapy is immediate, it is invariably temporary. Consequently, while passive immunotherapies have shown clinical benefits in some cancers, and some have improved safety profiles compared to existing therapies, they require repeated infusions and can cause the destruction of normal cells as well as cancer cells.

An active immunotherapy generates an adaptive immune response by introducing an antigen into a patient, often in combination with other components that can enhance an immune response to the antigen. The specific adaptive immunity generated can include both the production of antigen-specific antibodies made by B-cells, known as humoral immunity, and the production of antigen-specific T-cells, known as cellular immunity.

Active immunotherapies have been successful in preventing many infectious diseases, such as measles, mumps or diphtheria, but the approach has been less successful in treating cancer. Historically, the reasons that effective active immunotherapies for cancer have been difficult to develop included the:

- inability of tumor antigens to elicit an effective immune response;
- difficulty in identifying suitable target tumor antigens;
- inability to manufacture tumor antigens in sufficiently pure form;
- inability to manufacture sufficient quantities of tumor antigens;
- failure to identify effective components to combine with tumor antigens to enhance an immune response; and
- failure to employ immunization methods that elicit an effective immune response.

We believe that an effective active immunotherapeutic approach for cancer would result from immunizing patients with sufficient quantities of purified, tumor-specific antigens administered with additional components to increase the immunogenicity of these antigens. Immunogenicity is the ability of an antigen to evoke an immune response within an organism. Utilizing this type of immunotherapy should allow a patient's own immune system to produce both B-cells and T-cells which recognize numerous portions of the tumor antigen and generate clinically significant immune responses. During the late 1980s, physicians at Stanford began development of an active immunotherapy with these characteristics for the treatment of indolent B-cell NHL.

### **Non-Hodgkin's Lymphoma**

*Background.* NHL is a cancer of B-cell and T-cell lymphocytes. Currently, in the United States there are over 300,000 patients diagnosed with NHL, with approximately 55,000 newly diagnosed cases annually. Approximately 85% to 90% of patients diagnosed with NHL in the United States have B-cell NHL. The international market for NHL is estimated to be at least equal in size to the United States market. NHL is the sixth most common cancer and the sixth leading cause of death among cancers in the United States.

NHL is clinically classified as being either slow-growing, referred to as indolent, or fast-growing, referred to as aggressive, depending on whether the patient's survival time after relapse from the initial therapy is measured in years or in months. Indolent and aggressive NHL each constitute approximately half of all newly diagnosed B-cell NHL, and roughly half of the indolent B-cell NHL is follicular B-cell NHL. Although indolent B-cell NHL progresses at a slow rate, it is inevitably fatal and there is no cure currently available. According to the American Cancer Society, the median survival time from diagnosis for patients with indolent B-cell NHL having stage III/IV follicular B-cell NHL is between seven and ten years. Unlike indolent B-cell NHL, approximately 40% of aggressive B-cell NHL cases are cured by standard chemotherapy. The remaining patients with aggressive B-cell NHL relapse and cannot be effectively treated.

*Current Treatments.* Chemotherapy is widely used as a first-line therapy for NHL and has been effective in managing some forms of these cancers. Although chemotherapy can substantially reduce the tumor mass and in most cases achieve a clinical remission, the remissions have not been durable. Indolent B-cell NHL patients relapse within a few months or years of initial treatment, and the cancer becomes increasingly resistant to further chemotherapy treatments. Eventually, patients may become refractory to chemotherapy, meaning their response to therapy is so brief that further chemotherapy regimens would offer no significant benefit.

Several passive immunotherapies, such as Rituxan, have demonstrated the ability to induce remission in patients with indolent B-cell NHL. To date, these therapies administered alone have failed to provide long-term remissions for most patients.

Salvage therapy consisting of high-dose chemotherapy may be performed to treat refractory indolent B-cell NHL patients or those at high risk for relapse from primary therapy. This therapy results in the destruction of essential levels of red and white blood cells and requires stem cell transplants to be performed to restore a patient's blood count. Stem cell transplants continue to be expensive and associated with high morbidity and significant mortality. Ultimately, even these very aggressive treatment regimens do not provide long-term remission for most patients.

### **Active Idiotype Immunotherapy**

The active immunotherapy developed at Stanford was focused on the treatment of a cancer of B-lymphocytes known as indolent B-cell NHL. This immunotherapy consists of a patient-specific tumor protein and a foreign carrier protein administered with an adjuvant to enhance the immune response. Patient-specific tumor proteins, which include idiotype proteins, are proteins expressed by a tumor cell that are unique to an individual's tumor cell. A foreign carrier protein is a type of protein, which when coupled to a non-immunogenic or weakly immunogenic antigen, increases the immunogenicity of the antigen. An adjuvant is a substance that is administered with an antigen to enhance or increase the immune response to that antigen.

The key to the cancer immunotherapy developed at Stanford is the fact that the patient-specific tumor protein is the antibody expressed by the cancerous B-cells. Because the patient's cancerous B-cells are replicates of a single malignant B-cell, all of the cancerous B-cells express the same antibody. Each antibody has unique portions, collectively known as the idiotype, which can be recognized by the immune system. This type of active immunotherapy is referred to as an active idiotype immunotherapy. It utilizes the patient- and tumor-specific antibody, or idiotype protein, as an antigen to direct the patient's immune system to mount an immune response against the targeted tumor cells. Because the antigen is specific to the cancerous B-cells and not found on normal B-cells, the immune system should target the cancerous B-cells for destruction while leaving normal B-cells unharmed.

The Stanford clinical trials began in 1988 for the treatment of a slower growing, or indolent, form of B-cell NHL. Indolent B-cell NHL has no cure and is treated primarily with chemotherapy. The first clinical trial involved 41 patients with indolent B-cell NHL who commenced their course of immunizations between November 1988 and December 1995. These patients were immunized while in remission following chemotherapy. The treated patients had either a complete response to chemotherapy, defined as no detectable tumor, or a partial response to chemotherapy, defined as at least a 50% reduction in their tumor volume. Of the

41 patients treated, 32 were in remission following their first course of chemotherapy, while the remaining patients were in remission following two or three courses of chemotherapy.

Positive immune responses to the patient-specific active idiotype immunotherapy were detected in 20 of the 41 immunized patients, including 14 of the 32 patients in first remission following chemotherapy. The median time to disease progression for all 41 patients in the clinical trial was reported to be 4.4 years from the last chemotherapy regimen. Time to disease progression measures the interval of time between response to chemotherapy and recurrence of disease. The median time to disease progression was further analyzed by dividing patients into two groups based upon the presence or absence of an immune response. The median time to disease progression was calculated to be 7.9 years for the 20 immune response positive patients and 1.3 years for the 21 immune response negative patients. The median time to disease progression for the 32 patients in first remission was virtually identical to that for the 41 total patients, which suggests that patient-specific active idiotype immunotherapy may be as effective in the larger population of relapsed patients as in the smaller population of newly diagnosed patients. Median survival time was also measured for patients treated in the clinical trial. At the time of publication, the median survival time of all 41 immunized patients had not been reached, and the investigators reported that the median survival time of all 41 patients was significantly longer than the median survival time seen in patients having the same type of NHL who were treated with chemotherapy alone. NHL patients treated at Stanford with chemotherapy alone had a median survival time of 10.9 years. The fact that the median survival time had not been reached for the 41 immunized patients demonstrates that these patients have a median survival time that is greater than 10.9 years. The median survival time of the 20 immune response positive patients had not been reached versus a median survival time of seven years calculated for the 21 immune response negative patients. The results are statistically significant and suggest that an active idiotype immunotherapy, similar to MyVax, may induce long term remission and improve survival in NHL patients.

Long-term results from the first Stanford clinical trial were published in the medical journal *Blood* in May 1997 and are presented in the following table.

	<u>Patients</u>	<u>Median Time to Disease Progression</u>	<u>Median Survival Time</u>
Total .....	41	4.4 years	Not Reached
Immune Response Positive .....	20	7.9 years*	Not Reached
Immune Response Negative .....	21	1.3 years	7.0 years*

\* Indicates a median calculated based on available data using Kaplan-Meier analysis. Kaplan-Meier analysis is a statistical calculation that allows for the estimation of a median time when not all of the patients have reached the event being measured (e.g., survival or progression) at the time of analysis.

An independent clinical trial of a patient-specific active idiotype immunotherapy similar to the one tested at Stanford was conducted at the NCI to treat patients with indolent B-cell NHL. The NCI clinical trial results were published in *Nature Medicine* in October 1999. Patients treated in the NCI clinical trial had previously achieved a clinical complete response following an initial course of chemotherapy, that is, no tumor was apparent by physical examination and CT scans. Positive immune responses to the patient-specific active idiotype immunotherapy were reported for 19 of 20 immunized patients. Despite the fact that all 20 patients were in clinical complete remission, 11 of these 20 patients were shown to have lymphoma cells in their peripheral blood following chemotherapy using a very sensitive DNA-based test. After completing the course of immunization with the active idiotype immunotherapy, eight of these 11 patients were shown to have no lymphoma cells in their peripheral blood using the DNA-based test. These results suggest that active idiotype immunotherapy was able to induce a molecular complete response in patients that had minimal residual disease following chemotherapy.

Despite the results of the Stanford and NCI clinical trials, further development of an active immunotherapeutic approach to the treatment of NHL historically has been limited by significant manufacturing difficulties. The production technology that was used to manufacture these active idiotype immunotherapies at

Stanford and NCI is known as rescue fusion. Rescue fusion is a method that generates cell lines, referred to as hybridomas, which are created by combining, or fusing, the patient's live tumor cells with cells from a cell line that grows indefinitely in culture. The resulting hybridomas are screened to identify those which secrete the idiotype protein present on the patient's tumor cells. We believe that rescue fusion cannot be used to produce these patient-specific immunotherapies for the number of patients and at a cost that would enable widespread commercial use. The barriers to commercialization using the rescue fusion method include:

- the need for a relatively large sample of fresh tumor cells, requiring a surgical biopsy;
- the need for rapid processing, as viable tumor cells are required;
- a 10% to 20% failure rate;
- inconsistent and variable manufacturing timelines which frequently fall outside the desired clinical treatment timeline; and
- low productivity on a per technician basis.

### **MyVax Personalized Immunotherapy**

MyVax is an injectable patient-specific active idiotype immunotherapy that we are developing initially for the treatment of indolent and aggressive B-cell NHL. MyVax combines a patient and tumor-specific antibody, or idiotype protein, with a foreign carrier protein and is administered with an adjuvant. We have developed a proprietary manufacturing process for MyVax, which includes our patented Hi-GET gene amplification technology. Our manufacturing process is designed to overcome the barriers to commercialization of active idiotype immunotherapies that are associated with the use of a hybridoma-based process such as rescue fusion. In comparison to other cancer therapies, MyVax is designed to provide:

*Efficacious and lasting treatment:* We believe, based on our analysis of our clinical trials, that (1) MyVax has the potential to provide durable remissions and extend survival in a substantial percentage of the B-cell NHL patients who are treated with MyVax and (2) this therapeutic benefit could be greater than the benefit that is provided by currently available therapies, including passive immunotherapies such as Rituxan.

*Safety:* MyVax has demonstrated an excellent safety profile to date. MyVax has been well tolerated in clinical trials, with the majority of side effects being only mild to moderate. In our clinical trials, these side effects have included injection site and systemic effects. The most commonly reported injection site effects were bruising, swelling, redness, itching, inflammation, pain and other similar reactions at the injection site. The most commonly reported systemic effects were fatigue, influenza-like illness, fever, chills, nausea, pain, back, chest or muscle pain, rash and diarrhea. Furthermore, MyVax is designed to target only the idiotype protein unique to tumor cells and, thus, should not harm normal cells or impair a patient's immune system. With an intact immune system, patients are less likely to develop significant complications, such as infections that have been reported in patients treated with Rituxan.

*Ease of administration:* The administration of MyVax can be accomplished during a 30-minute outpatient visit, which includes the immunizations followed by an observation period, with each injection taking less than a minute. In comparison, currently available passive immunotherapies such as Rituxan must be administered via a series of lengthy, intravenous infusions. Each infusion of a passive immunotherapy takes hours, requires patients to be monitored for infusion reactions on multiple occasions during the infusion and can result in serious complications for patients.

*Ease of sample collection:* The tumor samples used to produce MyVax are collected using standard medical procedures that are commonly used in the diagnosis and staging of cancer patients. Our manufacturing process is designed to require only a small number of tumor cells, which need not be living cells, in order to produce MyVax or any other active idiotype immunotherapies that we may develop. The required tumor samples can be acquired by surgical or non-surgical means, can be frozen and are shipped to our central facility, eliminating the need for on-site processing.

*Efficient manufacturing:* Our manufacturing process is designed to enable MyVax to be produced within a clinically relevant time-frame for virtually every B-cell NHL patient whose tumor expresses an idiotype protein, enabling an oncologist to schedule a patient's therapy with a high degree of certainty. In addition, our manufacturing process is designed to enable the reliable production of patient-specific active immunotherapies utilizing a less labor-intensive process than is associated with rescue fusion, permitting us to produce MyVax at cost levels that can yield margins that are competitive with current cancer treatments. Finally, our manufacturing process is designed to permit the expansion of production capacity to meet market demand.

*Commercial feasibility:* We believe that our ability to combine a potentially safe and efficacious active idiotype immunotherapy that offers ease of administration and ease of sample collection with an efficient, scalable and reproducible manufacturing process should make MyVax a commercially feasible treatment for indolent and aggressive B-cell NHL. The safety and ease of administration of MyVax compared to currently available passive immunotherapies such as Rituxan should reduce the medical intervention required on behalf of patients during and after treatment and subsequently reduce the associated cost of care for patients with B-cell NHL.

## **Our Strategy**

Our objective is to commercialize MyVax for the treatment of NHL, as well as other immunotherapies for the treatment of other types of cancer. Our strategy to achieve this objective includes the following:

***Commercialize MyVax for NHL.*** In order to commercialize MyVax for NHL, we plan to:

*Obtain regulatory approval of MyVax.* We are focused on completing clinical trials, filing a Biologics License application, or BLA, and obtaining regulatory approval for MyVax, initially in North America.

*Expand manufacturing capacity.* We plan to expand our manufacturing capacity to meet anticipated demand upon commercialization. We believe that our scalable manufacturing process will enable us to expand our manufacturing capacity in an efficient and timely manner.

*Build North American sales and marketing infrastructure.* Our goal is to directly commercialize MyVax in North America. We plan to build a small, highly-focused sales and marketing infrastructure to market MyVax to the relatively small and well-established community and institutional referral networks of cancer treatment physicians. We believe that the oncology market in North America is readily accessible by a limited sales and marketing presence due to the concentration of prescribing physicians.

*Commercialize MyVax internationally.* We plan to commercialize MyVax in markets outside North America. As appropriate, we intend to establish collaborations to assist in the international commercialization of MyVax.

***Commercialize MyVax for other types of B-cell cancers.*** We believe that MyVax has potential applications beyond B-cell NHL. We plan to develop MyVax for additional types of B-cell cancers where we believe that it is a potentially effective treatment. In particular, we are currently developing MyVax for the treatment of CLL and intend to commence a Phase 2 clinical trial in 2005. We believe that the favorable safety profile of MyVax could accelerate the clinical development and approval of MyVax for additional types of B-cell cancers.

***Leverage our technology to other types of immunotherapies for other diseases.*** We believe that our patented Hi-GET technology has potential applications beyond MyVax. We believe our technology could be used to produce target proteins for other immunotherapies, such as monoclonal antibodies used in passive immunotherapies, and other therapeutic proteins. We plan to leverage our technology in these areas.

## MyVax Clinical Development Program

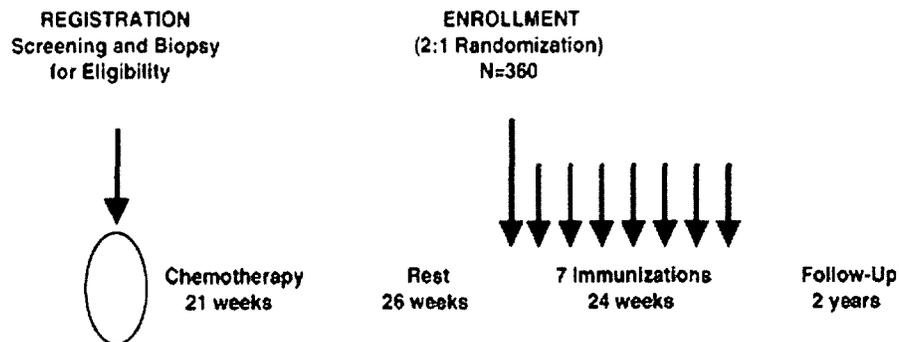
The following chart summarizes the results of our ongoing, recently completed and currently planned clinical trials for MyVax.

<u>Indication</u>	<u>Trial No.</u>	<u>Clinical Phase</u>	<u>No. of Patients Treated</u>	<u>Median Time to Disease Progression</u>	<u>Status</u>
<b>Follicular B-cell NHL</b>					
• Patients in first remission following chemotherapy; 7 immunizations over 24 weeks	2000#03	Phase 3	270 - 300 expected	Treatment phase in process	Patient registration completed; treatment phase to be completed in 2005
• Patients in first remission following chemotherapy; 5 immunizations over 24 weeks	9901	Phase 2	21	37.7 months	Treatment phase completed; patients in long-term follow-up
• Patients in first remission following chemotherapy, administered with reduced amount of adjuvant; 5 immunizations over 24 weeks	2000#07	Phase 2	11	23.8 months	Treatment phase completed; patients in long-term follow-up
• Sole initial therapy; 5 immunizations over 24 weeks, with patients demonstrating either a clinical or an immune response receiving 3 additional immunizations over 8 weeks	2000#04	Phase 2	16	Not applicable	Treatment phase completed; Patients in long-term follow-up
• Patients who relapsed following chemotherapy and were subsequently treated with Rituxan; 8 immunizations over 14 weeks	2002#09	Phase 2	40-60 expected	Treatment phase in process	Enrolling patients
<b>Aggressive B-cell NHL</b>					
• Patients in first remission following chemotherapy	9902	Phase 2	27		
• Schedule A: 5 immunizations over 24 weeks	9902-A	Phase 2	14	10.8 months	Treatment phase completed; patients in long-term follow-up
• Schedule B: 8 immunizations over 18 weeks	9902-B	Phase 2	13	15.7 months	Treatment phase completed; patients in long-term follow-up
<b>Chronic Lymphocytic Leukemia</b>	To be determined	Phase 2	To be determined	—	Phase 2 planned

### *Pivotal Phase 3 Follicular B-cell NHL Clinical Trial — the 2000#03 Trial*

We filed an Investigational New Drug application, or IND, for MyVax with the Food and Drug Administration, or FDA, in April 1999. In November 2000, based on positive interim Phase 2 results from our 9901 trial, we initiated a pivotal, double-blind, controlled Phase 3 clinical trial, our 2000#03 trial, to treat patients with a type of indolent B-cell NHL known as follicular B-cell NHL, which represents approximately half of the cases of indolent B-cell NHL. Patients entering the clinical trial have previously untreated follicular B-cell NHL, are then treated with standard chemotherapy and are in their first remission. The clinical trial is being conducted at 34 treatment centers in the United States and Canada. Two-thirds of the patients will be randomized to receive MyVax, while the remaining patients will receive the control substance consisting only of the foreign carrier protein used in MyVax and the adjuvant administered with MyVax.

The following chart summarizes the treatment schedule of patients in the clinical trial.



Patients are receiving seven immunizations over a 24-week period, which represents two more immunizations than were administered in our 9901 Phase 2 clinical trial described below. Physical evaluations of the patients are conducted monthly during the immunization period and every three months after completion of the course of immunizations. A CT scan occurs prior to the first immunization and every six months following the last immunization for the two years of follow-up and then once a year to detect disease progression. CT scans are read by an independent, central radiology group, which is designed to ensure a consistent determination of patients' responses to MyVax. The primary endpoint of the clinical trial is progression free survival, which is the interval of time measured from enrollment during which a patient is alive with no evidence of disease progression. Enrollment occurs when the patient is assigned to receive either MyVax or the control substance. The clinical trial is designed to evaluate whether a statistically significant increase in progression free survival is observed in patients receiving MyVax compared to patients receiving the control substance. We completed patient registration, the process during which a patient is screened and a biopsy is taken to determine whether the patient is eligible to participate in the clinical trial in April of 2004. Our DSMB met on November 14, 2004 to review data in the clinical trial. After reviewing safety data for the entire Phase 3 clinical trial and blinded, preliminary immune response data for more than 100 of the initial patients immunized in the clinical trial, the DSMB noted no concerns and recommended that the trial continue as planned. We currently anticipate that the two planned interim analyses will be initiated in approximately the second quarter of 2005 and the second quarter of 2006, with the detailed follow-up period of the clinical trial scheduled to conclude approximately in the fourth quarter of 2007. Upon completion of the detailed follow-up period of the pivotal Phase 3 clinical trial, we intend to continue to follow the patients for survival. We believe that, if successful, the results of the trial will support our application for regulatory approval of MyVax for the treatment of follicular B-cell NHL.

#### ***Supporting Phase 2 Follicular B-cell NHL Clinical Trial — the 9901 Trial***

In June 2001, we completed the treatment of 21 patients in a Phase 2 clinical trial, our 9901 trial, to evaluate the ability of patients to mount an immune response to MyVax and to examine its safety profile. The clinical trial involved patients with follicular B-cell NHL in first remission following chemotherapy. The clinical trial was conducted at Stanford University Medical Center and University of Nebraska Medical Center. The primary endpoint of the clinical trial was the generation of a specific anti-idiotype immune response. Positive immune responses were observed. Patients who participated in this clinical trial continue to be monitored for safety, disease progression and survival.

The clinical protocol for this Phase 2 clinical trial was based on the original treatment protocols used in the Stanford and NCI clinical trials. We used MyVax, which is comprised of the same basic components of active idiotype immunotherapy used in the Stanford and NCI trials. MyVax includes the tumor-specific idiotype protein linked to a foreign carrier protein called keyhole limpet hemocyanin, or KLH, which is derived from a giant sea snail, and was given in the same dose as used in the Stanford and NCI clinical trials.

The adjuvant administered with MyVax was Leukine, a recombinant human granulocyte macrophage colony stimulating factor, or GM-CSF, which was also used in the NCI clinical trial. In addition, we produced MyVax using our proprietary manufacturing process instead of rescue fusion. Upon diagnosis, a biopsy was obtained to provide a tumor sample sufficient to produce the patient-specific active idiotype immunotherapy. After obtaining an adequate biopsy, a four-to-seven month regimen of conventional chemotherapy was administered to reduce the tumor mass in the patient. Following an approximately six month rest period to allow the immune system to recuperate from the chemotherapy, the patient received a series of five immunizations over 24 weeks. Patients were evaluated for an immune response during the course of immunizations and two weeks following the final immunization. The entire treatment protocol from the initiation of chemotherapy through the final immunization lasted about 18 months.

A median time to disease progression of 37.7 months has been reached in the patients in this clinical trial, compared to a median time to disease progression of 15 months observed in another clinical trial in which follicular B-cell NHL patients were treated with chemotherapy alone. Ten of the 21 patients in the 9901 trial remained in remission between 39.6 and 59.1 months from the end of chemotherapy as of their last clinical follow-up reported to us and collected from our database in the second quarter of 2004. MyVax was generally well tolerated in our trial, with patients reporting side effects of injection site reactions and flu-like symptoms.

#### ***Additional Phase 2 Follicular B-cell NHL Clinical Trials — the 2000#07, 2000#04 and 2002#09 Trials***

We have completed the treatment phase of two additional Phase 2 clinical trials to study the use of MyVax in treating follicular B-cell NHL. One Phase 2 clinical trial, our 2000#07 trial, evaluated the use of a reduced amount of the GM-CSF administered with MyVax. Patients in this clinical trial were in first remission following chemotherapy after initial diagnosis. This clinical trial is being conducted at the University of Nebraska Medical Center. The 11 patients in this clinical trial received five immunizations over 24 weeks between March 2001 and January 2002. The primary endpoint of the clinical trial was the generation of an anti-idiotype immune response using MyVax. Positive immune responses were observed. A median time to disease progression of 23.8 months has been reached in the patients in this clinical trial. Patients who participated in this clinical trial continue to be monitored for safety, disease progression and survival.

A second Phase 2 clinical trial, our 2000#04 trial, evaluated the use of MyVax as the sole initial therapy for patients with follicular B-cell NHL. This clinical trial is being conducted at Stanford University Medical Center. A significant percentage of patients with follicular B-cell NHL do not clinically require immediate treatment upon diagnosis. As there is no curative treatment, many physicians elect to monitor this population of patients until their clinical symptoms require treatment. Patients in this clinical trial were initially administered five immunizations over 24 weeks. For those demonstrating an immune response or a clinical response, three additional immunizations were administered. The primary endpoint of the clinical trial was the generation of an anti-idiotype immune response using MyVax. Positive immune responses were observed. Patients who participated in this clinical trial continue to be monitored for safety, disease progression and survival.

We initiated a Phase 2 clinical trial in March 2003, our 2002#09 trial, to treat approximately 40 patients with follicular B-cell NHL who have relapsed following chemotherapy. These patients will be treated with MyVax following a course of treatment with Rituxan. This clinical trial is designed to evaluate the use of MyVax in patients treated with Rituxan after relapsing following chemotherapy. The primary endpoint of the clinical trial is time to disease progression. The clinical trial will also evaluate whether an anti-idiotype immune response can be generated.

#### ***Phase 2 Aggressive B-cell NHL Clinical Trial — the 9902 Trial***

We also have completed the treatment phase of a Phase 2 clinical trial, our 9902 trial, to treat patients initially diagnosed with aggressive B-cell NHL. This is the first clinical trial of an active idiotype immunotherapy in newly diagnosed aggressive B-cell NHL patients. Patients enrolled are in first remission following chemotherapy after initial diagnosis. The clinical trial is being conducted at Stanford University Medical Center, University of Nebraska Medical Center and Weill Medical College of Cornell University.

We have enrolled 27 patients in first remission following chemotherapy. The primary endpoint of the clinical trial is the generation of an anti-idiotypic immune response using MyVax. Patients are also being monitored for safety, disease progression and survival.

Because patients with aggressive B-cell NHL tend to relapse much sooner following the completion of chemotherapy than patients with indolent B-cell NHL, the treatment regimen was altered from the one used in indolent B-cell NHL clinical trials. Patients began immunization three months after the end of their chemotherapy, as opposed to after a six-month rest period. Two different administration schedules were examined: 14 patients on Schedule A received five immunizations over a 24-week period and 13 patients on Schedule B received eight immunizations over an 18-week period. Positive immune responses were observed on both Schedule A and Schedule B.

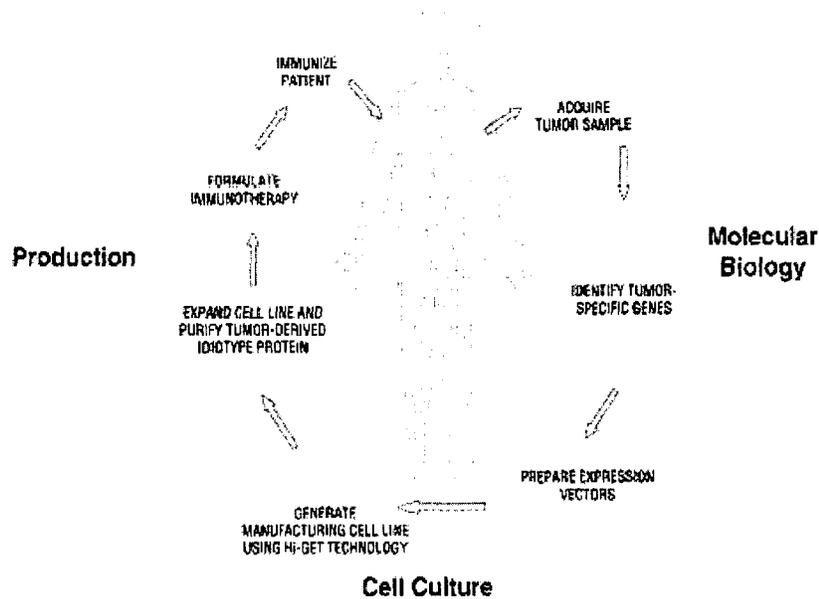
The patients on Schedule A have a median time to disease progression of 10.8 months, which could suggest that giving five immunizations over a 24-week period does not allow for the establishment of a clinically effective response before the fast-growing aggressive B-cell NHL reappears following chemotherapy. In contrast, patients on Schedule B have a median time to disease progression of 15.7 months. The results from Schedule B are encouraging as 11 of the 13 patients treated on Schedule B have a form of aggressive B-cell NHL called mantle cell lymphoma, which is a type of B-cell NHL that is widely viewed as incurable. Based on these results, we plan to initiate a larger clinical trial for patients with mantle cell lymphoma. This trial will be designed to obtain regulatory approval for the use of MyVax for the treatment of mantle cell lymphoma.

**Additional Clinical Programs**

We believe active immunotherapy can be applied successfully to the treatment of other cancers. We are developing MyVax for the treatment of chronic lymphocytic leukemia, or CLL. Like NHL, CLL is primarily a B-cell cancer. We believe CLL can be treated with MyVax, and the same method of manufacturing would be used to produce active idiotypic immunotherapies for CLL as is currently used for aggressive and indolent B-cell NHL patients. We plan to initiate a clinical program for an active immunotherapy to treat CLL during 2005.

**Manufacturing Process**

Our manufacturing process is divided into three phases: molecular biology, cell culture and production, as illustrated below.



Each phase of our manufacturing process uses standard procedures that apply to each personalized immunotherapy that we produce. The manufacturing of each patient's active idiotype immunotherapy begins with the collection of a tumor sample by routine biopsy of the patient. The tumor samples can be acquired by surgical or non-surgical means, can be frozen and are shipped via an overnight courier to our manufacturing facility for processing. After processing, each patient's active idiotype immunotherapy is shipped to the clinical site or the treating physician for immunization of the patient.

### ***Molecular Biology***

Upon arrival of the tumor sample at our manufacturing facility, we extract genetic material from the sample and isolate the genes that encode the two unique regions of a patient's tumor-specific idiotype protein. Our proprietary knowledge allows us to identify the genes encoding the idiotype protein generally within a few weeks. We then generate a pair of expression vectors encoding the idiotype protein. An expression vector is a DNA molecule that contains all of the elements required for the production of the tumor-derived idiotype protein in a host cell.

### ***Cell Culture***

The expression vectors encoding the idiotype protein are then introduced into mammalian cells. Individual mammalian cell lines producing the idiotype protein are then generated using a series of cycles of growth and selection steps. These cycles of growth and selection, known as gene amplification, are completed using our patented Hi-GET technology that provides for the rapid and efficient isolation of mammalian cell lines expressing increased levels of the idiotype protein. These cell lines are referred to as manufacturing cell lines.

In comparison to alternative methods of gene amplification, our Hi-GET technology more efficiently and reproducibly generates stable cell lines containing increased copies of the expression vectors that encode the patient's idiotype protein. Consequently, fewer candidate cell lines must be subjected to selection techniques in order to identify a suitable manufacturing cell line, thus reducing the amount of time a technician must spend to identify a cell line that is expressing sufficient levels of idiotype protein. This allows each of our technicians to work on the development of ten to 20 different manufacturing cell lines at the same time.

### ***Production***

Upon isolation of a manufacturing cell line, the size of the culture is expanded to allow for the production of an appropriate amount of the idiotype protein. Following a standard purification process, the idiotype protein is linked to KLH, a foreign carrier protein, resulting in MyVax. After release testing, the frozen MyVax product and GM-CSF adjuvant are shipped to the clinical trial site or the treating physician for immunization of the patient.

We purchase KLH from biosyn Arzneimittel GmbH, or biosyn, a single source supplier. We have entered into a supply agreement with biosyn, dated December 9, 1998, pursuant to which biosyn has agreed to supply us with KLH of suitable quality. Pursuant to the supply agreement, biosyn is obligated to supply us a maximum amount of KLH in any one month. Under the agreement, biosyn may, but is not required to, supply us with KLH in excess of the contractual monthly maximum. Since early 2001, we have purchased an average amount of KLH per month that is greater than the monthly maximum amount and annual minimum amount of KLH that biosyn is required to supply us under the supply agreement. Over the next 12 months, we expect our requirements for KLH may exceed the amount that biosyn is required to supply us under the supply agreement. The supply agreement expires on December 9, 2005. Either party may terminate the supply agreement earlier upon a breach that is not cured within 60 days or other events relating to insolvency or bankruptcy. We are currently evaluating all of our options in regard to securing future supplies of KLH for our clinical trials and commercial operations.

### ***Manufacturing Safeguards***

We have instituted several safeguards in our manufacturing process that are designed to ensure batch integrity and prevent patient therapies from being sent to the incorrect patient. Throughout the process we carefully handle manufacturing materials and record data. The DNA sequences of the tumor-specific idiotype protein genes are determined early in the molecular biology phase of the process. These DNA sequences serve as a reference that permits the identification of manufacturing intermediates, such as expression vectors, and stable cell lines containing these vectors, as belonging to a specific patient's sample. At later stages of the process, we use tests to demonstrate that the subtype of the idiotype protein present in both purified idiotype protein preparations and in the final MyVax product, the idiotype protein-KLH conjugate, is in conformance with the expected subtype.

In addition to safeguards designed to ensure segregation of each patient's therapy, we archive intermediates throughout the manufacturing process, which allows us to quickly produce additional vials of a patient's therapy if needed. These archival procedures include the storage of the manufacturing cell line produced for each patient and purified preparations of the patient's tumor-specific idiotype protein.

### **Additional Hi-GET Technology Applications**

Our patented Hi-GET technology has additional potential applications, including producing target proteins for other immunotherapies, such as monoclonal antibodies used in passive immunotherapies, and other therapeutic proteins. Our Hi-GET technology can also be used to produce proteins for research, for example, to support genomic companies' needs to strengthen their patent positions by enabling them to link protein function with their DNA sequences more quickly. Our Hi-GET technology has also been used to produce both single and multi-chain proteins that are secreted into the culture medium, proteins that are located in the cytoplasm of the cell and proteins that are located in the membrane of the cell. Many proteins of therapeutic and diagnostic interest must be produced in mammalian cells in order for the proteins to retain their characteristic features and biologic activities. Our Hi-GET technology can be used to efficiently produce a wide variety of proteins in mammalian cell lines.

### **Competition**

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Due to the high demand for new cancer therapies, research is intense and new treatments are being sought out and developed by our competitors.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

Several companies, such as Corixa Corporation, Biogen Idec Inc. and Immunomedics, Inc. are involved in the development of passive immunotherapies for the treatment of NHL. Various products are currently marketed for treatment of NHL. Rituxan, a monoclonal antibody co-marketed by Genentech, Inc. and Biogen Idec Inc., is approved for the treatment of relapsed or refractory, low grade B-cell NHL. In addition, Biogen Idec, Inc. has received FDA approval for marketing its passive radioimmunotherapy product, Zevalin, and GlaxoSmithKline Plc and Corixa Corporation recently received FDA approval for marketing their version of passive radioimmunotherapy product, Bexxar, for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell NHL.

In addition, there are several companies focusing on the development of active immunotherapies for the treatment of NHL, including Antigenics, Inc., Faville, Inc. and Large Scale Biology Corporation. These companies' product candidates are in various stages of development. In addition, we are aware that the NCI, in collaboration with Biovest International, Inc., is currently conducting a Phase 3 clinical trial of active immunotherapy in patients with follicular NHL. If any are successfully developed and approved, they could compete directly with MyVax, if it is approved.

## **Sales and Marketing**

We recently began building our marketing capabilities. In order to commercially market our active immunotherapies if we obtain regulatory approval, we must either develop a sales and marketing infrastructure or collaborate with third parties with more sales and marketing experience. We plan to build a small, highly-focused sales and marketing infrastructure to market MyVax to the relatively small and well-established community and institutional referral networks of cancer treatment physicians. We believe that the oncology market in North America is readily accessible by a limited sales and marketing presence due to the concentration of prescribing physicians. To penetrate oncology markets outside the United States, as appropriate, we may establish collaborations to assist in the commercialization of MyVax.

## **Intellectual Property**

We rely on the proprietary nature of our technology and production processes for the protection of MyVax and any other immunotherapies that we may develop. We plan to prosecute and defend aggressively our patents and proprietary technology. Our policy is to patent the technology, inventions and improvements that we consider important to the development of our business. We hold two United States patents related to our core gene amplification technology, including composition of matter claims directed to cell lines and claims directed to methods of making proteins derived from patients' tumors. These patents expire in 2016. Corresponding patents, although more constrained in scope due to rules not applicable in the United States, have been issued in Australia, Canada and South Africa, all of which expire in 2017. We have also filed additional United States and corresponding foreign patent applications relating to our Hi-GET gene amplification technology and expect to continue to file additional patent applications.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement, through which we seek to protect our intellectual property. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

The biotechnology and biopharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. While our active immunotherapies are in clinical trials, and prior to commercialization, we believe our current activities fall within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States and Section 55.2(1) of the Canadian Patent Act, each of which covers activities related to developing information for submission to the FDA and its counterpart agency in Canada. As our active immunotherapies progress toward commercialization, the possibility of an infringement claim against us increases. While we attempt to ensure that our active immunotherapies and the methods we employ to manufacture them do not infringe other parties' patents and other proprietary rights, competitors or other parties may assert that we infringe on their proprietary rights. In particular, we are aware of patents held jointly by Genentech, Inc. and City of Hope National Medical Center relating to expression of recombinant antibodies, by British Technology Group PLC relating to expression of recombinant proteins in mammalian cells, by the Board of Trustees of the Leland Stanford Junior University relating to expression of recombinant antibodies and by Stratagene relating to generation of DNA that encodes antibodies.

We believe that we have valid defenses to any assertion that MyVax, or any other similar antibody-based active immunotherapies that we may develop, or the methods that we employ to manufacture them, infringes the claims of the patent held jointly by Genentech, Inc. and City of Hope National Medical Center relating to expression of recombinant antibodies. We also believe that the patent may be invalid and/or unenforceable. The relevant patent was issued to Genentech, Inc. in 2001 in connection with the settlement of an interference proceeding in the United States Patent and Trademark Office between Genentech, Inc. and Celltech R&D Ltd. We believe other biotechnology companies are aware of and are considering the possible impact of this patent. Other companies have negotiated license agreements for this patent. We have not attempted to obtain such a license because we believe that properly construed claims do not cover activities related to the manufacture of MyVax. If we decide to attempt to obtain a license for this patent, we cannot guarantee that we would be able to obtain such a license on commercially reasonable terms, or at all. We are aware of a complaint filed by Medimmune, Inc. against Genentech, Inc., City of Hope National Medical Center and Celltech in April 2003 in the United States District Court for the Central District of California seeking, among other things, judicial declarations that the patent is invalid and that the patent is unenforceable due to the patent applicants' inequitable conduct before the United States Patent and Trademark Office and that the settlement agreement between Genentech and Celltech violates certain United States antitrust and unfair competition laws. In March and April 2004, the antitrust and patent elements of the case were dismissed. With respect to the latter, the court cited a recent decision by the Federal Circuit that controversies over patent validity, enforcement or infringement would not be recognized while license agreements protected the licensee from suit for infringement. MedImmune is appealing the dismissals. We cannot predict whether we would be successful in demonstrating that MyVax, or any other similar antibody-based active immunotherapies that we may develop, or the methods that we employ to manufacture them, does not infringe the claims of the patent held jointly by Genentech, Inc. and City of Hope National Medical Center or that the patent is invalid and/or unenforceable.

We also believe that we have valid defenses to any assertion that MyVax, or any other active immunotherapies that we may develop, infringes the claims of the patent held by British Technology Group PLC relating to expression of recombinant proteins in mammalian cells, that MyVax, or any other similar antibody-based active immunotherapies that we may develop, infringes the claims of the patent held by the Board of Trustees of the Leland Stanford Junior University relating to expression of recombinant antibodies or that MyVax, or any other similar antibody-based active immunotherapies that we may develop, infringes the claims of the patent held by Stratagene relating to generation of DNA that encodes antibodies. The relevant British Technology Group patent was issued in 1990 and was subsequently assigned to British Technology Group. We believe that the patent is invalid and, therefore, that the patent does not impact our ability to commercialize MyVax. The relevant Stanford patent was issued in 1998. We believe that MyVax, and the methods that we employ to manufacture MyVax, do not infringe the claims of the patent. The relevant Stratagene patent was issued in 2002. We believe that the patent is invalid, and that the methods that we employ to manufacture MyVax do not infringe the claims of the patent.

If any of these patents is found to cover MyVax, or any other immunotherapies that we may develop, or the methods that we employ to manufacture them, we could be required to pay damages and could be unable to commercialize MyVax, or any other immunotherapies that we may develop, unless we obtain a license from the applicable patent holder. A license may not be available to us on acceptable terms in the future, or at all. In addition, litigation of any intellectual property claims with any of these patent holders, with or without merit, would likely be expensive and time-consuming and divert management's attention from our core business.

See "Risk Factors — Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection."

In June 2002, Pharmacia & Upjohn AB filed an opposition to the registration of our "GENITOPE" trademark alleging that a likelihood of confusion exists between our Genitope trademark and Pharmacia's "GENOTROPIN" trademark. In March 2004, a settlement agreement was executed by both parties, ending the dispute. We have filed an amendment to modify our trademark to a house mark. Pharmacia Corporation and Pharmacia & Upjohn AB and Pfizer have agreed to withdraw the trademark opposition filed against the

“Genitope” mark and agreed to not interfere with or object to the use or registration by us of our “Genitope” house marks, our trade names or our “genitope.com” domain name as a house mark.

## **Government Regulation**

### ***Regulation of MyVax and Any Other Active Immunotherapies that We May Develop in the United States and Canada***

MyVax and any other immunotherapies that we may develop will require regulatory approval prior to commercialization. At the present time, we believe that MyVax and any other immunotherapies that we may develop will be regulated in the United States by the FDA as biologics.

The Investigational New Drug application, or IND, for our lead product candidate, MyVax personalized immunotherapy, was submitted to the FDA in April 1999. We received approval from the FDA to begin clinical trials with a Phase 2 clinical trial in May 1999. A pre-Phase 3 clinical trial meeting was held with the FDA in August 2000. Our pivotal Phase 3 clinical trial for the treatment of follicular B-cell NHL began in November 2000. The IND was submitted in Canada in December 2000. Our pivotal Phase 3 clinical trial is currently ongoing in the United States and Canada.

We plan to submit marketing applications for approval of MyVax initially in the United States and Canada. The initial application is expected to be based on one adequate and well-controlled Phase 3 clinical trial, our 2000#03 trial, with supporting data from our Phase 2 clinical trials. In the United States, we expect the Biologics License application, or BLA, to be reviewed under accelerated approval, with time of progression free survival as a surrogate for survival. We expect to follow patients for long term survival as a post-approval commitment. We expect to conduct further clinical trials to support BLAs for approvals of MyVax for additional indications.

We have not started the regulatory approval process in any jurisdiction other than the United States and Canada, and we are unable to estimate when, if ever, we will commence the regulatory approval process in any other foreign jurisdiction. In general, we will have to complete an approval process similar to the United States approval process in foreign markets for MyVax and any other immunotherapies that we may develop before we can commercialize them in those countries. The approval procedure and the time required for approval vary from country to country and can involve additional testing. Foreign approvals may not be granted on a timely basis, or at all. Regulatory approval of product prices is required in most countries other than the United States. The prices approved for our products may be too low to generate an acceptable return to us.

Our manufacturing facility is currently subject to licensing requirements of the California Department of Health Services, and we received a license during the second quarter of 2004. Our facility is subject to inspection by the FDA as well as by the California Department of Health Services at any time. Failure to maintain a license from the California Department of Health Services, or to meet the inspection criteria of the FDA or the California Department of Health Services, would disrupt our manufacturing processes and would harm our business.

### ***Product Regulation***

Governmental authorities in the United States and other countries extensively regulate the preclinical studies and clinical testing, manufacture, labeling, storage, record keeping, advertising, promotion, export and marketing, among other things, of drugs, medical devices and biological materials, including MyVax and any other immunotherapies that we may develop. In the United States, pharmaceutical products are regulated by the FDA under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. The steps required before a novel biologic may be approved for marketing in the United States generally include:

- preclinical laboratory tests and preclinical studies in animals;
- the submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may commence;

- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- the submission to the FDA of a BLA; and
- FDA review and approval of such application, including a pre-approval inspection of the manufacturing facility and FDA inspection of clinical study sites.

The testing and approval process requires substantial time, effort and financial resources. We cannot be certain that any approval will be granted on a timely basis, if at all. Prior to and following approval, if granted, the establishment or establishments where the product is manufactured are subject to inspection by the FDA and must comply with current good manufacturing practices, or cGMP, requirements enforced by the FDA through its facilities inspection program. In addition, drug manufacturing facilities in California are subject to licensing requirements of the California Department of Health Services. Facilities are subject to inspection by the FDA as well as by the California Department of Health Services at any time.

Preclinical studies generally include animal studies to evaluate the mechanism of action of the product, as well as animal studies to assess the potential safety and efficacy of the product. Compounds must be produced according to applicable cGMP requirements and preclinical safety tests must be conducted in compliance with FDA and international regulations regarding good laboratory practices. The results of the preclinical tests, together with manufacturing information and analytical data, are generally submitted to the FDA as part of an IND, which must become effective before human clinical trials may be commenced. The IND will automatically become effective 30 days after receipt by the FDA, unless the FDA before that time requests an extension or raises concerns about the conduct of the clinical trials as outlined in the application. In such latter case, the sponsor of the application and the FDA must resolve any outstanding concerns before clinical trials can proceed. Clinical trials involve the administration of the investigational product to healthy volunteers or to patients, under the supervision of a qualified principal investigator, and must be conducted in accordance with good clinical practices. Clinical trials are conducted in accordance with protocols that detail many items, including:

- the objectives of the study;
- the parameters to be used to monitor safety; and
- the efficacy criteria to be evaluated.

Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be reviewed and approved by an independent institutional review board, or IRB, at each institution at which the study will be commenced, prior to the recruitment of subjects. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into human subjects, the drug is tested for safety and, as appropriate, for absorption, metabolism, distribution, excretion, pharmacodynamics and pharmacokinetics. Phase 2 usually involves studies in a limited patient population to evaluate preliminarily the efficacy of the drug for specific targeted indications, determine dosage tolerance and optimal dosage and identify possible adverse effects and safety risks.

Phase 3 clinical trials are undertaken to further evaluate clinical efficacy and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. Phase 1, Phase 2 or Phase 3 testing may not be completed successfully within any specific time period, if at all, with respect to any products being tested by a sponsor. Furthermore, the FDA or the IRB may suspend clinical trials at any time on various grounds, including a finding that the healthy volunteers or patients are being exposed to an unacceptable health risk.

The results of the preclinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval for the marketing of the product. The FDA may refuse to accept the BLA for review or deny approval of the application if applicable regulatory criteria are not satisfied, or if additional testing or information is required.

Post-marketing testing and surveillance to monitor the safety or efficacy of a product may be required, and the FDA may limit further marketing of the product based on the results of post-market testing. FDA approval of any application may include many delays or never be granted. Moreover, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. Among the conditions for approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to cGMP requirements. These requirements must be followed at all times in the manufacture of the approved product. In complying with these requirements, manufacturers must continue to expend time, monies and effort in the area of production and quality control to ensure full compliance. Failure to comply may subject us to fines and civil penalties, suspension or delay in product approval, seizure or recall of the product, or product approval withdrawal.

New products that are being developed for the treatment of serious or life-threatening diseases where the product would provide therapeutic advantage over the existing treatment may be considered for accelerated approval by the FDA. In these cases, approval can be based on criteria that are indicative of the desired clinical benefit. These products generally receive high priority review by the FDA. Sponsors of products that receive accelerated approval must carry out clinical trials post-approval to verify the desired clinical benefit.

Both before and after the FDA approves a product, the manufacturer and the holder or holders of the BLA for the product are subject to comprehensive regulatory oversight. Violations of regulatory requirements at any stage, including the preclinical and clinical testing process, the review process, or at any time afterward, including after approval, may result in various adverse consequences, including the FDA's delay in approving or refusal to approve a product, suspension or withdrawal of an approved product from the market, seizure or recall of a product and/or the imposition of criminal penalties against the manufacturer and/or the license holder. In addition, later discovery of previously unknown problems may result in restrictions on a product, its manufacturer, or the BLA holder, or market restrictions through labeling changes or product withdrawal. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

With respect to post market product advertising and promotion, the FDA imposes a number of complex regulations on entities that advertise and promote pharmaceuticals and biologics, which include, among others, standards for and regulations of direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA has very broad enforcement authority under the Federal Food Drug and Cosmetic Act, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA has broad regulatory and enforcement powers, including the ability to impose fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect upon us.

No patient-specific active idiotype immunotherapeutic for cancer has been approved by the FDA for marketing. The FDA has not yet established particular regulatory guidelines for patient-specific immunotherapies, nor has it issued any interim guidelines.

#### ***Other Regulations***

We are also subject to regulation by the Occupational Safety and Health Administration, or OSHA, and the state and federal environmental protection agencies and to regulation under the Toxic Substances Control Act and other regulatory statutes, and may in the future be subject to other federal, state or local regulations. Either OSHA or the environmental protection agencies, or all of them, may promulgate regulations that may

affect our research and development programs. We are unable to predict whether any agency will adopt any regulation, which could limit or impede on our operations.

**Employees**

As of December 31, 2004 we had 128 employees, including 109 in research and development (including ten in medical affairs, 55 in manufacturing, 27 in quality control and assurance, 13 in process and technical development and four in regulatory affairs), four in strategic marketing, and 15 in general and administrative positions. Ten of our employees have Ph.D.s, one has an M.D., and one has a Pharm. D. None of our employees is subject to a collective bargaining agreement. We believe that we have good relations with our employees.

**Research and Development**

Since our inception, we have made substantial investments in research and development. During 2004, 2003 and 2002, we incurred research and development expenditures of \$22.6 million, \$19.7 million and \$15.9 million, respectively. Since inception to December 31, 2004, we have incurred research and development expenditures of \$75.1 million.

**Executive Officers of the Registrant**

The following table sets forth, as of February 28, 2005, information about our executive and other officers.

<u>Name</u>	<u>Age</u>	<u>Position Held</u>
Dan W. Denney, Jr., Ph.D. ....	51	Chairman, Chief Executive Officer, and Director
John M. Vuko .....	54	Vice President of Finance and Chief Financial Officer
Michael J. Buckley, Ph.D. ....	44	Vice President, Manufacturing
Steven Chamow, Ph.D. ....	51	Vice President, Process Sciences
Bonnie Charpentier, Ph.D. ....	53	Vice President, Regulatory Affairs
Thomas DeZao .....	47	Vice President, Strategic Marketing and Sales
Diane Ingolia, J.D., Ph.D. ....	46	Vice President, Technical Development and Intellectual Property Counsel
Claude Miller .....	54	Vice President, Quality
Thomas Theriault, Ph.D. ....	42	Vice President, Research

*Dan W. Denney Jr., Ph.D.* is our founder and has served as our Chief Executive Officer since November 1999 and Chairman of the Board since August 1996. Dr. Denney did his postdoctoral research in the Chemistry Department at Stanford University, where he was a Merck Fellow. Dr. Denney then served as a Visiting Scholar at the University of Alberta in Canada prior to founding Genitope. Dr. Denney holds a B.A. from Vanderbilt University and a Ph.D. in Microbiology and Immunology from Stanford University School of Medicine.

*John M. Vuko* has served as our Vice President of Finance and Chief Financial Officer since April 2004. From December 1999 to October 2003, Mr. Vuko was Executive Vice President and Chief Financial Officer at Incyte Corporation, a biopharmaceutical company. Prior to joining Incyte, Mr. Vuko served as Senior Vice President and Chief Financial Officer of Achievement Radio Holdings, Inc., an owner and operator of radio broadcasting stations, from March 1997 to December 1999, and ultimately held a similar position with Ross Stores, Inc., a retail clothing company, from October 1989 to March 1997. Mr. Vuko holds a B.A. in Business Administration from San Francisco State University.

*Michael J. Buckley, Ph.D.* has served as our Vice President of Manufacturing since January 2005. Dr. Buckley joined us after serving as Vice President of Bexxar Operations at Corixa Corporation, a biopharmaceutical company, from January 2003 to August 2004. Dr. Buckley joined Coulter Pharmaceutical, Inc., a biopharmaceutical company, in 1996, which was later acquired by Corixa, where he served in positions

of increasing responsibility, including as Sr. Director of Product Development. Dr. Buckley holds a B.A. from the College of Wooster and a Ph.D. in Immunology from the University of Medicine and Dentistry of New Jersey.

*Steven Chamow, Ph.D.* has served as our Vice President of Process Sciences since January 2005. Dr. Chamow joined us after serving as Vice President of Process Sciences at Abgenix, Inc., a biopharmaceutical company from March 2000 to June 2004. Prior to Abgenix, Dr. Chamow served in positions of increasing responsibility in process development and manufacturing, including as Director of Biopharmaceutical Development, at Scios, Inc., a biopharmaceutical company, from March 1998 to March 2000. Prior to joining Scios, Dr. Chamow served as Senior Scientist at Genentech, Inc., a biopharmaceutical company, from September 1987 to March 1998. Dr. Chamow holds a B.A. in biology from University of California, Santa Cruz and a Ph.D. in biochemistry from the University of California, Davis and completed postdoctoral training at the National Institutes of Health.

*Bonnie Charpentier, Ph.D.* has served as our Vice President of Regulatory Affairs since December 2001. From June 1995 to December 2001, Dr. Charpentier held a number of regulatory positions at Roche Global Development, a division of F. Hoffman-La Roche Ltd., a pharmaceuticals and diagnostics company, including Vice President and Regulatory Site Head. From December 1993 to June 1995, Dr. Charpentier served as Regulatory Program Director at Syntex Corporation, a biopharmaceutical company, where she joined as a Manager of Human Pharmaceutical Regulatory in 1991. Dr. Charpentier holds a B.A. and a Ph.D. in Biology from the University of Houston.

*Thomas DeZao* has served as our Vice President of Strategic Marketing and Sales since February 2002. From August 1999 to January 2002, Mr. DeZao was Vice President of Marketing and Medical Affairs at Corixa Corporation, a biopharmaceutical company, and Coulter Pharmaceutical, Inc., a wholly owned subsidiary of Corixa Corporation, where he was responsible for all aspects of the marketing plan for Bexxar, a radio-labeled monoclonal antibody developed to treat non-Hodgkin's lymphoma. From July 1998 to June 1999, Mr. DeZao was the Vice President of Marketing and Sales for Asta Medica, a biopharmaceutical company, where he developed commercialization plans for an emerging United States oncology business. From October 1987 to March 1998, Mr. DeZao held a number of management positions for Chiron Corporation, a global pharmaceutical company, both in oncology marketing and sales. Mr. DeZao holds a B.A. from Montclair State University.

*Diane Ingolia, J.D., Ph.D.* currently serves as our Vice President of Technical Development and Intellectual Property Counsel. Dr. Ingolia joined us in May 1997 as our Senior Scientist and Intellectual Property Counsel, a position she held until April 2000. From May 2000 to May 2002, Dr. Ingolia served as our Vice President of Product Development and Intellectual Property Counsel. From 1994 to 1997, Dr. Ingolia was a patent attorney at Medlen & Carroll, LLP. Dr. Ingolia holds a B.S. degree from University of New Orleans and a Ph.D. in Biochemistry from Baylor College of Medicine. Dr. Ingolia conducted her postdoctoral research at Stanford University School of Medicine in the laboratory of Dr. Irving Weissman. Dr. Ingolia holds a J.D. from Santa Clara Law School.

*Claude Miller* has served as our Vice President of Quality since February 2004. From September 2000 to November 2003, Mr. Miller held a number of key management positions at Alpha Therapeutic Corporation, a plasma fractionation biologics company, starting as Vice President of Regulatory and Quality before being elevated to the position of President and Chief Operating Officer in March 2002. From April 1997 to September 2000, Mr. Miller was Senior Director of Operations at SangStat Medical Corporation, a transplant company. Prior to joining SangStat, Mr. Miller held a number of positions in Quality and Compliance at Somatix, Collagen Corporation and LifeScan Inc. Claude Miller received his B.S. and M.S. in Molecular Biology/Microbiology from California State University, Long Beach.

*Thomas Theriault, Ph.D.*, has served as our Vice President, Research and Development since February 2005. From August 1996 to April 2004, Dr. Theriault held a number of positions at Incyte Corporation, a biopharmaceutical company, most recently as Vice President of Research from August 2003 to April 2004. From May 2004 until January 2005, Dr. Theriault was an independent consultant. Dr. Theriault was a co-founder and Director of Research at Combion, a privately held DNA microarray company focused on genetic

and genomic applications, which was acquired by Incyte Corporation in 1996. Dr. Theriault holds a B.A. degree in Chemistry from Dartmouth College, a Ph.D. in Biophysical Chemistry from Stanford University and completed post doctoral training at the California Institute of Technology.

### **Available Information**

We maintain a site on the world wide web at [www.genitope.com](http://www.genitope.com); however, information found on, or that can be accessed through, our website is not incorporated by reference into this annual report. We make available free of charge on or through our website our filings with the Securities and Exchange Commission ("SEC"), including our annual report of Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, a copy of this annual report is located at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding our filings at [www.sec.gov](http://www.sec.gov).

In 2003, we adopted a Code of Business Conduct and Ethics ("Code") that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted the text of our Code on our website at [www.genitope.com](http://www.genitope.com) in connection with "Investor" materials. We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code by posting such information on our website, at the address and location specified above. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our Code that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future. You may also request a copy of the Code by contacting our investor relations department at [IR@genitope.com](mailto:IR@genitope.com).

## RISK FACTORS

### Risks Related to Our Business

*If clinical trials of MyVax, or any other immunotherapies that we may develop, do not produce successful clinical trial results, we will be unable to commercialize these products.*

To receive regulatory approval for the commercial sale of MyVax, or any other immunotherapies that we may develop, we must conduct, at our own expense, extensive clinical trials to demonstrate safety and efficacy in humans. Clinical testing is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the testing. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of MyVax, or any other immunotherapies that we may develop, including the following:

- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing;
- safety and efficacy results attained in our pivotal Phase 3 clinical trial for MyVax may be less positive than the results obtained in our Phase 2 clinical trials for MyVax;
- costs of our clinical trials may be greater than we currently anticipate;
- after reviewing test results, we may abandon projects that we might have previously believed to be promising;
- we, or regulators, may suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks; and
- the effects of MyVax, or any other immunotherapies that we may develop, on patients may not be the desired effects or may include undesirable side effects or other characteristics that may delay or preclude regulatory approval or limit their commercial use if approved.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. For example, positive time to disease progression results in small scale Phase 2 clinical trials are not necessarily indicative of the time to disease progression results in larger Phase 3 clinical trials. Moreover, all preliminary clinical data reported from time to time prior to the release of final results of a trial regarding time to disease progression is not fully audited and has been taken from databases that have not been fully reconciled against medical records kept at the clinical sites or that may not include the most current information on patient disease progressions. The DSMB's recommendation that we continue our ongoing pivotal Phase 3 clinical trial for MyVax is not indicative of any results of the Phase 3 clinical trial, and failure can occur at any stage of testing. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier clinical trials. The data collected from our clinical trials may not be sufficient to support regulatory approval of MyVax, or any other immunotherapies that we may develop. We do not know whether our existing or any future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. Our failure to adequately demonstrate the safety and efficacy of MyVax, or any other immunotherapies that we may develop, will prevent receipt of regulatory approval and, ultimately, commercialization of MyVax, or any other immunotherapies that we may develop. Furthermore, because we have devoted most of our resources to the development of MyVax, our lead product candidate, we are dependent on its success.

*We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial losses for the foreseeable future.*

We are a development stage company with a limited operating history. We have focused primarily on conducting clinical trials and seeking regulatory approval for our lead product candidate, MyVax personalized immunotherapy, a patient-specific active immunotherapy that is based on the unique genetic makeup of a patient's tumor and is designed to activate a patient's immune system to identify and attack cancer cells. We have incurred losses in each year since our inception in 1996. Net losses were \$27.0 million in 2004,

\$48.9 million in 2003 and \$19.9 million in 2002. As of December 31, 2004, we had an accumulated deficit of \$114.8 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to increase in connection with our ongoing pivotal Phase 3 clinical trial and additional Phase 2 clinical trials for MyVax and any other clinical trials that we may initiate. In addition, subject to regulatory approval of MyVax, we expect to incur sales, marketing and manufacturing expenses, including expenses associated with the construction and qualification of a commercial scale manufacturing facility. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing immunotherapeutic drugs, we are unable to predict the extent of any future losses or when we will achieve or sustain product revenues or become profitable, if ever.

*We currently have no source of revenue and may never become profitable.*

Our ability to become profitable depends upon our ability to generate revenue. To date, MyVax has not generated any revenue, and we do not know when or if MyVax will generate revenue. Our ability to generate revenue depends on a number of factors, including our ability to:

- successfully complete our ongoing pivotal Phase 3 clinical trial for MyVax;
- obtain regulatory approval for MyVax, including regulatory approval for our commercial scale manufacturing facility and process;
- manufacture commercial quantities of MyVax at acceptable cost levels; and
- successfully market and sell MyVax.

We anticipate the earliest we could realize product revenue is in 2006. We do not anticipate that we will achieve profitability for at least several years after generating revenues. If we are unable to generate sufficient revenue, we will not become profitable, and we may be unable to continue our operations.

*We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.*

Developing patient-specific active immunotherapies, conducting clinical trials, establishing manufacturing facilities and marketing immunotherapies that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and clinical trials;
- continue our research and development;
- complete the construction and qualification of a commercial scale manufacturing facility; and
- commercialize MyVax, or any other immunotherapies that we may develop, if any such immunotherapies receive regulatory approval.

We believe that our current cash resources, together with the interest thereon, will provide us with sufficient financial resources for at least the next 12 months. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the risk factors discussed in this report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will need to raise additional funds complete the construction and qualification of a commercial scale manufacturing facility and to commercialize MyVax if MyVax receives regulatory approval for the treatment of follicular B-cell NHL. A manufacturing facility must be built and qualified and pass a pre-approval inspection from the appropriate regulatory agency prior to any regulatory approval for MyVax.

Our future funding requirements will depend on many factors, including, but not limited to:

- the cost and timing of leasing and completing the construction of a commercial scale manufacturing facility;
- the rate of progress and magnitude and cost of our product development efforts and other research and development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the success of the commercialization of MyVax;
- the effect of competing technological and market developments; and
- our ability to establish collaborative, licensing or other arrangements for the development, sale, marketing or distribution of our product candidates and the terms of those arrangements.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

Even if we achieve positive interim results in our pivotal Phase 3 clinical trial and receive regulatory approval for MyVax, including regulatory approval of a commercial scale manufacturing facility, we anticipate the earliest we could realize product revenue is in 2006. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.

*We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize MyVax, or any other immunotherapies that we may develop.*

Our pivotal Phase 3 clinical trial of MyVax for the treatment of follicular B-cell NHL is being conducted at 34 treatment centers in the United States and Canada. We do not have the ability to independently conduct clinical trials for MyVax, or any other immunotherapies that we may develop, and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third-party couriers to transport patient tissue samples and MyVax. If any of our relationships with these contract research organizations, medical institutions, clinical investigators, contract laboratories or third-party couriers terminate, we may not be able to enter into arrangements with alternative third parties. If certain of these third parties, such as medical institutions, clinical investigators or contract laboratories, do not successfully carry out their contractual duties or obligations, do not meet expected deadlines or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize MyVax, or any other immunotherapies that we may develop.

***We rely on third parties to provide materials and services needed for the manufacture of MyVax. If these third parties do not adequately provide materials or fail to carry out their contractual duties or obligations, we may not be able to successfully manufacture or commercialize MyVax, or any other immunotherapies that we may develop.***

We currently rely on third parties, such as vendors, suppliers and contract laboratories, to provide materials and services necessary for the manufacture and testing of MyVax. If any of our relationships with these vendors, suppliers or contract laboratories terminate, we may not be able to enter into arrangements with alternative third parties. If certain of these third parties do not successfully carry out their contractual duties or obligations, do not provide materials or services of suitable quality, we may experience delays in obtaining regulatory approval for or successfully commercializing MyVax, or any other immunotherapies that we may develop.

***We have no experience manufacturing MyVax, or any other immunotherapies, for the number of patients and at a cost that would enable widespread commercial use.***

To date, we have only manufactured MyVax in quantities necessary to support our ongoing pivotal Phase 3 clinical trial and Phase 2 clinical trials for MyVax. We have no experience in manufacturing MyVax, or any other immunotherapies, for the number of patients and at a cost that would support commercial use. In addition, since no other company has manufactured an immunotherapeutic product for commercial sale, there are no precedents from which we could learn. To commercialize MyVax, we will need to construct and qualify a commercial scale manufacturing facility that meets cGMP standards. In doing so, we may encounter problems with, among other things, controlling costs and quality control and assurance.

If we cannot manufacture a sufficient supply of MyVax on acceptable terms, the commercialization of MyVax will be delayed or prevented.

***We currently depend on single source suppliers for critical raw materials for manufacturing, as well as other components required for the administration of MyVax. The loss of these suppliers could delay our clinical trials or prevent or delay commercialization of MyVax.***

We currently depend on single source suppliers for critical raw materials used in MyVax and other components used in the manufacturing process and required for the administration of MyVax. In particular, manufacturing of MyVax requires KLH, a foreign carrier protein which is derived from a giant sea snail. We purchase KLH from biosyn Arzneimittel GmbH, or biosyn, a single source supplier. We have entered into a supply agreement with biosyn, dated December 9, 1998, pursuant to which biosyn has agreed to supply us with KLH. The supply agreement expires on December 9, 2005. Either party may terminate the supply agreement earlier upon a breach that is not cured within 60 days or other events relating to insolvency or bankruptcy. Biosyn is not contractually obligated to supply us with the amounts of KLH they have previously supplied. There may be no other supplier of KLH of suitable quality for our purposes, and there are significant risks associated with our ability to produce KLH of suitable quality ourselves. Even if we identify another supplier of KLH, or produce KLH ourselves, we will not be able to use the alternative source of KLH for the commercial manufacture of MyVax unless the KLH is found to be comparable to the existing KLH. Any inability to obtain a sufficient supply of KLH of suitable quality from biosyn or an alternate supplier, or produce such KLH ourselves, could delay completion of our clinical trials and commercialization of MyVax.

In addition, we currently purchase specialized cell culture containers, which are critical components of our manufacturing process, from Medtronic, Inc., a single source supplier. We do not have a long-term contract with Medtronic and rely on purchase orders to obtain the necessary cell culture containers. To date, Medtronic has met our requirements for our clinical trials. There are, in general, few alternative sources of supply for the cell culture containers.

Administration of MyVax requires an adjuvant to enhance the immune response. We use Leukine sargramostim, a commercially available recombinant human granulocyte-macrophage colony stimulating factor known as GM-CSF, as an adjuvant for MyVax. An adjuvant is a substance that is administered with an antigen to enhance or increase the immune response to that antigen. We currently rely on purchase orders to

purchase GM-CSF from Berlex Laboratories, Inc. We do not have a long-term contract with Berlex. GM-CSF is not commercially available from other sources in the United States or Canada.

Establishing additional or replacement suppliers for these materials or components may take a substantial amount of time. In addition, we may have difficulty obtaining similar materials from other suppliers that are acceptable to the FDA. If we have to switch to a replacement supplier, we may face additional regulatory delays and the manufacture and delivery of MyVax, or any other immunotherapies that we may develop, could be interrupted for an extended period of time, which may delay completion of our clinical trials or commercialization of MyVax, or any other immunotherapies that we may develop. If we are unable to obtain adequate amounts of these materials, our clinical trials will be delayed. In addition, we will be required to obtain regulatory clearance from the FDA to use different materials that may not be as safe or as effective. As a result, regulatory approval of MyVax may not be received at all.

*Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.*

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of MyVax, or any other immunotherapies that we may develop, and the methods we employ to manufacture them, as well as successfully defending these patents against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

As of December 31, 2004, we held two United States patents covering our core gene amplification technology, including composition of matter claims directed to cell lines and claims directed to methods of making proteins derived from patients' tumors. These patents expire in 2016.

Corresponding patents, although more constrained in scope due to rules not applicable in the United States, have been issued in South Africa, Canada and Australia, all of which expire in 2017. We have also filed additional United States and corresponding foreign patent applications relating to our Hi-GET gene amplification technology. We expect to continue to file additional patent applications.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States. The biotechnology patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that none of our pending patent applications will result in issued patents;
- our issued patents may not provide a basis for commercially-viable active immunotherapies, or may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

***We will need to increase the size of our organization, and we may experience difficulties in managing growth.***

In order to continue our clinical trials and commercialize MyVax, or any other immunotherapies that we may develop, we will need to expand our employee base for managerial, operational, financial and other resources. We anticipate that we will need more than 350 employees by the time MyVax is initially commercialized. We do not expect to be able to commercially launch MyVax until 2006, at the earliest. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize MyVax, or any other immunotherapies that we may develop, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage our research and development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- develop our administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

***We may experience difficulties in manufacturing MyVax, or any other immunotherapy that we may develop, which could prevent us from completing our clinical trials and delay the commercialization of MyVax, or any other immunotherapies that we may develop.***

Manufacturing MyVax is a complex multi-step process that requires us to expend significant time, money and effort on production, record keeping and quality control systems to assure that MyVax will meet product specifications and other regulatory requirements. In addition, manufacturing MyVax requires coordination internally among our employees as well as externally with physicians, hospitals and third-party suppliers and carriers. This process involves several risks that may lead to failures or delays in manufacturing MyVax, including:

- failure to obtain a sufficient supply of key raw materials of suitable quality;
- difficulties in manufacturing MyVax for multiple patients simultaneously;
- difficulties in obtaining adequate tumor samples from physicians;
- difficulties in the timely shipping of tumor samples to us or in the shipping of MyVax to the treating physicians due to errors by third-party carriers, transportation restrictions or other reasons;
- difficulties in completing the development and validation of the specialized assays required to ensure the consistency of MyVax;
- failure to ensure adequate quality control and assurances in the manufacturing process as we increase the production quantities of MyVax;
- destruction of, or damage to, tumor samples or MyVax during the shipping process due to improper handling by third-party carriers, hospitals, physicians or us;

- destruction of, or damage to, tumor samples or MyVax during storage at our facility;
- difficulties in establishing and effectively operating a commercial-scale manufacturing facility;
- failure to comply with, or significant changes in, regulatory requirements, such as FDA regulations and environmental laws;
- damage to or destruction of our manufacturing facility or equipment;
- shortages of qualified personnel; and
- difficulties in ensuring the quality and consistency of materials and services provided by our suppliers.

If we experience any difficulties in manufacturing MyVax, or any other immunotherapies that we may develop, our ongoing clinical trials may be delayed and commercialization of MyVax, or any other immunotherapies that we may develop, may be delayed.

*We rely on the availability and condition of our sole manufacturing facility in Redwood City, California. If we are not able to renew the subleases or if the facility is damaged or destroyed, then our ability to manufacture products will be significantly affected and we will be delayed or prevented from completing our clinical trials and commercializing MyVax, or any other immunotherapies that we may develop.*

We currently rely on the availability and condition of our sole manufacturing facility, located in Redwood City, California, to manufacture MyVax. Our facility is located in a seismic zone, and there is the possibility of an earthquake which, depending on its magnitude, could be disruptive to our operations. Our subleases for this facility expire as early as May 2006 and as late as November 2006, and because we have no options to extend the terms of these subleases, we may not be able to negotiate new subleases for this facility. In addition, if the facility or the equipment in the facility is significantly damaged or destroyed for any reason, we will not be able to quickly or inexpensively replace our manufacturing capacity. The inability to renew the subleases or the damage or destruction of the facility would significantly affect our ability to manufacture MyVax, or any other immunotherapies that we may develop, and would delay or prevent us from completing our clinical trials and commercializing MyVax, or any other immunotherapies that we may develop.

*If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.*

Our ability to commercialize MyVax, or any other immunotherapies that we may develop, depends upon our ability to develop, manufacture, market and sell MyVax, or any other immunotherapies that we may develop, without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general field of immunotherapy and gene expression. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that MyVax, or any other immunotherapies that we may develop, may infringe. There could also be existing patents of which we are not aware that MyVax, or any other immunotherapies that we may develop, may inadvertently infringe.

In particular, we are aware of patents held jointly by Genentech, Inc. and City of Hope National Medical Center relating to expression of recombinant antibodies, by British Technology Group PLC relating to expression of recombinant proteins in mammalian cells, by the Board of Trustees of the Leland Stanford Junior University relating to expression of recombinant antibodies and by Stratagene relating to generation of DNA that encodes antibodies. To date, we have elected not to seek licenses for these patents because, among other reasons, we believe that our pre-commercialization activities fall within the scope of an available exemption. In addition, we do not believe that we will be required to seek any licenses upon completion of our pre-commercialization activities. For more information, please refer to the section in this annual report entitled "Business — Intellectual Property". We may be exposed to future litigation by the companies holding

these patents or other third parties based on claims that MyVax, or any other immunotherapies that we may develop, or the methods we employ to manufacture them, infringe their intellectual property rights. Our ability to manufacture and commercialize MyVax, or any other immunotherapies that we may develop, may depend on our ability to demonstrate that MyVax, or any other immunotherapies that we may develop, and our manufacturing processes do not infringe third-party patents. If these patents were found to cover MyVax, or any other immunotherapies that we may develop, or our manufacturing process, we could be required to pay damages and could be unable to commercialize MyVax, or any other immunotherapies that we may develop, unless we obtained a license. A license may not be available to us on acceptable terms in the future, if at all.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it is not required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our process so it does not infringe which may not be possible or could require substantial funds and time.

***We are not able to prevent others, including potential competitors, from using the patient-specific idiotype protein- keyhole limpet hemocyanin, or KLH, conjugate, comprising a single idiotype protein, that we use in our lead product candidate, MyVax, for the treatment of indolent B-cell NHL.***

The patient-specific idiotype-KLH conjugate, comprising a single idiotype protein, and its use for the treatment of indolent B-cell NHL is in the public domain and therefore cannot be patented. Consequently, we are only able to receive patent protection for our amplified cell lines and the process we use to manufacture the tumor-derived idiotype protein used in MyVax. As a result, we cannot prevent other companies using different manufacturing processes from developing active immunotherapies that directly compete with MyVax.

***We are subject to extensive regulation, which can be costly and time consuming and could subject us to unanticipated delays or prevent us from obtaining the required approvals to commercialize MyVax, or any other immunotherapies that we may develop.***

MyVax and any other immunotherapies that we may develop, clinical trials and manufacturing activities are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. The process of obtaining these approvals is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change. In addition, patient-specific active immunotherapies are complex, and regulatory agencies lack experience with them, which may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our lead product candidate, MyVax, or any other immunotherapies that we may develop. The FDA has not approved the marketing of any immunotherapeutic drug based on a patient-specific active immunotherapy. Consequently, there is no precedent for the successful commercialization of a patient-specific active idiotype immunotherapeutic drug. In addition, we have not previously filed the marketing applications necessary to gain regulatory approvals. This lack of experience may impede our ability to obtain timely FDA approval, if at all. We will not be able to commercialize MyVax, or any other immunotherapies that we may develop, until we obtain FDA approval in the United States or approval by comparable authorities in other countries. We do not expect to receive regulatory approval for the commercial sale of MyVax until 2006, at the earliest. Any delay in obtaining, or

inability to obtain, FDA approval would prevent us from commercializing MyVax, or any other immunotherapies that we may develop.

*Even if MyVax, or any other immunotherapies that we may develop, receives regulatory approval, we may still face development and regulatory difficulties relating to MyVax, or any other immunotherapies that we may develop, in the future.*

If we receive regulatory approval to sell MyVax, or any other immunotherapies that we may develop, the FDA and foreign regulatory authorities may, nevertheless, impose significant restrictions on the indicated uses or marketing of MyVax, or any other immunotherapies that we may develop, or impose ongoing requirements for post-approval studies. In addition, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If we discover previously unknown problems with a product or our manufacturing and laboratory facility, a regulatory agency may impose restrictions on that product or on us, including requiring us to withdraw the product from the market. We will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend our regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations, including closing our facility; or
- seize or detain products or require a product recall.

*Obtaining regulatory approval of our manufacturing facility or disruptions in our manufacturing process may delay or disrupt our commercialization efforts.*

Before we can begin to commercially manufacture MyVax, we must obtain regulatory approval from the FDA for our manufacturing facility and process. In addition, we must pass a pre-approval inspection of our manufacturing facility by the FDA before MyVax can obtain marketing approval. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with the current Good Manufacturing Practices, or cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers are found to be out of compliance with cGMP, we may experience delays or disruptions in the manufacturing of MyVax while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. We have undertaken steps towards achieving compliance with these regulatory requirements required for commercialization. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell MyVax, or any other immunotherapies that we may develop.

We are currently manufacturing the necessary quantities of MyVax for our clinical trials at our existing facility in Redwood City, California. Our manufacturing facility is currently subject to licensing requirements of the California Department of Health Services, and we received this license during the second quarter of 2004. Our facility is subject to inspection by the FDA as well as by the California Department of Health Services at any time. Failure to maintain our license from the California Department of Health Services or to meet the inspection criteria of the FDA and the California Department of Health Services would disrupt our manufacturing processes and would harm our business. If an inspection by the FDA, California Department of Health Services or foreign regulatory authorities indicates that there are deficiencies, we could be required to take remedial actions, or our facility may be closed.

In order to commercialize MyVax, or any other immunotherapies that we may develop, we will need to construct and qualify a commercial scale manufacturing facility. Preparing a facility for commercial manufacturing may involve unanticipated delays and the costs of complying with FDA regulations may be higher than we anticipated. In addition, any material changes we make to the manufacturing process may require approval by the FDA and state or foreign regulatory authorities. Obtaining these approvals is a lengthy, involved process, and we may experience delays. Such delays could increase costs and adversely affect our business.

***Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders or require us to relinquish rights to our technologies, MyVax or any other immunotherapies that we may develop.***

We may raise additional funds through public or private equity offerings, debt financings, corporate collaboration or licensing arrangements or other arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies, MyVax or any other immunotherapies that we may develop, or grant licenses on terms that are not favorable to us.

***Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.***

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence and continue a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective sites, delays in obtaining institutional review board approval to conduct a study at a prospective site and delays in recruiting patients to participate in a study.

In addition, we typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of such clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not perform their obligations in a timely fashion. If we have significant delays in testing or regulatory approvals, our financial results and the commercial prospects for MyVax, or any other immunotherapies that we may develop, will be harmed, our costs could increase and our ability to generate revenue could be delayed.

***The commercial success of MyVax, or any other immunotherapies that we may develop, will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community.***

MyVax, or any other immunotherapies that we may develop, may not gain market acceptance among physicians, patients, health care payors and the medical community. The degree of market acceptance of any approved immunotherapies will depend on a number of factors, including:

- market acceptance of patient-specific active immunotherapies;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- ability to produce an active immunotherapy at a competitive price;
- relative convenience and ease of administration;
- publicity concerning our products or competitive products;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If MyVax, or any other immunotherapies that we may develop, are approved but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenue and we may not become profitable.

***If we are unable to obtain acceptable prices or adequate reimbursement from third-party payors for MyVax, or any other immunotherapies that we may develop, our revenues and prospects for profitability will suffer.***

Our ability to commercialize MyVax, or any other immunotherapies that we may develop, is highly dependent on the extent to which coverage and reimbursement for MyVax, or any other immunotherapies that we may develop, will be available from:

- governmental payors, such as Medicare and Medicaid;
- private health insurers, including managed care organizations; and
- other third-party payors.

Many patients will not be capable of paying for MyVax, or any other immunotherapies that we may develop, themselves and will rely on third-party payors to pay for their medical needs. A primary current trend in the United States health care industry is toward cost containment. Large private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly approved health care products. In particular, third-party payors may limit the indications for which they will reimburse patients who use MyVax, or any other immunotherapies that we may develop. On December 8, 2003, President Bush signed into law the Medicare Prescription Drug Improvement and Modernization Act of 2003. We have not determined the full impact of this new law on our business; however, we believe that legislation that could limit reimbursement for MyVax, or any other immunotherapies that we may develop, could adversely impact how much or under what circumstances healthcare providers would prescribe or administer our products, and could decrease the price we might establish for MyVax, or any other immunotherapies that we may develop, which would result in lower product revenues. Other cost-control initiatives could also decrease the price we might establish for MyVax, or any other immunotherapies that we may develop, which would also result in lower product revenues. If governmental and other third-party payors do not provide adequate coverage and reimbursement levels for MyVax, or any other immunotherapies that we may develop, our revenue and prospects for profitability will suffer.

***If our competitors are better able to develop and market products that are more effective than MyVax, or any other immunotherapies that we may develop, our commercial opportunity will be reduced or eliminated.***

We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Various products are currently marketed for the treatment of NHL, and a number of companies are developing new treatments. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than MyVax, or any other immunotherapies that we may develop. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully and rapidly complete clinical trials and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our manufacturing process and other technology;
- attract and retain key personnel; and
- build an adequate sales and marketing infrastructure for MyVax.

Several companies, such as Corixa Corporation, Biogen Idec Inc. and Immunomedics, Inc., are involved in the development of passive immunotherapies for the treatment of NHL. Various products are currently marketed for treatment of NHL. Rituxan, a passive immunotherapy co-marketed by Genentech, Inc. and Biogen Idec Inc., is approved for the treatment of relapsed or refractory, low grade B-cell NHL. In addition, Biogen Idec Inc. has received FDA approval for marketing its passive radioimmunotherapy product, Zevalin, and GlaxoSmithKline Plc and Corixa Corporation received FDA approval for marketing their version of passive radioimmunotherapy product, Bexxar, for the treatment of relapsed or refractory low grade, follicular, or transformed B-cell NHL. For more information, please refer to the section entitled "Business — MyVax Personalized Immunotherapy" in this annual report.

In addition, there are several companies focusing on the development of active immunotherapies for the treatment of NHL, including Antigenics, Inc., Favrilite, Inc. and Large Scale Biology Corporation. We are aware that the National Cancer Institute, or NCI, in collaboration with Biovest International, Inc., is currently conducting a Phase 3 clinical trial of active immunotherapy in patients with follicular NHL. If any are successfully developed and approved, they could compete directly with MyVax, if it is approved. In addition, researchers are continually learning more about NHL and other forms of cancer, and new discoveries may lead to new technologies for treatment. As a result, MyVax, or any other immunotherapies that we may develop, may be rendered obsolete and noncompetitive at any time.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

***Our efforts to discover, develop and commercialize MyVax for indications other than follicular B-cell NHL are at an early stage and are subject to high risk of failure.***

The process of successfully developing product candidates is very time-consuming, expensive and unpredictable. We have recently begun to direct our efforts toward the development of MyVax for indications other than follicular B-cell NHL. We do not know whether our planned clinical trials for MyVax in indications other than follicular B-cell NHL will begin on time or be completed on schedule, if at all. In addition, we do not know whether these clinical trials will result in marketable products. Typically, there is a high rate of attrition for product candidates in clinical trials. We do not anticipate that MyVax for indications other than follicular B-cell NHL will reach the market for at least several years, if at all.

***If we are unable to establish sales and marketing capabilities or enter into agreements with companies to sell and market MyVax, we may be unable to generate product revenue.***

We do not have a sales organization and have no experience as a company in the sales, marketing and distribution of pharmaceutical products. In order to commercialize any products, we must develop our sales, marketing and distribution capabilities or make arrangements with a third party to perform these services. If MyVax is approved for commercial sale, we currently plan to establish our own sales force to market it in the United States. Developing a sales force is expensive and time consuming and could delay any product launch. We cannot be certain that we would be able to develop this capacity. If we are unable to establish our sales and marketing capability, we will need to contract with third parties to market and sell MyVax in the United States. We will also need to develop a plan to market and sell MyVax outside the United States. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues are likely to be lower than if we directly marketed and sold MyVax, or any other

immunotherapies that we may develop. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

***If product liability lawsuits are successfully brought against us, we will incur substantial liabilities and may be required to limit commercialization of MyVax, or any other immunotherapies that we may develop.***

We face an inherent risk of product liability exposure related to the testing of MyVax, or any other immunotherapies that we may develop, in human clinical trials and will face an even greater risk if we sell MyVax, or any other immunotherapies that we may develop, commercially. Currently, we are not aware of any historical or anticipated product liability claims. In the future, an individual may bring a liability claim against us if MyVax, or any other immunotherapies that we may develop, causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for MyVax, or any other immunotherapies that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients;
- loss of revenues; and
- the inability to commercialize MyVax, or any other immunotherapies that we may develop.

We have product liability insurance that covers our clinical trials up to a \$3.0 million annual aggregate limit. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for MyVax, or any other immunotherapies that we may develop. We believe that our current insurance coverage is adequate. However, insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise.

***We may incur significant costs complying with environmental laws and regulations.***

We use hazardous materials that could be dangerous to human health, safety or the environment. As appropriate, we store these materials and various wastes resulting from their use at our facility pending ultimate use and disposal. We currently contract with a third party to dispose of these materials and various wastes resulting from the use of such materials at our facility. We are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these materials and wastes resulting from the use of such materials. While our costs for compliance, including costs related to the disposal of hazardous materials, to date have been nominal, we may incur significant costs complying with both existing and future environmental laws and regulations. We are subject to regulation by the Occupational Safety and Health Administration, or OSHA, the California and federal environmental protection agencies and to regulation under the Toxic Substances Control Act. OSHA or the California or federal Environmental Protection Agency, may adopt regulations that may affect our research and development programs. We are unable to predict whether any agency will adopt any regulations that could have a material adverse effect on our operations.

***If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.***

Our research and development and manufacturing activities involve the use of biological and hazardous materials that could be dangerous to human health, safety or the environment. Even if our safety procedures

for handling, storage and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages. We have general liability insurance of up to \$3.0 million per occurrence. We believe our current insurance coverage is adequate. However, this insurance may not cover a claim that arises if it is related to our biological or hazardous materials. However, if we were to be held liable for an accident involving our biological or hazardous materials, this liability could exceed our insurance coverage and our other financial resources.

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop MyVax, or any other immunotherapies that we may develop, conduct our clinical trials and commercialize MyVax, or any other immunotherapies that we may develop.***

Our success depends on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. We are highly dependent upon our senior management and scientific staff, particularly Dan W. Denney, Jr., our founder, Chairman and Chief Executive Officer. The loss of services of Dr. Denney or one or more of our other members of senior management could delay or prevent the successful completion of our pivotal Phase 3 clinical trial or the commercialization of MyVax. Currently, we do not have employment agreements with any members of senior management. As of December 31, 2004, Dr. Denney owned 1,216,900 shares of our common stock that were not subject to any vesting and options to purchase 225,000 shares of our common stock, of which approximately 43,748 shares were vested. We do not carry "key person" insurance covering members of senior management other than Dr. Denney. The insurance covering Dr. Denney is in the amount of \$10.0 million.

The competition for qualified personnel in the biotechnology field is intense. In particular, our ability to deliver patient therapies depends on our ability to attract and retain quality assurance and control personnel. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities. We are not aware of any key personnel planning to retire or leave us in the near future.

### **Other Risks**

***Our stock price may be volatile, and your investment in our stock could decline in value.***

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or non-approval of MyVax, or any other immunotherapies that we may develop, or delays in the FDA review process;
- actions taken by regulatory agencies with respect to MyVax, or any other immunotherapies that we may develop, clinical trials, manufacturing process or sales and marketing activities;
- regulatory developments in the United States and foreign countries;
- the success of our research efforts and clinical trials;
- any intellectual property infringement lawsuit involving us;
- announcements concerning our competitors, or the biotechnology or biopharmaceutical industries in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- sales of large blocks of our common stock;

- sales of our common stock by our executive officers, directors and significant stockholders;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In particular, you may not be able to resell your shares at or above your purchase price. The stock markets in general, and the markets for biotechnology stocks in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which would hurt our business, operating results and financial condition.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our bylaws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include a classified board of directors and a prohibition on actions by our stockholders by written consent. In addition, our Board of Directors has the right to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us in certain circumstances. Finally, these provisions establish advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings. Although we believe these provisions together provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders.

***The ownership interests of our officers, directors and largest stockholders could conflict with the interests of our other stockholders.***

As of December 31, 2004, our officers, directors and holders of 5% or more of our outstanding common stock beneficially owned approximately 31.6% of our common stock (assuming no exercise of outstanding options or warrants). As a result, these stockholders, acting together, are able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of this group of stockholders may not always coincide with our interests or the interests of other stockholders.

***Future sales of our common stock could lower the market price of our common stock.***

Sales of substantial amounts of shares in the public market could harm the market price of our common stock. As of December 31, 2004, 28,191,145 shares of our common stock were outstanding. Each of our directors and executive officers and certain of our stockholders, which directors, executive officers and stockholders held in the aggregate approximately 15% of our outstanding common stock as of December 31, 2004, have agreed, subject to specified exceptions, that without the prior written consent of WR Hambrecht + Co, they will not, directly or indirectly, (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of any shares of our common stock or any securities

convertible into or exercisable or exchangeable for our common stock (including without limitation, common stock which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations of the Securities and Exchange Commission and securities which may be issued upon exercise of a stock option or warrant), or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock for the period ending on March 23, 2005. WR Hambrecht + Co, may, in its sole discretion, permit early release of shares subject to the lock-up agreements. All of the shares of our common stock that were outstanding as of December 31, 2004, are eligible for sale in the public market under Rules 144, 144(k) and 701, subject in some cases to volume and other limitations and the 90-day lock-up agreements described above. In addition, of the 1,577,173 shares issuable upon exercise of options to purchase our common stock outstanding as of December 31, 2004, approximately 395,841 shares were vested and eligible for sale as of December 31, 2004. In addition, if we propose to register any of our securities under the Securities Act of 1933, as amended, either for our own account or for the accounts of other security holders, subject to certain conditions and limitations, the holders of registration rights will be entitled to include their shares of common stock. In addition, holders of registration rights may require us on not more than two occasions at any time to file a registration statement under the Securities Act with respect to their shares of common stock. Further, the holders of registration rights may require us to register their shares on Form S-3. These rights shall terminate altogether three years after the effective date of our initial public offering, and, with respect to each holder of such rights, on the date when such holder holds less than 1% of our outstanding shares of common stock and is able to sell all of its shares pursuant to Rule 144 under the Securities Act in any 90-day period. These registration rights are subject to certain conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. In the future, we may also issue additional shares to our employees, directors or consultants, in connection with corporate alliances or acquisitions, and issue additional shares in follow-on offerings to raise additional capital. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time. Such sales could reduce the market price of our common stock.

***We will need to implement additional finance and accounting systems, procedures and controls as we grow our business and organization and to satisfy new reporting requirements.***

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 and other requirements will increase our costs and require additional management resources. We may need to continue to implement additional finance and accounting systems, procedures and controls to satisfy new reporting requirements. Compliance with Section 404 will first apply to this annual report. While we are able to complete a favorable assessment as to the adequacy of our internal control reporting for our fiscal year ending December 31, 2004, there is no assurance that we will be able to complete future favorable assessments as to the adequacy of our internal control reporting.

***The adoption of Statement of Financial Accounting Standard No. 123R and changes to existing accounting pronouncements or taxation rules or practices may affect how we conduct our business and affect our reported results of operations.***

On December 16, 2004, the Financial Accounting Standards Board adopted Statement of Financial Accounting Standard No. 123R, "Share Based Payment — An Amendment of FASB Statements No. 123 and 95," ("SFAS 123R") which will require us, starting in the third quarter of fiscal year 2005, to measure compensation costs for all stock-based compensation (including stock options and our employee stock purchase plan, as currently constructed) at fair value and record compensation expense in our statement of operations. SFAS 123R is effective for public companies in periods beginning after June 15, 2005. The cumulative effect of adoption, if any, applied on a prospective basis, would be measured and recognized on July 1, 2005. The adoption of SFAS 123R and other potential changes could materially impact our results of operations. Also, a change in accounting pronouncements or taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is

effective. Other new accounting pronouncements or taxation rules and varying interpretations of accounting pronouncements or taxation practice have occurred and may occur in the future. Changes to existing rules, future changes, if any, or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

**ITEM 2. PROPERTIES**

We sublease 13,426 square feet of laboratory and production space in Redwood City, California, under lease agreements that terminate in May and November 2006, respectively. In the same facility, we also lease an additional 18,512 square feet of corporate office space under a lease agreement that we entered into on March 10, 2005 with Metropolitan Life Insurance Company which terminates in July 2006. We also have a sublease for 14,842 square feet of laboratory space in Foster City, California which terminates in January 2006. We believe that our facilities will be sufficient for the production of active immunotherapies for our planned clinical trials. We plan to build a new manufacturing facility for the commercialization of MyVax and any other immunotherapies that we may develop. We anticipate completion of the construction of a commercial manufacturing facility in 2006. Unless we are able to renew our existing leases, we may need to find temporary facilities until our new facility can be completed.

**ITEM 3. LEGAL PROCEEDINGS**

None.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of our stockholders, through solicitation of proxies or otherwise, during the fourth quarter of fiscal year 2004.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER REPURCHASES OF EQUITY SECURITIES.**

Our common stock has traded on the Nasdaq National Market under the symbol "GTOP" since October 30, 2003. The following table sets forth, for the period indicated, the high and low closing sales prices for our common stock as reported by the Nasdaq National Market:

	Common Stock Price	
	High	Low
Quarter ended December 31, 2003 (commencing October 30, 2003) . . . . .	\$14.50	\$ 9.18
First Quarter 2004 . . . . .	12.89	9.00
Second Quarter 2004 . . . . .	11.31	7.81
Third Quarter 2004 . . . . .	10.30	8.51
Fourth Quarter 2004 . . . . .	17.20	9.50

**Holders**

As of February 28, 2005, there were approximately 354 stockholders of record of Genitope common stock.

## Dividends

Since inception, we have not paid dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and currently do not plan to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

## Use of Proceeds

The Securities and Exchange Commission declared our first registration statement, filed on Form S-1 (SEC File No. 333-107719) under the Securities Act in connection with the initial public offering of our common stock, effective on October 29, 2003, covering an aggregate of 4,179,860 shares of common stock, including shares that were issued upon the partial exercise by the underwriters of their over-allotment option. The aggregate gross proceeds from the shares of common stock sold were approximately \$37,619,000. In connection with the offering, we paid the underwriters a commission of approximately \$2,633,000 and incurred offering expenses of \$1,251,000. After deducting the underwriters' commission and the estimated offering expenses, we received net proceeds of approximately \$33,735,000 from the offering.

From the time of receipt through December 31, 2004, we have applied the net proceeds from the offering as follows:

	<u>(Estimations, in thousands)</u>
Capital Expenditures .....	\$ 805
Operating Activities .....	28,681

We plan to use the balance of such proceeds of the initial public offering to fund expenses related to the manufacturing and potential commercialization of MyVax, clinical trials and other research, sales and marketing and for other general corporate purposes. We may also use a portion of the net proceeds from the offering to acquire products, technologies or businesses related to immunotherapies for cancer or a related field, although no acquisitions are currently planned or being negotiated and we have not allocated any portion of the net proceeds for any specific acquisition. None of the net proceeds of the initial public offering were paid directly or indirectly to any of our directors, officers, or their associates, persons or entities owning 10% or more of any class of our equity securities, affiliates or others (other than salaries to officers arising out of normal operating activities). We expect that our use of proceeds from the offering will conform to the intended use of proceeds as described in our initial public offering prospectus dated October 29, 2003.

## ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below are derived from our financial statements. The statement of operations data for the years ended December 31, 2004, 2003 and 2002, and the balance sheet data as of December 31, 2004 and 2003 are derived from our audited financial statements included elsewhere in this Form 10-K. The statement of operations data for the years ended December 31, 2001 and 2000, and the balance sheet data as of December 31, 2002, 2001 and 2000 are derived from our audited financial statements not included in this Form 10-K. The historical results are not necessarily indicative of results to be expected for any future period. The data presented below has been derived from financial statements that have been prepared in accordance with accounting principles generally accepted in the United States of America and should be read with our financial statements, including the accompanying Notes to the Financial Statements, and with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Form 10-K.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands, except per share data)				
<b>Statement of Operations Data:</b>					
Operating expenses:					
Research and development(1) .....	\$ 22,571	\$ 19,678	\$ 15,915	\$ 8,791	\$ 3,993
Sales and marketing(1) .....	1,793	1,591	1,338	—	—
General and administrative(1) .....	3,356	2,937	2,832	1,463	634
Total operating expenses .....	<u>27,720</u>	<u>24,206</u>	<u>20,085</u>	<u>10,254</u>	<u>4,627</u>
Loss from operations .....	(27,720)	(24,206)	(20,085)	(10,254)	(4,627)
Loss on extinguishment of convertible notes and cancellation of Series E convertible preferred stock warrants .....	—	(3,509)	—	—	—
Interest expense .....	(4)	(2,845)	—	—	—
Interest and other income, net .....	698	97	221	474	782
Net loss .....	(27,026)	(30,463)	(19,864)	(9,780)	(3,845)
Dividend related to issuance of convertible preferred shares and the beneficial conversion feature of preferred stock .....	—	(18,407)	—	—	—
Net loss attributable to common stockholders..	<u>\$(27,026)</u>	<u>\$(48,870)</u>	<u>\$(19,864)</u>	<u>\$(9,780)</u>	<u>\$(3,845)</u>
Basic and diluted net loss per share attributable to common stockholders.....	<u>\$ (1.31)</u>	<u>\$ (11.86)</u>	<u>\$ (11.62)</u>	<u>\$ (6.58)</u>	<u>\$ (2.78)</u>
Shares used in computing basic and diluted net loss attributable to common stockholders....	<u>20,683</u>	<u>4,122</u>	<u>1,710</u>	<u>1,487</u>	<u>1,385</u>

(1) Includes non-cash stock-based compensation of the following:

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
Research and development .....	\$627	\$1,046	\$ 589	\$181	\$—
Sales and marketing .....	143	176	141	—	—
General and administrative .....	210	679	635	257	20
Total .....	<u>\$980</u>	<u>\$1,901</u>	<u>\$1,365</u>	<u>\$438</u>	<u>\$20</u>

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities .....	\$ 116,509	\$ 29,790	\$ 9,422	\$ 6,080	\$17,033
Working capital .....	113,989	26,590	7,929	4,918	16,687
Total assets .....	119,865	32,352	11,986	9,396	17,474
Convertible preferred stock .....	—	—	46,853	26,151	26,151
Deficit accumulated during development stage .....	(114,789)	(87,763)	(38,893)	(19,029)	(9,249)
Total stockholders' equity (deficit) .....	116,196	28,742	(36,414)	(18,094)	(9,025)

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of the financial condition and results of operations should be read in conjunction with our financial statements and notes to those statements included elsewhere in this Form 10-K.*

### Overview

We are a biotechnology company focused on the research and development of novel immunotherapies for the treatment of cancer. Immunotherapies are treatments that utilize the immune system to combat diseases. Our lead product candidate, MyVax® personalized immunotherapy, is a patient-specific active immunotherapy that is based on the unique genetic makeup of a patient's tumor and is designed to activate a patient's immune system to identify and attack cancer cells. MyVax is currently in a pivotal Phase 3 clinical trial and additional Phase 2 clinical trials for the treatment of B-cell non-Hodgkin's lymphoma, or B-cell NHL. B-cells, also called B lymphocytes, are one of the two major classes of lymphocytes, which are types of white blood cells. In the United States, B-cell NHL represents approximately 85% to 90% of over 300,000 existing and approximately 55,000 newly diagnosed NHL patients each year. NHL is clinically classified as either slow-growing, referred to as indolent, or fast-growing, referred to as aggressive. There are approximately 25,000 patients diagnosed with indolent B-cell NHL in the United States each year. Our pivotal Phase 3 clinical trial is for the treatment of follicular B-cell NHL, which represents approximately half of the cases of indolent B-cell NHL. Results from our completed and ongoing clinical trials of MyVax for the treatment of B-cell NHL indicate that MyVax is generally safe and well tolerated. We believe that patient-specific active immunotherapies can also be applied successfully to the treatment of other cancers. As a result, we are also developing MyVax for the treatment of chronic lymphocytic leukemia, or CLL.

In November 2000, based on positive interim Phase 2 clinical trial results from our 9901 trial, we initiated a pivotal, double-blind, controlled Phase 3 clinical trial, our 2000#03 trial, to treat patients with follicular B-cell NHL. We believe that, if successful, the results of the trial will support our application for regulatory approval of MyVax for the treatment of follicular B-cell NHL. We completed patient registration, the process during which a patient is screened and a biopsy is taken to determine whether the patient is eligible to participate in the clinical trial, in April 2004. Our independent Data Safety Monitoring Board, or DSMB met on November 15, 2004 to review data in the clinical trial. After reviewing safety data for the entire Phase 3 clinical trial and blinded, preliminary immune response data for more than 100 of the initial patients immunized in the clinical trial, the DSMB noted no concerns and recommended that the trial continue as planned. We currently anticipate that the two planned interim analyses will be initiated in approximately the second quarter of 2005 and the second quarter of 2006, with the detailed follow-up period of the clinical trial scheduled to conclude in approximately the fourth quarter of 2007. The total research and development costs associated with and incurred for the development of MyVax for the treatment of B-cell NHL were \$22.6 million, \$19.7 million and \$15.9 million for the years ended December 31, 2004, 2003 and 2002, respectively. From inception through December 31, 2004, the total research and development costs associated

with and incurred for the development of MyVax for the treatment of B-cell NHL were approximately \$75.1 million.

We have not generated any revenues, and we have financed our operations and internal growth through private placements of common and preferred stock, including our recent private placement of common stock in December 2004, our line of credit facilities, our completed initial public offering in November 2003, our completed follow-on public offering in June 2004, and interest income earned from our cash, cash equivalents and marketable securities. We are a development stage enterprise and have incurred significant losses since our inception in 1996 as we have devoted substantially all of our efforts to research and development activities, including clinical trials. As of December 31, 2004, we had an accumulated deficit of \$114.8 million. Our accumulated deficit resulted principally from our research and development activities associated with MyVax, including our pivotal Phase 3 clinical trial and additional Phase 2 clinical trials, and several non-cash charges associated with our preferred stock financings. Our accumulated deficit includes a non-cash dividend of \$18.4 million related to our preferred stock financings in April and May of 2003, a non-cash charge of \$3.5 million associated with the extinguishment of convertible notes and cancellation of the related warrants issued to preferred stockholders in August 2003 and non-cash interest expense of \$0.8 million relating to the amortization of the discount on the convertible notes, and non-cash interest expense of \$1.9 million associated with the amortization of the warrants issued to the guarantor of our lines of credit. We have repaid all outstanding borrowings under these facilities, and in November 2003, we terminated both facilities. As of December 31, 2004, we had cash, cash equivalents and marketable securities of \$116.5 million.

We anticipate working on a number of long-term development projects which will involve experimental and unproven technology. The projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. We will need operating funds to continue our research and development activities, clinical trials, pursue regulatory approvals and build production, sales and marketing capabilities, as necessary.

Even if we achieve positive interim results in our pivotal Phase 3 clinical trial and receive regulatory approval for MyVax, including regulatory approval of a commercial scale manufacturing facility, we anticipate that the earliest we could realize product revenue is 2006. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or our commercialization efforts. Any additional equity financing may be dilutive to stockholders, and any additional debt financing, if available, may involve restrictive covenants.

Drug development in the United States is a process that includes several steps defined by the Food and Drug Administration, or FDA. The FDA approval process for a new biologic or drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, a New Drug application, or NDA, or a Biologics License application, or BLA, may be filed with the FDA. In responding to an NDA or a BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

The successful development of our drug candidates is highly uncertain. We cannot estimate with certainty or know the exact nature, timing and estimated costs of the efforts necessary to complete the development of MyVax or the date of completion of these development efforts. We anticipate that the earliest we could realize product revenues is 2006 and we cannot reasonably estimate when we may have material net

cash inflows from sales of MyVax, if ever. We cannot estimate with certainty any of the foregoing due to the numerous risks and uncertainties associated with developing MyVax, including:

- the possibility of delays in the collection of clinical trial data and the uncertainty of the timing of the interim analyses of our pivotal Phase 3 clinical trial;
- the uncertainty of clinical trial results;
- extensive governmental regulation, both foreign and domestic, for approval of new therapies; and
- the uncertainty related to the leasing and completion of construction and qualification of a commercial scale manufacturing facility.

If we fail to complete the development of MyVax in a timely manner, it could have a material adverse effect on our operations, financial position and liquidity. In addition, any failure by us to obtain, or any delay in obtaining, regulatory approvals could have a material adverse effect on our results of operations.

A further discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and certain consequences of failing to do so are set forth in the risk factors entitled *"We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts," "We currently have no source of revenue and may never become profitable," "If clinical trials of MyVax, or any other immunotherapies that we may develop, do not produce successful clinical trial results, we will be unable to commercialize these products"* and *"Our efforts to discover, develop and commercialize MyVax for indications other than follicular B-cell NHL are at an early stage and are subject to high risk of failure,"* as well as other risk factors. We expect to continue to incur net losses over the next several years as we continue our clinical development, apply for regulatory approvals, construct and qualify a commercial scale facility for the manufacture of MyVax, develop active immunotherapies for CLL and T-cell NHL and potentially other forms of cancer, establish sales and marketing and distribution capabilities and expand our operations.

### ***Significant Financing Events***

Since 1996, we have been successful in completing several rounds of private equity financing. In 2002, the sale of Series E convertible preferred stock generated \$20.7 million of cash proceeds. In April and May of 2003, we raised \$6.5 million through the sale of additional Series E convertible preferred stock, convertible notes (which converted into Series E convertible preferred stock during the quarter ended September 30, 2003) and warrants.

In November 2003, we sold 4,179,860 shares of common stock in an initial public offering for aggregate gross proceeds of \$37.6 million. After deducting the underwriters' commission and offering expenses, we received net proceeds of \$33.7 million.

In June 2004, we completed a follow-on offering in which we sold 7,013,646 shares of common stock at a public offering price of \$8.50 per share for aggregate gross proceeds of \$59.6 million. After deducting the underwriters' commission and offering expenses, we received net proceeds of approximately \$55.7 million.

In December 2004, we completed a private placement in which we sold 4,250,000 shares of common stock at an offering price of \$14.25 per share for aggregate gross proceeds of \$60.6 million. After deducting the placement agent's fee and offering expenses, we received net proceeds of approximately \$57.3 million.

### **Critical Accounting Policies and Significant Estimates**

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an on-going basis, we evaluate our estimates. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances, the results of which form our 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 those estimates under different assumptions or conditions.

We believe the following critical accounting policies affect the more significant judgments and estimates used in the preparation of our consolidated financial statements:

*Clinical Trial Accruals.* Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and clinical research organizations. These costs are a significant component of research and development expenses. In the normal course of business, we contract with third parties to perform various clinical trial activities in the on-going development of MyVax. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful accrual of patients or the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. We accrue for the costs of clinical studies conducted by contract research organizations, or CROs, based on estimated costs over the life of the individual study. Further, we monitor patient registration levels and related activity to the extent possible and adjust our estimates on a monthly basis. In addition to considering information from our clinical operations group regarding the status of our clinical trials, we rely on information from CROs, to calculate our accrual for direct clinical expenses at the end of each reporting period. For indirect expenses, which relate to site and other administrative costs to manage our clinical trials, we rely on information provided by the CRO, including costs incurred by the CRO as of a particular reporting date, to calculate our indirect clinical expenses. Our estimates and assumptions may not match the timing of actual services performed by the organizations, which may result in adjustments to our research and development expenses in future periods

*Marketable Securities.* We classify all of our marketable securities as available-for-sale. We carry these investments at fair value, based on quoted market prices, and unrealized gains and losses are included in accumulated other comprehensive income which is reflected as a separate component of stockholders' equity. The amortized cost of securities in this category is adjusted for amortization of premiums and accretions of discounts to maturity. Such amortization is included in interest income. Realized gains and losses are recorded in our statement of operations. If we believe that an other-than-temporary decline exists, it is our policy to record a write-down to reduce the investments to fair value and record the related charge as a reduction of interest income.

*Stock-Based Compensation.* We have a stock option plan to reward and provide incentives to our employees, which is described more fully in Note 10 to the financial statements. We account for this plan under the recognition and measurement principles of Accounting Principles Board Opinion No. 25 ("APB 25") and related interpretations and apply the disclosure provisions of Statements of Financial Accounting Standards ("SFAS") No. 123, as amended by SFAS No. 148. We amortize stock-based compensation in accordance with Financial Accounting Standards Board ("FASB") Interpretation No. 28, an accelerated vesting model.

For financial reporting purposes, we have recorded stock-based compensation representing the difference between the deemed fair value of common stock and the option exercise price. Prior to the closing of our initial public offering, we determined the deemed fair value of our common stock based upon several factors, including significant clinical milestones attained, sales of our convertible preferred stock, changes in valuations of existing comparable publicly-registered biotechnology companies, trends in the broad market for biotechnology stocks and the expected valuation we would obtain in our initial public offering. Subsequent to the offering, we determined the deemed fair value of our common stock based on quoted market prices. All stock options granted subsequent to the offering were granted at exercise prices equal to the fair market value. We recorded deferred stock-based compensation of \$3.4 million and \$1.6 million for stock options granted to employees during the years ended December 31, 2003 and 2002, respectively. For the year ended December 31, 2004, there was no deferred stock-based compensation recorded. We have amortized \$1.0 million, \$1.7 million and \$1.2 million of these amounts in the years ended December 31, 2004, 2003, and 2002,

respectively. The compensation expense will be decreased in the period of forfeiture for any accrued but unvested compensation arising from the early termination of an option holder's services.

We disclose in Note 1 to the financial statements the pro forma impact of applying the provision of SFAS 123, as amended, to our stock awards. Prior to the closing of our initial public offering, the fair value of options issued, pursuant to our option plan at the grant date, were estimated using the minimum value method. This model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. Following the offering, the value of each option has been estimated using the Black-Scholes Model. The effects of applying pro forma disclosures of net loss and net loss per share are not likely to be representative of the pro forma effects on net loss and net loss per share in the future as the number of shares to be issued under the plan (including any future plans) is not known and the assumptions used to determine the fair value can vary significantly.

Additionally, as described more fully in Note 1 to the financial statements, we issue stock options to non-employees, generally for services, which we account for under the provisions of SFAS 123 and Emerging Issues Task Force ("EITF") No. 96-18. These options are also valued using the Black-Scholes Model. For stock options issued to non-employees, we amortized \$0.2 million and \$0.1 million of stock compensation expense for the years ended December 31, 2003, and 2002, respectively. For the year ended December 31, 2004, there was no amortization.

### **Recent Accounting Pronouncements**

In March 2004, the EITF reached a consensus on recognition and measurement guidance previously discussed under EITF No. 03-01 "*The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments*," ("EITF 03-01"). The consensus clarifies the meaning of other than temporary impairment and its application to investments classified as either available-for-sale or held to maturity under SFAS No. 115 "*Accounting for Certain Investments in Debt and Equity Securities*," and investments accounted for under the cost method or equity method. The recognition and measurement guidance for which the consensus was reached is to be applied to other than temporary impairment evaluations. In September 2004, the FASB issued a final FASB staff position ("FSP"), FSP EITF 03-01-01, that delays the effective date for the measurement and recognition guidance of EITF 03-01. We are currently evaluating the impact of adopting EITF 03-01.

In April 2004, the EITF issued EITF No. 03-06, "*Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings per Share*," ("EITF 03-06"). EITF 03-06 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-06 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-06 is effective for fiscal periods beginning after March 31, 2004. The adoption of EITF 03-06 did not have a material effect on our results of operations.

In December 2004, the FASB issued SFAS No. 123R, "*Share-Based Payment — An Amendment of FASB Statements No. 123 and 95*". The new pronouncement replaces the existing requirements under SFAS 123 and APB 25. According to SFAS 123R, all forms of share-based payments to employees, including employee stock options and employee stock purchase plans, would be treated the same as any other form of compensation by recognizing the related cost in the statement of operations. This pronouncement eliminates the ability to account for stock-based compensation transactions using APB 25 and generally would require that such transactions be accounted for using a fair-value based method. For public companies, the FASB has determined that SFAS 123R is effective for awards and stock options granted, modified or settled in cash in interim or annual periods beginning after June 15, 2005. SFAS 123R provides transition alternatives for public companies to restate prior interim periods or prior years. We are in the process of evaluating the impact of this standard on our financial statements.

## Results of Operations

### Research and development expenses

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
	(In millions, except percentages)				
Staffing related .....	\$ 9.5	\$ 7.6	\$ 5.2	25%	46%
Clinical trial and manufacturing material costs	8.5	7.0	5.2	21%	35%
Amortization of deferred stock-based compensation .....	0.6	1.1	0.6	(45)%	83%
Facilities and other costs .....	4.0	4.0	4.9	—%	(18)%
Total research and development expenses ....	<u>\$22.6</u>	<u>\$19.7</u>	<u>\$15.9</u>	15%	24%

Research and development expenses represented approximately 81% of our total operating expenses for each of the years ended December 31, 2004 and 2003 and approximately 79% of our total operating expenses for the year ended December 31, 2002. Research and development expenses include the personnel costs related to our development activities and clinical trial preparations, preclinical and clinical trial expenses, including costs related to registration, treatment and monitoring expenses, costs related to regulatory matters and the costs related to the development of our manufacturing process.

Research and development expenses increased in 2004 from 2003 due primarily to higher staffing levels and recruiting costs, of which \$1.9 million was related to the addition of manufacturing and quality assurance and control personnel. In addition, clinical trial costs associated with our lead product, MyVax, and costs related to manufacturing materials and external testing, increased by \$1.5 million. This was offset partially by a decrease in non-cash stock-based compensation expense of \$0.5 million related to the cancellation of unvested stock options. The increase in 2003 from 2002 was a result of continued increase in patient registration in our pivotal Phase 3 clinical trial. These increases were primarily related to higher staffing levels, of which \$2.4 million was related to the addition of manufacturing and quality assurance and control personnel. In addition, clinical trial costs and costs related to manufacturing materials and external testing increased by \$1.8 million and non-cash stock-based compensation expense increased by \$0.5 million related to the cancellation of unvested stock options. This was partially offset by a decrease in facilities and other costs of \$0.9 million related to lower depreciation and lower occupancy costs due to a decrease in rental rates.

We expect to devote substantial resources to research and development in future periods as we continue our development of MyVax and expect our research and development expenditures to increase during 2005 and subsequent years. Many factors can affect the cost and timing of our clinical trials, including inconclusive results requiring additional clinical trials, slow patient enrollment, adverse side effects among patients, insufficient supplies for our clinical trials and real or perceived lack of effectiveness or safety of our clinical trials. In addition, the development of our products will be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of further development and approval of our products.

### Sales and marketing expenses

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
	(In millions, except percentages)				
Staffing related .....	\$0.5	\$0.5	\$0.4	—%	25%
Product advocacy costs .....	1.0	0.8	0.7	25%	14%
Amortization of deferred stock-based compensation	0.1	0.2	0.1	(50)%	100%
Facilities and other costs .....	0.2	0.1	0.1	100%	—%
Total sales and marketing expenses .....	<u>\$1.8</u>	<u>\$1.6</u>	<u>\$1.3</u>	13%	23%

Sales and marketing expenses primarily consist of personnel costs and outside marketing activities related to product support and awareness.

The increase in sales and marketing expenses in 2004 from 2003 and in 2003 from 2002 was primarily due to increased product advocacy costs related to clinical trial support and awareness and initiation of commercialization planning projects for MyVax. We expect sales and marketing spending to increase in 2005 and subsequent years as we prepare for the possible commercialization of MyVax for the treatment of B-cell NHL.

**General and administrative expenses**

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
	(In millions, except percentages)				
Staffing related . . . . .	\$1.4	\$1.3	\$1.0	8%	30%
Legal, professional fees and insurance . . . . .	1.1	0.4	0.6	175%	(33)%
Amortization of deferred stock-based compensation . . . . .	0.2	0.6	0.6	(67)%	—%
Facilities and other costs . . . . .	<u>0.6</u>	<u>0.6</u>	<u>0.6</u>	—%	—%
Total general and administrative expenses . . . . .	<u>\$3.3</u>	<u>\$2.9</u>	<u>\$2.8</u>	14%	4%

General and administrative expenses consist primarily of costs of administrative personnel and related costs to support our organizational growth, as well as legal, accounting and other professional fees.

The increase in 2004 from 2003 was primarily attributable to additional administrative expenses of approximately \$0.8 million related to higher staffing costs, legal and professional fees and corporate insurance costs to support the organizational growth and responsibilities of being a public company. This was partially offset by a decrease of \$0.4 million in non-cash stock-based compensation expense related to the cancellation of unvested stock options. The increase in 2003 from 2002 was due to an increase in staffing costs, legal and accounting fees and corporate insurance costs of \$0.4 million related to supporting the organizational growth and responsibilities of being a public company. These increases were partially offset by a decrease in professional fees of \$0.3 million incurred in 2002 associated with unsuccessful financings.

We expect our general and administrative expenses to increase during 2005 as a result of additional administrative and infrastructure costs associated with being a public company, including costs associated with ongoing compliance with the requirements of the Sarbanes-Oxley Act of 2002 and potential implementation of new finance and accounting systems.

**Loss on Extinguishment of Convertible Notes and Cancellation of Series E Convertible Preferred Stock Warrants**

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
	(In millions, except percentages)				
Loss on extinguishment of convertible notes and cancellation of Series E convertible preferred stock warrants . . . . .	\$—	\$(3.5)	\$—	(100)%	N/A

We recorded a \$3.5 million loss related to the extinguishment of convertible notes and cancellation of convertible preferred stock warrants for the year ended December 31, 2003. No such charge was recorded during the corresponding period in 2004 or in 2002.

### Interest Expense

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
(In millions, except percentages)					
Interest expense .....	\$—	\$ (2.8)	\$—	(100)%	N/A

Interest expense for the year ended December 31, 2004 was \$4,000, compared to interest expense of \$2.8 million for the year ended December 31, 2003 and \$0 for the year ended December 31, 2002. During the year ended December 31, 2003, we recorded interest expense of \$0.8 million related to the amortization of the discount on our convertible notes, \$1.9 million related to the amortization of the warrant issued in connection with our lines of credit and \$0.1 million related to the stated interest on the convertible notes. No such charges were recorded during the corresponding period in 2004 or 2002. Interest expense for the year ended December 31, 2004 was related to expense incurred for our capital lease obligations.

### Interest and Other Income, Net

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
(In millions, except percentages)					
Interest and other income, net .....	\$0.7	\$0.1	\$0.2	600%	(50)%

Interest and other income, net for the year ended December 31, 2004 was \$0.7 million, compared to \$0.1 million for the year ended December 31, 2003 and \$0.2 million for the year ended December 31, 2002. The increase in 2004 from 2003 was due to interest on higher average cash balances as a result of the cash proceeds received from our completed initial public offering in November 2003, and our completed follow-on public offering in June 2004. The decrease in 2003 from 2002 was due to lower average cash balances and lower interest rates in 2003.

### Dividend Related to Issuance of Convertible Preferred Shares and the Beneficial Conversion Feature of Preferred Stock

	Year Ended December 31,			Annual Percent Change	
	2004	2003	2002	2004/2003	2003/2002
(In millions, except percentages)					
Dividend related to issuance of convertible preferred shares and beneficial conversion feature of preferred stock .....	\$—	\$18.4	\$—	(100)%	N/A

We recorded a non-cash dividend of \$18.4 million related to the issuance of convertible preferred shares and the beneficial conversion feature of preferred stock for the year ended December 31, 2003. No such charge was recorded for the years ended December 31, 2004 or 2002.

### Liquidity and Capital Resources

	As of December 31,		
	2004	2003	2002
(In millions)			
Cash, cash equivalents and marketable securities .....	\$116.5	\$29.8	\$9.4

	<u>Year Ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Cash flows:			
Net cash used in operating activities .....	<u>\$(25.8)</u>	<u>\$(20.2)</u>	<u>\$(16.6)</u>
Net cash used in investing activities .....	<u>\$(57.3)</u>	<u>\$ (0.3)</u>	<u>\$ (0.9)</u>
Net cash provided by financing activities .....	<u>\$113.3</u>	<u>\$ 40.9</u>	<u>\$ 20.9</u>

As of December 31, 2004, we had cash, cash equivalents and marketable securities of \$116.5 million, compared to \$29.8 million as of December 31, 2003.

We have not generated any revenues, and we have financed our operations and internal growth through private placements of common and preferred stock, including our recently completed private placement of common stock in December 2004, our line of credit facilities, our completed initial public offering in November 2003, our completed follow-on offering in June 2004, and interest income earned from our cash and cash equivalents and marketable securities. We have incurred significant losses since our inception in 1996 and as of December 31, 2004, we had an accumulated deficit of \$114.8 million. Our accumulated deficit resulted principally from our research and development activities associated with MyVax, including our pivotal Phase 3 clinical trial and additional Phase 2 clinical trials, and several non-cash charges associated with our preferred stock financings. Included in our accumulated deficit is a non-cash dividend of \$18.4 million related to our preferred stock financings in April and May 2003. Also, our accumulated deficit includes a non-cash charge of \$3.5 million associated with the extinguishment of convertible notes and cancellation of the related warrants issued to preferred stockholders in August 2003 and \$0.8 million of non-cash interest expense relating to the amortization of the discount on the convertible notes. Additionally, there was non-cash interest expense of \$1.9 million associated with the amortization of the warrant issued to the guarantor of our lines of credit. Through December 31, 2004, we had amortized and expensed non-cash stock-based compensation of \$1.0 million.

Net cash used in operating activities was \$25.8 million, \$20.2 million and \$16.6 million for the years ended December 31, 2004, 2003 and 2002, respectively. The increased use of cash in operations for 2004 compared to 2003 was primarily due to our continued research and development activities associated with MyVax for the treatment of B-cell NHL and higher cash usage for prepaids and other assets and accounts payable, due to the timing of payments made, offset partially by an increase in accrued liabilities. The change in net cash used in 2003 compared to 2002 was primarily due to the increase in net loss in 2003, adjusted for non-cash items such as interest expense on convertible notes, amortization of warrant issued to guarantor of lines of credit, loss on extinguishment of convertible notes and cancellation of convertible preferred stock warrants, as well as an increase in accounts payable, due to the timing of payments made.

Net cash used in investing activities was \$57.3 million, \$0.3 million and \$0.9 million for the years ended December 31, 2004, 2003 and 2002, respectively. Capital expenditures, consisting of purchases of office and laboratory equipment and leasehold improvements to our facilities, were \$0.8 million, \$0.3 million and \$0.9 million for the years ended December 31, 2004, 2003, and 2002, respectively. We expect our capital expenditures to increase in future years to support our development and commercialization efforts. During the year ended December 31, 2004, we purchased \$159.8 million of marketable securities, which was partially offset by maturities and sales of marketable securities of \$103.3 million. During the years ended December 2003 and 2002, we did not have any marketable securities. In the future, net cash used by investing activities may fluctuate from period to period due to timing of payments for capital expenditures and maturities/sales and purchases of marketable securities.

Net cash provided by financing activities was \$113.3 million, \$40.9 million and \$20.9 million for the years ended December 31, 2004, 2003 and 2002, respectively. During the year ended December 31, 2004, we completed a follow-on public offering, in which we sold 7,013,646 shares of common stock at a public offering price of \$8.50 per share for aggregate gross proceeds of \$59.6 million. After deducting the underwriters' commission and offering expenses, we received net proceeds of approximately \$55.7 million. In December

2004, we completed a private placement in which we sold 4,250,000 shares of common stock at an offering price of \$14.25 per share for aggregate gross proceeds of \$60.6 million. After deducting the placement agent's fee and offering expenses, we received net proceeds of approximately \$57.3 million. We also received approximately \$0.6 million related to proceeds from the issuance of common stock under our stock option and employee stock purchase plans. These proceeds were offset partially by payments of \$0.4 million related to offering costs from our initial public offering. The net cash provided by financing activities in 2003 was primarily attributable to net proceeds received from the sale of common stock in our initial public offering of \$34.1 million, the private sale of \$2.2 million of preferred stock, the sale of \$4.3 million of convertible promissory notes and warrants and proceeds received from line of credit facilities of \$8.0 million, partially offset by payments of \$8.0 million related to the same line of credit facilities. Net cash provided by financing activities in 2002 was primarily due to net proceeds received from the issuance of convertible preferred stock of \$20.7 million.

As of December 31, 2004, we had contractual obligations related to operating and capital leases as follows (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1 - 3 Years	4 - 5 Years	Beyond 5 Years
<b>Contractual obligations:</b>					
Non-cancelable operating lease obligations . . . . .	\$739	\$516	\$223	\$—	\$—
Capital lease obligations . . . . .	95	47	48	—	—
Total contractual obligations . . . . .	<u>\$834</u>	<u>\$563</u>	<u>\$271</u>	<u>\$—</u>	<u>\$—</u>

Our long term commitments under operating leases shown above consist of payments relating to four real estate leases and subleases covering the 46,780 square feet of our present facility. These leases and subleases expire between January 2006 and November 2006. In March 2005, we entered into a new real estate lease related to one of these subleases. This new lease expires in July 2006 and we estimate that our commitment under this lease is approximately \$0.3 million through July 30, 2006.

We anticipate working on a number of long-term development projects which will involve experimental and unproven technology. The projects may require many years and substantial expenditures to complete and may ultimately be unsuccessful. We will need operating funds to continue our research and development activities and clinical trials, pursue regulatory approvals and build production, sales and marketing capabilities, as necessary.

We believe that our current cash resources, together with the interest thereon, will provide us with sufficient financial resources for at least the next 12 months. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the risk factors discussed in this report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We expect that our cash consumption will increase in 2005 as we anticipate an increase in operating expenses related to the growth of the company, as well as the build-out of our commercial manufacturing facility. We will need to raise additional funds to complete the construction and qualification of a commercial scale manufacturing facility and to commercialize MyVax if MyVax receives regulatory approval for the treatment of follicular B-cell NHL.

A commercial scale manufacturing facility must be built and qualified and pass a pre-approval inspection from the appropriate regulatory agency prior to any regulatory approval for MyVax. We anticipate spending for a commercial scale manufacturing facility to begin in the first half of 2005. We estimate that the total cost of the facility, including related manufacturing equipment, could exceed \$65 million or more.

Even if we achieve positive interim results in our pivotal Phase 3 clinical trial and receive regulatory approval for MyVax, including regulatory approval of our commercial scale manufacturing facility, we

anticipate that the earliest we could realize product revenue is 2006. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, corporate collaboration or licensing arrangements or other arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies, MyVax or any other immunotherapies that we may develop, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs or our commercialization efforts.

#### **Off-balance Sheet Arrangements**

As of December 31, 2004, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Interest Rate Risk.* We are exposed to interest rate risk primarily through our marketable securities. The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing risk of loss. We do not use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over yield considerations. As of December 31, 2004, cash, cash equivalents and marketable securities were \$116.5 million. Due to the nature of these investments, if market interest rates were to increase immediately and uniformly by 10% from levels as of December 31, 2004, the decline in the total fair value of our cash, cash equivalents and marketable securities would be immaterial.

In addition, we do not have any material exposure to foreign currency rate fluctuations as we operate primarily in the United States.

ITEM 8. *FINANCIAL STATEMENTS*

GENETOPE CORPORATION  
(A DEVELOPMENT STAGE ENTERPRISE)  
INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm .....	53
Balance Sheets .....	55
Statements of Operations .....	56
Statements of Stockholders' Equity (Deficit) .....	57
Statements of Cash Flows .....	61
Notes to the Financial Statements .....	63

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Genitope Corporation  
(a development stage enterprise)

We have completed an integrated audit of Genitope Corporation's 2004 financial statements and of its internal control over financial reporting as of December 31, 2004 and audits of its 2003 and 2002 financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

### *Financial statements*

In our opinion, the financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Genitope Corporation at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, and cumulatively, for the period from August 15, 1996 (date of inception) to December 31, 2004 in conformity with accounting principles generally accepted in the United States of America. 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 of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

### *Internal control over financial reporting*

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of December 31, 2004 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control — Integrated Framework* issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the

company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California  
March 14, 2005

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**BALANCE SHEETS**

	December 31,	
	2004	2003
	(In thousands, except share and per share data)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 60,087	\$ 29,790
Marketable securities .....	56,422	—
Prepaid expenses and other current assets .....	1,101	388
Total current assets .....	117,610	30,178
Property and equipment, net .....	2,196	1,917
Other assets .....	59	257
Total assets .....	\$ 119,865	\$ 32,352
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 2,073	\$ 2,781
Accrued and other current liabilities .....	1,502	781
Current lease obligations .....	46	26
Total current liabilities .....	3,621	3,588
Noncurrent lease obligations .....	48	22
Total liabilities .....	3,669	3,610
Commitments (Note 6)		
Stockholders' equity:		
Common stock; \$0.001 par value:		
Authorized: 65,000,000 shares at December 31, 2004 and 2003; Issued and outstanding: 28,191,145 shares at December 31, 2004 and 16,819,501 shares at December 31, 2003 .....	28	17
Additional paid-in capital .....	231,784	119,323
Notes receivable from stockholders .....	—	(48)
Deferred stock-based compensation .....	(733)	(2,787)
Accumulated other comprehensive loss .....	(94)	—
Deficit accumulated during the development stage .....	(114,789)	(87,763)
Total stockholders' equity .....	116,196	28,742
Total liabilities and stockholders' equity .....	\$ 119,865	\$ 32,352

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

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**  
**STATEMENTS OF OPERATIONS**

	<u>Year Ended December 31,</u>			<u>Cumulative</u> <u>Period from</u> <u>August 15, 1996</u> <u>(Date of Inception)</u> <u>to December 31,</u>
	<u>2004</u>	<u>2003</u>	<u>2002</u>	<u>2004</u>
	(In thousands, except per share data)			
Operating expenses:				
Research and development .....	\$ 22,571	\$ 19,678	\$ 15,915	\$ 75,066
Sales and marketing .....	1,793	1,591	1,338	4,723
General and administrative .....	<u>3,356</u>	<u>2,937</u>	<u>2,832</u>	<u>12,584</u>
Total operating expenses .....	<u>27,720</u>	<u>24,206</u>	<u>20,085</u>	<u>92,373</u>
Loss from operations .....	(27,720)	(24,206)	(20,085)	(92,373)
Loss on extinguishment of convertible notes and cancellation of Series E convertible preferred stock warrants .....	—	(3,509)	—	(3,509)
Interest expense .....	(4)	(2,845)	—	(2,982)
Interest and other income, net .....	<u>698</u>	<u>97</u>	<u>221</u>	<u>2,482</u>
Net loss .....	(27,026)	(30,463)	(19,864)	(96,382)
Dividend related to issuance of convertible preferred shares and the beneficial conversion feature of preferred stock .....	—	(18,407)	—	(18,407)
Net loss attributable to common stockholders .....	<u>\$(27,026)</u>	<u>\$(48,870)</u>	<u>\$(19,864)</u>	<u>\$(114,789)</u>
Basic and diluted net loss per share attributable to common stockholders .....	<u>\$ (1.31)</u>	<u>\$ (11.86)</u>	<u>\$ (11.62)</u>	
Shares used in computing basic and diluted net loss attributable to common stockholders .....	<u>20,683</u>	<u>4,122</u>	<u>1,710</u>	

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

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE PERIOD  
FROM AUGUST 15, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2004**

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Notes Receivable from Stockholders</u>	<u>Deferred Stock-Based Compensation</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>						
(In thousands, except per share data)								
Issuance of common stock at \$0.001 per share to founders for cash & technology .....	1,259	\$ 1	\$ 3	\$ —	\$ —	\$ —	\$ —	\$ 4
Issuance of common stock at \$0.15 per share in exchange for cash and services .....	9	—	1	—	—	—	—	1
Net loss .....	—	—	—	—	—	—	(76)	(76)
<b>Balance at December 31, 1996</b> ...	1,268	1	4	—	—	—	(76)	(71)
Issuance of common stock at \$0.15 per share in exchange for cash and services .....	30	—	4	—	—	—	—	4
Issuance of common stock at \$0.15 per share in exchange for cash upon exercise of stock options .....	10	—	2	—	—	—	—	2
Net loss .....	—	—	—	—	—	—	(980)	(980)
<b>Balances at December 31, 1997</b> ...	1,308	1	10	—	—	—	(1,056)	(1,045)
Net loss .....	—	—	—	—	—	—	(1,596)	(1,596)
<b>Balances at December 31, 1998</b> ...	1,308	1	10	—	—	—	(2,652)	(2,641)
Net issuance and repurchase of common stock to a director as part of a stock issuance agreement at \$0.60 per share ...	62	—	37	(37)	—	—	—	—
Issuance of common stock at \$0.45 per share in exchange for cash upon exercise of stock options .....	2	—	1	—	—	—	—	1
Net loss .....	—	—	—	—	—	—	(2,752)	(2,752)
<b>Balances at December 31, 1999</b> ...	1,372	1	48	(37)	—	—	(5,404)	(5,392)

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE PERIOD**  
**FROM AUGUST 15, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2004 — (Continued)**

	Common Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount						
(In thousands, except per share data)								
Issuance of common stock at a price of \$0.15 to \$0.60 per share in exchange for cash upon exercise of stock options .....	10	—	2	—	—	—	—	2
Proceeds from promissory note ...	—	—	—	37	—	—	—	37
Issuance of stock options to nonemployees in exchange for services .....	—	—	20	—	—	—	—	20
Issuance of common stock to nonemployees in exchange for services .....	8	—	9	—	—	—	—	9
Issuance of warrants to purchase shares of convertible preferred stock in exchange for services ..	—	—	144	—	—	—	—	144
Net loss .....	—	—	—	—	—	—	(3,845)	(3,845)
<b>Balances at December 31, 2000 ..</b>	<b>1,390</b>	<b>1</b>	<b>223</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(9,249)</b>	<b>(9,025)</b>
Issuance of common stock at a price of \$0.15 to \$0.60 per share in exchange for cash and notes upon exercise of stock options ..	365	1	323	(48)	—	—	—	276
Repurchase of unvested common stock .....	(3)	—	(3)	—	—	—	—	(3)
Deferred stock-based compensation .....	—	—	1,036	—	(1,036)	—	—	—
Amortization of stock-based compensation .....	—	—	110	—	328	—	—	438
Net loss .....	—	—	—	—	—	—	(9,780)	(9,780)
<b>Balances at December 31, 2001 ..</b>	<b>1,752</b>	<b>2</b>	<b>1,689</b>	<b>(48)</b>	<b>(708)</b>	<b>—</b>	<b>(19,029)</b>	<b>(18,094)</b>
Issuance of common stock at a price of \$0.60 to \$1.20 per share in exchange for cash and notes upon exercise of stock options ..	171	—	202	(12)	—	—	—	190
Repurchase of unvested common stock .....	(10)	—	(11)	—	—	—	—	(11)
Deferred stock-based compensation .....	—	—	1,607	—	(1,607)	—	—	—
Amortization of stock-based compensation .....	—	—	122	—	1,243	—	—	1,365
Net loss .....	—	—	—	—	—	—	(19,864)	(19,864)
<b>Balances at December 31, 2002 ..</b>	<b>1,913</b>	<b>2</b>	<b>3,609</b>	<b>(60)</b>	<b>(1,072)</b>	<b>—</b>	<b>(38,893)</b>	<b>(36,414)</b>

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE PERIOD**  
**FROM AUGUST 15, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2004 — (Continued)**

	Common Stock		Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Stock-Based Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount						
(In thousands, except per share data)								
Conversion of preferred stock to common stock .....	10,638	11	53,559	—	—	—	—	53,570
Issuance of common stock at \$9.00 per share related to initial public offering, net of issuance costs .....	4,180	4	33,731	—	—	—	—	33,735
Dividend related to issuance of convertible preferred shares and the beneficial conversion feature of preferred stock .....	—	—	18,407	—	—	—	(18,407)	—
Discount on convertible notes relating to warrants and beneficial conversion of preferred stock .....	—	—	4,280	—	—	—	—	4,280
Warrant to purchase convertible preferred stock issued to guarantor of the lines of credit	—	—	1,933	—	—	—	—	1,933
Issuance of common stock at a price of \$1.20 to \$1.80 per share in exchange for cash upon exercise of stock options .....	99	—	179	—	—	—	—	179
Issuance of common stock to non- employees in exchange for services .....	6	—	29	—	—	—	—	29
Repurchase of unvested common stock .....	(16)	—	(20)	—	—	—	—	(20)
Proceeds from repayment of promissory note .....	—	—	—	12	—	—	—	12
Deferred stock-based compensation .....	—	—	3,408	—	(3,408)	—	—	—
Amortization of stock-based compensation .....	—	—	208	—	1,693	—	—	1,901
Net loss .....	—	—	—	—	—	—	(30,463)	(30,463)
<b>Balances at December 31, 2003 ..</b>	<b>16,820</b>	<b>17</b>	<b>119,323</b>	<b>(48)</b>	<b>(2,787)</b>	<b>—</b>	<b>(87,763)</b>	<b>28,742</b>

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE PERIOD**  
**FROM AUGUST 15, 1996 (DATE OF INCEPTION) TO DECEMBER 31, 2004 — (Continued)**

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Notes Receivable from Stockholders</u>	<u>Deferred Stock-Based Compensation</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>						
(In thousands, except per share data)								
Issuance of common stock at a price of \$1.20 to \$11.64 per share in exchange for cash upon exercise of stock options .....	89	—	170	—	—	—	—	170
Issuance of common stock at \$8.50 per share related to follow-on offering, net of issuance costs .....	7,014	7	55,711	—	—	—	—	55,718
Issuance of common stock at \$14.25 per share related to private placement, net of issuance costs .....	4,250	4	57,266	—	—	—	—	57,270
Issuance of common stock related to ESPP .....	57	—	437	—	—	—	—	437
Proceeds from repayment of stockholder note .....	—	—	—	48	—	—	—	48
Repurchase of unvested common stock .....	(39)	—	(49)	—	—	—	—	(49)
Deferred stock-based compensation .....	—	—	(1,074)	—	1,074	—	—	—
Amortization of stock-based compensation .....	—	—	—	—	980	—	—	980
Components of other comprehensive loss:								
Unrealized loss on marketable securities .....	—	—	—	—	—	(94)	—	(94)
Net loss .....	—	—	—	—	—	—	(27,026)	(27,026)
Comprehensive loss .....	—	—	—	—	—	—	—	(27,120)
<b>Balances at December 31, 2004 ..</b>	<u>28,191</u>	<u>\$28</u>	<u>\$231,784</u>	<u>\$ —</u>	<u>\$ (733)</u>	<u>\$ (94)</u>	<u>\$(114,789)</u>	<u>\$116,196</u>

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

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**STATEMENTS OF CASH FLOWS**

	Year Ended December 31,			Cumulative Period from August 15, 1996 (Date of Inception) to December 31,
	2004	2003	2002	2004
	(In thousands)			
<b>Cash flows from operating activities:</b>				
Net loss	\$ (27,026)	\$(30,463)	\$(19,864)	\$ (96,382)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	771	716	1,589	4,416
Loss on disposal of assets	—	5	24	29
Stock-based compensation expense	980	1,901	1,365	4,704
Loss on extinguishment of convertible notes and cancellation of convertible preferred stock warrants	—	3,509	—	3,509
Amortization of warrant issued to guarantor of the lines of credit	—	1,933	—	1,933
Interest expense on convertible notes	—	892	—	892
Common stock issued for services	—	29	—	46
Changes in assets and liabilities:				
Prepays and other assets	(504)	(360)	85	(982)
Accounts payable	(707)	1,482	249	1,891
Accrued and other current liabilities	704	180	(41)	1,315
Net cash used in operating activities	<u>(25,782)</u>	<u>(20,176)</u>	<u>(16,593)</u>	<u>(78,629)</u>
<b>Cash flows from investing activities:</b>				
Purchase of property and equipment	(749)	(307)	(946)	(6,288)
Purchases of marketable securities	(159,772)	—	—	(159,772)
Sales of marketable securities	22,173	—	—	22,173
Maturities of marketable securities	81,083	—	—	81,083
Long term cash deposits	—	—	—	(167)
Net cash used in investing activities	<u>(57,265)</u>	<u>(307)</u>	<u>(946)</u>	<u>(62,971)</u>
<b>Cash flows from financing activities:</b>				
Net proceeds from issuance of convertible preferred stock	—	2,181	20,702	47,392
Net proceeds from issuance of common stock related to initial public offering	(353)	34,088	—	33,735
Net proceeds from issuance of common stock related to follow-on public offering	55,718	—	—	55,718
Net proceeds from issuance of common stock related to private placement	57,420	—	—	57,420
Borrowings under lines of credit	—	8,000	—	8,786
Repayment of borrowings under lines of credit	—	(8,000)	—	(8,786)
Proceeds from issuance of convertible notes and warrants	—	4,280	—	6,060
Proceeds from issuance of common stock under stock plans	596	179	190	1,248
Proceeds from exercise of Series D warrants	—	135	—	135
Repurchase of unvested common stock	(49)	(20)	(11)	(83)
Proceeds from note receivable from stockholder	48	12	—	102
Principal payments on capital lease obligations	(36)	(4)	—	(40)
Net cash provided by financing activities	<u>113,344</u>	<u>40,851</u>	<u>20,881</u>	<u>201,687</u>
Net increase in cash and cash equivalents	30,297	20,368	3,342	60,087
Cash and cash equivalents, beginning of period	29,790	9,422	6,080	—
Cash and cash equivalents, end of period	<u>\$ 60,087</u>	<u>\$ 29,790</u>	<u>\$ 9,422</u>	<u>\$ 60,087</u>

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**  
**STATEMENTS OF CASH FLOWS — (Continued)**

	Year Ended December 31,			Cumulative Period from August 15, 1996 (Date of Inception) to December 31,
	2004	2003	2002	2004
	(In thousands)			
<b>Supplemental disclosure:</b>				
Cash paid for interest . . . . .	\$ 4	\$ 14	\$ —	\$ 150
<b>Supplemental schedule of non-cash investing and financing activities:</b>				
Conversion of preferred stock into common stock . . . . .	\$ —	\$ 53,570	\$ —	\$ 53,570
Dividend related to issuance of convertible preferred shares and the beneficial conversion feature of preferred stock . . . . .	\$ —	\$ 18,407	\$ —	\$ 18,407
Discount on convertible notes for beneficial conversion feature of preferred stock and warrants . . . . .	\$ —	\$ 4,280	\$ —	\$ 4,280
Conversion of convertible notes into convertible preferred stock . . . . .	\$ —	\$ (4,280)	\$ —	\$ (4,280)
Warrants issued to guarantor of the lines of credit . . . . .	\$ —	\$ 1,933	\$ —	\$ 1,933
Warrant issued in connection with services related to convertible preferred stock . . . . .	\$ —	\$ —	\$ —	\$ 144
Accrued interest converted into convertible preferred stock . . . . .	\$ —	\$ 121	\$ —	\$ 121
Convertible preferred stock issued in exchange for note receivable from stockholder . . . . .	\$ —	\$ —	\$ —	\$ 5
Conversion of notes payable into convertible preferred stock . . . . .	\$ —	\$ —	\$ —	\$ 1,780
Accrued offering costs for issuance of common stock related to initial public offering . . . . .	\$ (353)	\$ 353	\$ —	\$ —
Accrued offering costs for issuance of common stock related to private placement . . . . .	\$ 150	\$ —	\$ —	\$ 150
Acquisition of property and equipment under capital leases . . . . .	\$ 82	\$ 52	\$ —	\$ 134
Accrued cost for acquisition of property and equipment . .	\$ 219	\$ —	\$ —	\$ 219
Receivable from issuance of common stock under stock plan . . . . .	\$ 11	\$ —	\$ —	\$ 11
Unrealized losses on marketable securities . . . . .	\$ (94)	\$ —	\$ —	\$ (94)

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

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**  
**NOTES TO THE FINANCIAL STATEMENTS**

**NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Organization and Business*

Genitope Corporation is a development stage enterprise focused on the research and development of novel immunotherapies for the treatment of cancer. Immunotherapies are treatments that utilize the immune system to combat diseases. Our lead product candidate, MyVax personalized immunotherapy, is a patient-specific active immunotherapy that is based on the unique genetic makeup of a patient's tumor and is designed to activate a patient's immune system to identify and attack cancer cells. MyVax is currently in a pivotal Phase 3 clinical trial and additional Phase 2 clinical trials for the treatment of B-cell non-Hodgkin's lymphoma ("B-cell NHL"). We were incorporated in the State of Delaware on August 15, 1996.

*Liquidity*

To date, we have not generated any revenues, and we have financed our operations and internal growth through private placements of common and preferred stock, including our recent private placement of common stock in December 2004, our line of credit facilities, our completed initial public offering in November 2003, our completed follow-on public offering in June 2004, and interest income earned from our cash and cash equivalents and marketable securities. We are a development stage enterprise and have incurred significant losses since our inception in 1996 as we have devoted substantially all of our efforts to research and development activities, including clinical trials. As of December 31, 2004, we had an accumulated deficit of \$114.8 million. As of December 31, 2004, we had cash, cash equivalents and marketable securities of \$116.5 million.

Since 1996, we have been successful in completing several rounds of private equity financing. In 2002, the sale of Series E convertible preferred stock generated \$20.7 million of cash proceeds. In April and May of 2003, we raised \$6.5 million through the sale of additional Series E convertible preferred stock, convertible notes (which converted into Series E convertible preferred stock during the quarter ended September 30, 2003) and warrants.

In November 2003, we sold 4,179,860 shares of common stock in an initial public offering for aggregate gross proceeds of \$37.6 million. After deducting the underwriters' commission and offering expenses, we received net proceeds of \$33.7 million.

In June 2004, we completed a follow-on offering in which we sold 7,013,646 shares of common stock at a public offering price of \$8.50 per share for aggregate gross proceeds of \$59.6 million. After deducting the underwriters' commission and offering expenses, we received net proceeds of approximately \$55.7 million.

In December 2004, we completed a private placement in which we sold 4,250,000 shares of common stock at an offering price of \$14.25 per share for aggregate gross proceeds of \$60.6 million. After deducting the placement agent's fee and offering expenses, we received net proceeds of approximately \$57.3 million.

*Basis of Presentation*

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the

**GENTOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

financial statements and reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Concentrations of Credit Risk***

Cash, cash equivalents, and marketable securities are financial instruments which potentially subject us to concentrations of credit risk. The estimated fair value of financial instruments approximates the carrying value based on available market information. We primarily invest our excess available funds in notes and bills issued by the U.S. government and its agencies and corporate debt securities and, by policy, limit the amount of credit exposure to any one issuer and to any one type of investment, other than securities issued or guaranteed by the U.S. government. We have not experienced any significant credit losses on cash, cash equivalents and marketable securities to date.

***Cash and Cash Equivalents***

Cash equivalents are defined as all liquid investments with maturity from date of purchase of 90 days or less that are readily convertible into cash and have insignificant interest rate risk. We invest our excess cash primarily in deposits with banks and in highly liquid money market funds.

***Marketable Securities***

All marketable securities are classified as available-for-sale. Available-for-sale securities are carried at fair value, based on quoted market prices, with unrealized gains and losses reported as a separate component of stockholders' equity. The amortized cost of securities in this category is adjusted for amortization of premiums and accretions of discounts to maturity. Such amortization is included in interest income. Realized gains and losses and declines in value judged to be other than temporary for available-for-sale securities are included in "Interest and other income, net." The cost of securities sold is based on the specific identification method.

Marketable securities include auction rate and floating rate securities. These securities are structured as short-term, highly liquid investments that can be readily converted into cash every 30, 60 or 90 days. However, since the stated or contractual maturities of these securities is greater than 90 days, these securities are classified as marketable securities and not cash equivalents.

***Certain Risks and Uncertainties***

Our product candidate under development requires approval from the Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance our products will receive the necessary clearance. If we are denied clearance or clearance is delayed, it may have a material adverse impact on us.

Our product is concentrated in rapidly changing, highly competitive markets, which are characterized by rapid technological advances, changes in customer requirements and evolving regulatory requirements and industry standards. Any failure by us to anticipate or to respond adequately to technological developments in our industry, changes in customer requirements or changes in regulatory requirements or industry standards, or any significant delays in the development or introduction of products or services, could have a material adverse effect on our business, operating results and future cash flows.

We depend on single source suppliers for critical raw materials for manufacturing, as well as other components required for the administration of MyVax. The loss of these suppliers could delay our clinical trials or prevent or delay commercialization of MyVax.

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Fixed assets are depreciated over a life of three to five years. Leasehold improvements are amortized using the straight-line method over the estimated useful life of the improvement, or the lease term, if shorter. Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Certain laboratory and computer equipment used by us could be subject to technological obsolescence in the event that significant advancement is made in competing or developing equipment technologies. Management continually reviews the estimated useful lives of technologically sensitive equipment and believes that those estimates appropriately reflect the current useful life of our assets. In the event that a currently unknown significantly advanced technology became commercially available, we would re-evaluate the value and estimated useful lives of our existing equipment, possibly having a material impact on the financial statements.

***Research and Development***

Research and development expenses consist of costs incurred for internally sponsored research and development. These costs include direct and research-related overhead expenses and clinical trials that are charged to expense as incurred.

***Advertising Costs***

Advertising costs are expensed as incurred. Advertising costs were not material for all periods presented.

***Impairment of Long-lived Assets***

Long-lived assets to be held and used are reviewed for impairment when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable, or its estimated useful life has changed significantly. When an asset's expected future undiscounted cash flows are less than its carrying value, an impairment loss is recognized and the asset is written down to its estimated fair value. Long-lived assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to dispose.

***Stock-based Compensation***

We account for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*" ("APB 25") and comply with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "*Accounting for Stock-Based Compensation*" ("SFAS 123"), as amended by Statement of Financial Accounting Standards No. 148 "*Accounting for Stock-Based Compensation, Transition and Disclosure*" ("SFAS 148"). Under APB 25, unearned stock compensation is based on the difference, if any, on the date of grant, between the deemed fair value of our common stock and the exercise price of stock option grants to employees.

We account for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force ("EITF") No. 96-18, "*Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*" ("EITF 96-18"). The equity instruments, consisting of stock options, are valued using the Black-Scholes Model. All unvested shares are marked to market until such options vest.

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

All stock compensation is amortized and expensed in accordance with Financial Accounting Standards Board Interpretation No. 28, "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans: an Interpretation of APB Opinions No. 15 and 25," ("FIN 28"). We are amortizing stock compensation to expense over the period during which the periods vest, generally four years, using an accelerated vesting model consistent with FIN 28. Amortization of stock-based compensation for employees and non-employees is as follows (in thousands):

	Year Ended December 31,			Cumulative Period from August 15, 1996 (Date of Inception) to December 31,
	2004	2003	2002	2004
Amortization of stock-based compensation:				
Research and development .....	\$627	\$1,046	\$ 589	\$2,443
Sales and marketing .....	143	176	141	460
General and administration .....	210	679	635	1,801
	<u>\$980</u>	<u>\$1,901</u>	<u>\$1,365</u>	<u>\$4,704</u>

Prior to the closing of our initial public offering, the fair value of options was computed using the minimum value method. Following the offering, the value of each option and employee purchase right has been estimated at the date of grant, using the Black-Scholes Model, assuming the following weighted-average assumptions:

	Employee Stock Options			Employee Stock Purchase Plan		
	2004	2003	2002	2004	2003	2002
Average risk-free interest rates .....	3.30%	2.82%	3.88%	1.33%	N/A	N/A
Average expected life (in years) .....	4.00	4.00	4.00	0.79	N/A	N/A
Dividend yield .....	0%	0%	0%	0%	N/A	N/A
Volatility .....	76%	92%	—%	64%	N/A	N/A
Weighted average fair values of option grants per share						
Fair value equal to exercise price .....	\$10.26	\$8.29	N/A	\$3.47	N/A	N/A
Fair value greater than exercise price .....	N/A	\$6.61	\$5.03	N/A	N/A	N/A

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

Had compensation cost for our stock-based compensation plans been determined based on the fair value of the awards consistent with the provisions of SFAS 123 at the grant date, our net loss would have been increased to the amounts below (in thousands, except per share data).

	Year Ended December 31,		
	2004	2003	2002
Net loss attributable to common stockholders, as reported .....	\$(27,026)	\$(48,870)	\$(19,864)
Add: Employee stock-based compensation included in reported net earnings .....	980	1,693	1,243
Deduct: Employee total stock-based compensation determined under fair value method .....	<u>(3,616)</u>	<u>(1,818)</u>	<u>(1,301)</u>
Adjusted net loss attributable to common stockholders .....	<u>\$(29,662)</u>	<u>\$(48,995)</u>	<u>\$(19,922)</u>
Basic and diluted net loss per share attributable to common stockholders:			
As reported .....	<u>\$ (1.31)</u>	<u>\$ (11.86)</u>	<u>\$ (11.62)</u>
Adjusted .....	<u>\$ (1.43)</u>	<u>\$ (11.89)</u>	<u>\$ (11.65)</u>

The resulting effect on net loss attributable to common stockholders and net loss per share attributable to common stockholders is not likely to be representative of the effects on net loss attributable to common stockholders and net loss per share attributable to common stockholders in future periods, due to subsequent periods including additional grants and periods of vesting.

***Comprehensive Loss***

Comprehensive loss is comprised of net loss and changes in unrealized gain/loss on marketable securities. There were no material differences between net loss and comprehensive loss for all periods presented.

***Income Taxes***

We use the liability method to account for income taxes as required by SFAS No. 109, "Accounting for Income Taxes." Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using enacted tax rules and laws that will be in effect when differences are expected to reverse.

***Segments***

We operate in one segment, drug discovery and development, using one measurement of profitability to manage our business, in accordance with SFAS No. 131 "Disclosures about Segments of an Enterprise and Related Information." All long-lived assets are maintained in the United States of America.

***Recent Accounting Pronouncements***

In March 2004, the EITF reached a consensus on recognition and measurement guidance previously discussed under EITF No. 03-01 "The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments," ("EITF 03-01"). The consensus clarifies the meaning of other than temporary impairment and its application to investments classified as either available-for-sale or held to maturity under SFAS 115 "Accounting for Certain Investments in Debt and Equity Securities," and investments accounted for under the cost method or equity method. The recognition and measurement guidance for which the consensus was reached is to be applied to other than temporary impairment evaluations. In September 2004, the

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

Financial Accounting Standards Board (“FASB”) issued a final FASB staff position (“FSP”), FSP EITF No. 03-01-01, that delays the effective date for the measurement and recognition guidance of EITF 03-01. We are currently evaluating the impact of adopting EITF 03-01.

In April 2004, the EITF issued Statement No. 03-06, “*Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings per Share*,” (“EITF 03-06”). EITF 03-06 addresses a number of questions regarding the computation of earnings per share by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. EITF 03-06 also provides further guidance in applying the two-class method of calculating earnings per share, clarifying what constitutes a participating security and how to apply the two-class method of computing earnings per share once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. EITF 03-06 is effective for fiscal periods beginning after March 31, 2004. The adoption of EITF 03-06 did not have a material effect on our results of operations.

In December 2004, the FASB issued SFAS No. 123R, “*Share-Based Payment — An Amendment of FASB Statements No. 123 and 95*” (“SFAS 123R”). The new pronouncement replaces the existing requirements under SFAS 123 and APB 25. According to SFAS 123R, all forms of share-based payments to employees, including employee stock options and employee stock purchase plans, would be treated the same as any other form of compensation by recognizing the related cost in the statement of operations. This pronouncement eliminates the ability to account for stock-based compensation transactions using APB 25 and generally would require that such transactions be accounted for using a fair-value based method. For public companies, the FASB has determined that SFAS 123R is effective for awards and stock options granted, modified or settled in cash in interim or annual periods beginning after June 15, 2005. SFAS 123R provides transition alternatives for public companies to restate prior interim periods or prior years. We are in the process of evaluating the impact of this standard on our financial statements.

**NOTE 2 — NET LOSS PER SHARE**

Basic net loss per share attributable to common stockholders is calculated based on the weighted-average number of shares of common stock outstanding during the period, excluding those shares that are subject to repurchase. Diluted net loss per share attributable to common stockholders would give effect to the dilutive effect of potential issuances of common stock consisting of stock options, warrants, common stock subject to repurchase, convertible preferred stock and convertible notes payable. Dilutive securities have been excluded from the diluted net loss per share computations as they have an antidilutive effect due to our net loss.

A reconciliation of shares used in the calculation is as follows (in thousands, except per share data):

	<u>Year Ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
<b>Numerator:</b>			
Net loss attributable to common stockholders . . . . .	\$(27,026)	\$(48,870)	\$(19,864)
<b>Denominator:</b>			
Weighted average common shares outstanding . . . . .	20,717	4,233	1,888
Less: Weighted average unvested common shares subject to repurchase . . . . .	<u>(34)</u>	<u>(111)</u>	<u>(178)</u>
Denominator for basic and diluted calculations . . . . .	<u>20,683</u>	<u>4,122</u>	<u>1,710</u>
Net loss per share attributable to common stockholders, basic and diluted . . . . .	<u>\$ (1.31)</u>	<u>\$ (11.86)</u>	<u>\$ (11.62)</u>

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

The following outstanding stock options and warrants, common stock subject to repurchase and convertible preferred stock (on an as-if-converted basis) were excluded from the computation of diluted net loss per share attributable to common stockholders as they had an antidilutive effect (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Shares issuable upon exercise of stock options .....	1,577	962	395
Shares issuable upon exercise of warrants .....	267	270	30
Shares issuable related to ESPP .....	4	—	—
Common stock subject to repurchase .....	18	84	154
Shares issuable upon conversion of convertible preferred stock .....	—	—	6,810
	1,866	1,316	7,389

**NOTE 3 — MARKETABLE SECURITIES**

As of December 31, 2004, all of our marketable securities are classified as short-term, as we have classified them as available-for-sale and may not hold until maturity. The following is a summary of our available-for-sale marketable securities as of December 31, 2004 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Maturing within one year:				
Commercial paper .....	\$ 990	\$—	\$ —	\$ 990
Corporate bonds .....	33,249	3	(46)	33,206
U.S. government and agency securities .....	16,324	—	(21)	16,303
	50,563	3	(67)	50,499
Maturing between one and two years:				
U.S. government and agency securities .....	5,953	—	(30)	5,923
Total available-for-sale marketable securities .....	\$56,516	\$ 3	\$(97)	\$56,422

Realized gains and losses from the sales of marketable securities for the year ended December 31, 2004 was not material.

**NOTE 4 — PROPERTY AND EQUIPMENT**

Property and equipment consists of the following (in thousands):

	December 31,	
	2004	2003
Computer and laboratory equipment .....	\$ 3,039	\$ 2,252
Furniture and fixtures .....	210	110
Leasehold improvements .....	3,337	3,174
	6,586	5,536
Less: Accumulated depreciation and amortization .....	(4,390)	(3,619)
	\$ 2,196	\$ 1,917

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

Depreciation expense, including amortization of assets under capital leases and leasehold improvements, was \$0.8 million, \$0.7 million, \$1.6 million and \$4.4 million for the year ended December 31, 2004, 2003, 2002, and the period from August 15, 1996 (date of inception) to December 31, 2004, respectively.

**NOTE 5 — ACCRUED AND OTHER CURRENT LIABILITIES**

Accrued and other current liabilities consists of the following (in thousands):

	December 31,	
	2004	2003
Employee benefits .....	\$ 430	\$356
Professional fees .....	674	270
Clinical trials .....	225	64
Other .....	173	91
	<u>\$1,502</u>	<u>\$781</u>

**NOTE 6 — COMMITMENTS**

We sublease space under four non-cancelable operating leases with terms through 2006. We also lease computer and lab equipment. The future minimum payments under the leases as of December 31, 2004 are as follows (in thousands):

	Operating Leases	Capital Leases
<b>Year Ending December 31:</b>		
2005 .....	\$516	\$ 47
2006 .....	223	24
2007 .....	—	24
Total minimum lease payments .....	<u>\$739</u>	95
Less: amount representing interest .....		(1)
Present value of minimum lease payments .....		94
Less: current portion .....		(46)
Noncurrent portion .....		<u>\$ 48</u>

Rent expense for the years ended December 31, 2004, 2003 and 2002, and the period from August 15, 1996 (date of inception) to December 31, 2004 was \$0.7 million, \$0.8 million, \$1.4 million and \$4.4 million respectively. In November 2004, we entered into a new sublease related to our Foster City, California location.

**Indemnification**

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, including business partners, contractors and parties performing our clinical trials. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party as a result of our activities. The terms of these indemnification agreements vary from contract to contract. The maximum potential amount of future payments we could be required to make under these agreements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the estimated fair value of

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

these agreements is minimal. We maintain commercial general liability and product liability insurance to offset certain of our potential liabilities under these indemnification provisions.

**NOTE 7 — CONVERTIBLE PREFERRED STOCK (“PREFERRED STOCK”)**

Our certificate of incorporation, as amended and restated, authorizes us to issue up to 5,000,000 shares of preferred stock, with a par value of \$0.001, in one or more series. Our Board of Directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. Upon closing of our initial public offering in November 2003, all of the outstanding convertible preferred stock automatically converted into common stock at a one-to-one ratio. As of December 31, 2004 and 2003, no shares of preferred stock were issued and outstanding.

*Series C and D Convertible Preferred Stock Warrants*

During 2000, we issued warrants to purchase up to 27,000 shares of the Series D convertible preferred stock, with an exercise price of \$7.80 per share expiring in June 2005, to individuals for services rendered in conjunction with a private placement of common stock. The aggregate value of these warrants of \$0.1 million determined using the Black-Scholes Model, has been recorded as issuance costs and netted against the proceeds received on the Series D convertible preferred stock. In connection with our initial public offering, these warrants were fully exercised and converted into 19,000 shares of common stock.

During 1999, we issued warrants to purchase up to 3,000 shares of Series C convertible preferred stock, with an exercise price of \$4.50 per share expiring on the longer of 10 years from the date of issue or seven years from the date of our initial public offering, to a bank in connection with a credit arrangement. The value of these warrants, determined using the Black-Scholes Model, was not material. In May 2004, these warrants were fully exercised and converted into 1,517 shares of common stock. As of December 31, 2004, no Series C warrants were outstanding.

**NOTE 8 — CONVERTIBLE NOTES, LINES OF CREDIT AND WARRANTS**

In April 2003, we entered into a note and warrant purchase agreement pursuant to which convertible notes (the “Notes”) and warrants (the “Warrants”) were issued to existing preferred stockholders. We received \$4.3 million in cash in exchange for the Notes bearing interest at 8% per annum and the Warrants to purchase approximately 285,000 shares of Series E (or an equal number of shares of common stock if converted after a qualified public offering) for an exercise price of \$4.50 per share. In the event that certain initial public offering procedures occurred, as defined in the agreement, on or before August 22, 2003, and the initial public offering closed on or before October 22, 2003, the outstanding principal balance of the Notes would have automatically converted into common stock at a conversion price equal to the initial public offering price. If these events did not occur, the Notes would have automatically converted into Series E on October 22, 2003 at a conversion price of \$4.50 per share. We were required to pay any accrued interest on the Notes in cash at the time of any of the aforementioned conversions. The difference between the conversion price and the fair market value of the common stock on the commitment date (transaction date) resulted in a beneficial conversion feature recorded on the convertible debt of \$3.1 million. The Warrants were assigned an initial value of \$1.2 million, estimated using the Black-Scholes Model and have been classified as equity. The Warrants became exercisable upon stockholder approval, which was obtained in August 2003, and would have expired in five years. The following assumptions were used to determine the fair value of the Warrants using

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

the Black-Scholes Model: term of five years, risk free rate of 3.10%, volatility of 90% and a dividend yield of zero. The initial values assigned to both the Notes and the Warrants were allocated based on the relative fair values of the Notes and Warrants. The discount on the Notes for the beneficial conversion feature and Warrants were being amortized, using the effective interest method, to interest expense over the stated term of the Note, which was six months.

In connection with the line of credit facilities discussed below, on August 29, 2003 upon receipt of stockholder approval of an amended and restated certificate of incorporation authorizing shares of Series F preferred stock, pursuant to agreements we entered into with the holders of the Notes and Warrants, the Notes and the accrued interest thereon automatically converted into 978,000 shares of Series E at a conversion price of \$4.50 per share and the Warrants were cancelled. As a result, we recorded a loss of \$3.5 million, on the extinguishment of the Notes and cancellation of the Warrants, in the accompanying statement of operations for the year ended December 31, 2003.

In August 2003, we entered into two line of credit facilities for an aggregate of \$8.0 million with a financial institution. The first line of credit for \$3.0 million bore interest at the prime rate, and the second line of credit for \$5.0 million bore interest at prime plus one-half percent. Both line of credit facilities had a maturity date of December 6, 2003. In connection with the line of credit facilities, we entered into an agreement with a stockholder, who is also a member of the Board of Directors and acting as a guarantor on the line of credit facilities, to issue a warrant to the guarantor. The warrant is to purchase 533,333 shares of Series F convertible preferred stock at an exercise price of \$4.50 per share, which, upon the closing of the initial public offering became exercisable into 266,666 shares of common stock at an exercise price per share based on the initial public offering price per share. The aggregate fair value of the warrant was \$1.9 million, which was determined using the Black-Scholes Model with the following assumptions: term of 5 years, risk free rate of 3.43%, volatility of 90% and a dividend yield of zero. The warrant was recorded as a deferred guarantee cost and was being amortized on straight-line basis over the term of the line of credit. Total expense recognized relating to the amortization of the warrant was \$1.9 million for the year ended December 31, 2003. As of December 31, 2004, this warrant remains outstanding. The warrant expires in August 2008.

During October and November 2003, we repaid all outstanding debt under the two line of credit facilities. In November 2003, we terminated the two line of credit facilities. As a result, we recorded the remaining unamortized deferred guarantee costs of \$1.3 million to expense in the fourth quarter of 2003. As of December 31, 2004 and 2003, we had no borrowings other than the equipment capital lease described in Note 6.

**NOTE 9 — COMMON STOCK**

Our certificate of incorporation, as amended and restated, authorizes us to issue 65,000,000 shares of \$0.001 par value common stock. Certain shares issued are subject to a right of repurchase by us, subject to vesting, which is generally over a four-year period from the issuance date until vesting is complete.

See Note 1 regarding financing activity that occurred in 2004.

**NOTE 10 — STOCK OPTION PLANS AND OTHER EMPLOYEE BENEFITS**

*1996 Stock Option Plan*

The 1996 Stock Option Plan (the "1996 Plan") was adopted in November 1996 and provides for the issuance of stock options. The 1996 Plan will terminate in November 2006, unless our Board of Directors terminates the plan earlier. The 1996 Plan provides for the issuance of up to 1,665,500 shares of common stock upon the exercise of options under the plan. Options to purchase an aggregate of 590,274 shares of common

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

stock were outstanding under the 1996 plan as of December 31, 2004 (828,597 shares of common stock at December 31, 2003).

Stock options granted under the 1996 Plan may be either incentive stock options or nonstatutory stock options. Incentive stock options may be granted to employees with exercise prices of no less than fair value and nonstatutory options may be granted to employees, directors, or consultants at exercise prices of no less than 85% of the fair value of the common stock on the date of grant. If, at the time we grant an option, the optionee owns or is deemed to own stock possessing more than 10% of the total combined voting power of all classes of our capital stock, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the Board of Directors, which is generally four years, with 25% vesting upon the first anniversary of the grant date, and the balance vesting ratably each month over a thirty-six month period. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated.

Stock options granted under the 1996 Plan may include a provision whereby the holder may elect at any time while an employee, director, or consultant to exercise the option as to any part or all of the shares subject to the option prior to the full vesting of the option. Any unvested shares so purchased are subject to repurchase by us at the option exercise price. As of December 31, 2004, approximately 18,385 shares of common stock are subject to repurchase (84,000 shares of common stock at December 31, 2003).

***2003 Equity Incentive Plan***

The 2003 Equity Incentive Plan (the "Incentive Plan") was adopted in August 2003 and became effective upon the closing of the initial public offering. The Incentive Plan will terminate when our Board of Directors terminates the plan. The Incentive Plan provides for the grant of nonstatutory stock options, restricted stock awards, stock appreciation rights, phantom stock and other forms of equity compensation, which may be granted to employees, including officers, non-employee directors and consultants. The Incentive Plan provides for the issuance of 2,083,333 shares of common stock upon the exercise of options under the plan. Authorized shares shall be increased annually on January 1st from 2004 until 2013, by 5% of the number of shares of common stock outstanding on such date; however, our Board of Directors has the authority to designate a smaller number of shares. Options to purchase an aggregate of 813,899 shares of common stock were outstanding under the Incentive Plan as of December 31, 2004 (8,400 shares of common stock as of December 31, 2003). The shares reserved under the Incentive Plan were increased by 840,975 and 1,408,644 shares on January 1, 2004 and 2005, respectively, in accordance with the plan provisions as noted above.

Nonstatutory options may be granted at exercise prices of no less than 85% of the fair market value of the common stock, which is the closing sales price as quoted on the Nasdaq National Market on the last trading day prior to the date of grant. If, at the time we grant an option, the optionee owns or is deemed to own stock possessing more than 10% of the total combined voting power of all classes of our capital stock, the option price shall be at least 110% of the fair market value and shall not be exercisable more than five years after the date of grant. Options granted generally vest over four years, with 25% vesting upon the first anniversary of the grant date, and the balance vesting ratably each month over a thirty-six month period. Except as noted above, options expire no more than 10 years after the date of grant or earlier if employment is terminated.

***2003 Non-Employee Directors' Stock Option Plan***

The 2003 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") was adopted in August 2003 and became effective upon the closing of the initial public offering. The Directors' Plan provides for the automatic grant of nonstatutory stock options to purchase shares of common stock to our non-employee directors. The Directors' Plan provides for the issuance of 133,000 shares of common stock upon exercise of

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

options under the plan. Authorized shares shall be increased annually on January 1st from 2004 until 2013, by the number of shares of common stock subject to options granted during the prior calendar year, however, the Board of Directors has the authority to designate a smaller number of shares. Options to purchase an aggregate of 173,000 shares of common stock were outstanding under the Directors' Plan as of December 31, 2004 (125,000 shares of common stock as of December 31, 2003). The shares reserved under the Directors' Plan were increased by 125,000 and 74,000 shares on January 1, 2004 and 2005, respectively, in accordance with the terms of the plan as noted above.

Upon completion of the initial public offering, each non-employee director was automatically granted an option to purchase 25,000 shares of common stock, the initial grant. Any new non-employee director thereafter will automatically be granted the initial grant upon being elected to the board of directors. Each non-employee director will automatically be granted an option to purchase an additional 10,000 shares of common stock on the day following our annual stockholders meeting, the annual grant. Each non-employee director who has been a director for less than 12 months will receive an annual grant that has been reduced *pro rata* for each quarter prior to the date of grant during which such person did not serve as a non-employee director. On the day following the our annual stockholders meeting, each non-employee director will automatically be granted an option to purchase 1,000 shares of common stock for each committee of which they are a member.

Stock options under the Directors' Plan are granted at exercise prices equal to the fair market value of the common stock, which is the closing sales price as quoted on the Nasdaq National Market on the last trading day prior to the date of grant. Initial grants and annual grants vest in 36 equal monthly installments over three years. Committee option grants vest in 12 equal monthly installments over one year from the grant date. No option granted under the directors' plan may be exercised after the expiration of ten years from the date it was granted.

***Stock-based Compensation***

During the years ended December 31, 2003 and 2002, we issued stock options under the plans at exercise prices below the deemed fair value of our common stock at the date of grant. Accordingly, for stock options issued to employees, we have recorded deferred stock-based compensation representing the difference between the deemed value of the common stock for accounting purposes and the option price at the date of the option grant. This deferred stock-based compensation is presented as a reduction of stockholders' equity and is amortized to expense over the vesting period, which is generally four years. For the years ended December 31, 2004, 2003 and 2002, we amortized and expensed \$1.0 million, \$1.7 million and \$1.2 million, respectively. Compensation expense is decreased in the period of forfeiture for any accrued but unvested compensation arising from the early termination of an option holder's services. For stock options issued to non-employees, generally for services, the estimated fair value of the options was determined using the Black-Scholes Model. As the non-employee fulfills the terms of the option relating to the continued service to us, we revalue the remaining unvested options, with the changes in fair value from period to period being recognized through compensation expense.

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

Our stock option activity is as follows (in thousands, except per share data):

	Options Outstanding	
	Number of Shares	Weighted Average Exercise Price per Share
Options granted .....	13	\$ 0.15
<b>Balances at December 31, 1996</b> .....	13	\$ 0.15
Options granted .....	159	\$ 0.21
Options exercised .....	(10)	\$ 0.15
Options canceled .....	(89)	\$ 0.15
<b>Balances at December 31, 1997</b> .....	73	\$ 0.28
Options granted .....	85	\$ 0.51
Options canceled .....	(5)	\$ 0.50
<b>Balances at December 31, 1998</b> .....	153	\$ 0.40
Options granted .....	77	\$ 0.60
Options exercised .....	(2)	\$ 0.45
Options canceled .....	(3)	\$ 0.47
<b>Balances at December 31, 1999</b> .....	225	\$ 0.47
Options granted .....	213	\$ 1.08
Options exercised .....	(10)	\$ 0.21
Options canceled .....	(6)	\$ 0.60
Options expired .....	(1)	\$ 0.60
<b>Balances at December 31, 2000</b> .....	421	\$ 0.78
Options granted .....	258	\$ 1.20
Options exercised .....	(365)	\$ 0.88
Options canceled .....	(69)	\$ 0.66
Options expired .....	(34)	\$ 0.71
<b>Balances at December 31, 2001</b> .....	211	\$ 1.18
Options granted .....	396	\$ 1.49
Options exercised .....	(171)	\$ 1.19
Options canceled .....	(39)	\$ 1.21
Options expired .....	(2)	\$ 1.20
<b>Balances at December 31, 2002</b> .....	395	\$ 1.48
Options granted .....	767	\$ 4.28
Options exercised .....	(99)	\$ 1.79
Options canceled .....	(99)	\$ 1.95
Options expired .....	(2)	\$ 1.73
<b>Balances at December 31, 2003</b> .....	962	\$ 3.66
Options granted .....	907	\$10.26
Options exercised .....	(89)	\$ 1.91
Options canceled .....	(198)	\$ 4.50
Options expired .....	(5)	\$12.26
<b>Balances at December 31, 2004</b> .....	<u>1,577</u>	\$ 7.42

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

Additional information regarding stock options outstanding under our stock option plans as of December 31, 2004 is as follows (in thousands, except per share data):

Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life/Years	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 0.00 – \$ 1.59 .....	90	6.8	\$ 1.17	81	\$ 1.17
\$ 1.59 – \$ 3.17 .....	492	8.2	\$ 2.42	214	\$ 2.27
\$ 3.17 – \$ 4.76 .....	8	8.8	\$ 4.50	2	\$ 4.50
\$ 4.76 – \$ 9.52 .....	118	9.4	\$ 9.12	16	\$ 9.02
\$ 9.52 – \$11.11 .....	598	9.5	\$ 9.80	40	\$ 9.73
\$11.11 – \$12.70 .....	196	9.0	\$12.25	43	\$12.43
\$12.70 – \$14.28 .....	75	9.9	\$13.88	—	\$ 0.00
	<u>1,577</u>	8.9	\$ 7.42	<u>396</u>	\$ 4.18

At December 31, 2003, we had 173,000 options exercisable at a weighted average exercise price of \$1.97 per share.

***2003 Employee Stock Purchase Plan***

The 2003 Employee Stock Purchase Plan (the “ESPP”) was adopted in August 2003 and became effective upon the closing of the initial public offering. The Board of Directors may suspend or terminate the ESPP at any time. Unless terminated earlier, the ESPP shall terminate at the time that all of the shares of common stock reserved for issuance under the plan have been issued under the terms of the plan. The ESPP provides for the issuance of 100,000 shares of common stock under the plan. Authorized shares shall be increased on the first day of our fiscal year, from 2004 until 2023, by the lesser of 166,666 shares or 1.5% of the number of shares of common stock outstanding on that date, however, our Board of Directors has the authority to designate a smaller number of shares by which the authorized number of shares of common stock will be increased on that date. The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. As of December 31, 2004, 56,883 shares of common stock had been purchased under the ESPP (no shares were purchased as of December 31, 2003). The shares reserved under the ESPP were increased by 166,666 and 166,000 shares on January 1, 2004 and 2005 in accordance with the terms of the plan as noted above.

The ESPP permits employees to purchase our common stock through payroll deductions of up to 15% of the participant’s earnings, or through a single lump sum cash payment in the case of the first offering period, subject to a maximum annual contribution of \$25,000. The first offering began on the effective date of the initial public offering and will be approximately 24 months in duration with purchases occurring every six months. The ESPP contains successive six-month offering periods and the price of common stock purchased under the ESPP is equal to the lower of 85% of the fair market value of a share of our common stock at the beginning of the offering period or at the end of the offering period.

***401(k) Savings Plan***

On January 1, 1998, we began a 401(k) savings plan (the “401(k) plan”). The 401(k) plan is a defined contribution plan intended to qualify under Section 401(a) and 401(k) of the Internal Revenue Code. All of our full-time and eligible part-time employees are eligible to participate pursuant to the terms of the 401(k) plan. Contributions by us are discretionary and we have not made any contributions for all periods presented.

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

**NOTE 11 — INCOME TAXES**

For financial reporting purposes, "Net loss" includes the following components for the years ended December 31, 2004, 2003, and 2002 (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Domestic .....	\$(27,026)	\$(30,463)	\$(19,864)

A reconciliation of income taxes at the statutory federal income tax rate to net income taxes included in the accompanying statements of operations is as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
U.S. federal taxes (benefit) at statutory rate .....	\$(9,189)	\$(10,357)	\$(6,754)
Unutilized (utilized) net operating losses .....	9,002	8,207	6,278
Stock-based compensation .....	178	646	464
Loss on extinguishment of convertible notes .....	—	1,496	—
Other .....	9	8	12
Total .....	\$ —	\$ —	\$ —

As of December 31, 2004, we have federal net operating loss carryforwards of approximately \$85.1 million, which expire beginning in the year 2011, if not utilized. We have state net operating losses carryforwards of approximately \$13.1 million which expire beginning in 2005, if not utilized. We also have federal and state research and development tax credit carryforwards of approximately \$2.6 million and \$2.7 million, respectively. The federal research and development tax credits will begin to expire in the year 2011 and state research and development tax credits have no expiration date. We also have a California Manufacturers' Investment Credit of \$0.1 million which will begin to expire in 2006.

Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to an ownership change as provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2004	2003
<b>Deferred tax assets:</b>		
Net operating loss carryforwards .....	\$ 29,703	\$ 20,327
Capitalized research .....	4,146	2,898
Research credits .....	4,468	2,656
Other .....	672	584
Total deferred tax assets .....	38,989	26,465
Valuation allowance .....	(38,989)	(26,465)
Net deferred tax assets .....	\$ —	\$ —

**GENITOPE CORPORATION**  
**(A DEVELOPMENT STAGE ENTERPRISE)**

**NOTES TO THE FINANCIAL STATEMENTS — (Continued)**

Realization of deferred tax assets is dependent upon future earnings. Management believes that, given our historical cumulative losses and the uncertainty regarding future profitability, it is more likely than not that the deferred tax assets will not be utilized. Accordingly, a full valuation allowance has been recorded for all periods presented. The change in the valuation allowance was \$12.5 million, \$10.6 million and \$8.2 million for the years ended December 31, 2004, 2003 and 2002, respectively.

**NOTE 12 — QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following table presents certain unaudited quarterly financial information for the eight quarters ended December 31, 2004. In management's opinion, this information has been prepared on the same basis as the audited financial statements and includes all adjustments necessary to present fairly the unaudited quarterly results of operations set forth herein.

<u>2004</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
	(In thousands, except per share data)			
Net loss attributable to common stockholders . . . . .	<u>\$ (6,654)</u>	<u>\$ (6,779)</u>	<u>\$ (6,744)</u>	<u>\$ (6,849)</u>
Basic and diluted net loss per share attributable to common stockholders . . . . .	<u>\$ (0.40)</u>	<u>\$ (0.37)</u>	<u>\$ (0.28)</u>	<u>\$ (0.28)</u>
Shares used in computation of basic and diluted net loss per share . . . . .	<u>16,762</u>	<u>18,562</u>	<u>23,852</u>	<u>24,165</u>
<u>2003</u>	<u>First Quarter</u>	<u>Second Quarter(1)</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
	(In thousands, except per share data)			
Net loss attributable to common stockholders . . . . .	<u>\$ (5,134)</u>	<u>\$ (24,941)</u>	<u>\$ (10,495)</u>	<u>\$ (8,300)</u>
Basic and diluted net loss per share attributable to common stockholders . . . . .	<u>\$ (2.89)</u>	<u>\$ (13.74)</u>	<u>\$ (5.62)</u>	<u>\$ (0.89)</u>
Shares used in computation of basic and diluted net loss per share . . . . .	<u>1,779</u>	<u>1,815</u>	<u>1,866</u>	<u>9,313</u>

(1) For the year ended December 31, 2003, we recorded a non-cash dividend of \$18.4 million related to the issuance of convertible preferred shares and the beneficial conversion feature of preferred stock.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

Under the supervision and with the participation of our management, including our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), we conducted an evaluation of our “disclosure controls and procedures”, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of December 31, 2004.

*Management’s Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management, including our CEO and CFO, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004. In making our evaluation, we used the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in *Internal Control — Integrated Framework*.

Based on our evaluation, under the framework set forth by the COSO in *Internal Control — Integrated Framework*, we concluded that, as of December 31, 2004, our internal control over financial reporting was effective. Our assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Our management, including our CEO and CFO, acknowledge that because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

*Changes in Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Information required by this item concerning our directors will be contained under the captions “Election of Class I Directors” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement with respect to our 2005 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of our fiscal year ended December 31, 2004 (the “Proxy Statement”), and is hereby incorporated by reference thereto. Certain information required by this item concerning our executive officers is contained in this Annual Report on Form 10-K under Item 1. Business — Executive Officers of the Registrant. Certain

additional information required by this item concerning our executive officers will be contained under the captions “Executive Officers and Key Employees,” “Executive Compensation” and “Section 16(a) Beneficial Ownership Reporting Compliance” in the Proxy Statement and is hereby incorporated by reference thereto.

Information concerning our code of business conduct and ethics is contained in this Annual Report on Form 10-K under Item 1. Business — Available Information.

#### **ITEM 11. EXECUTIVE COMPENSATION**

Information required by this item will be contained in the Proxy Statement under the caption “Executive Compensation” and is hereby incorporated by reference thereto.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information required by this item will be contained in the Proxy Statement under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” and is hereby incorporated by reference thereto.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Information required by this item will be contained in the Proxy Statement under the caption “Certain Transactions,” and is hereby incorporated by reference thereto.

#### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Information required by this item will be contained in the Proxy Statement under the caption “Principal Accountant Fees and Services” and is hereby incorporated by reference thereto.

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for disclosing the non-audit services approved by our Audit Committee to be performed by PricewaterhouseCoopers LLP, our independent registered public accounting firm. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. In the period covered by this report, our Audit Committee pre-approved all work required to be performed by PricewaterhouseCoopers LLP in connection with preparing and giving consents required to be given in connection with our filings with the Securities and Exchange Commission, a non-audit service currently being rendered, or to be rendered, to us by PricewaterhouseCoopers LLP.

**PART IV**

**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are being filed as part of this annual report:

(1) *Financial Statements.* The following financial statements of Genitope Corporation and the Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm, are included in Part II, Item 8:

	<u>Page #</u>
Report of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm . . . . .	53
Balance Sheets . . . . .	55
Statements of Operations . . . . .	56
Statements of Stockholders' Equity (Deficit) . . . . .	57
Statements of Cash Flows . . . . .	61
Notes to the Financial Statements . . . . .	63

(2) *Financial Statement Schedules.* All financial statement schedules are omitted because the information is inapplicable or presented in the Notes to the Financial Statements.

(3) *Exhibits.* The items listed on the Index to Exhibits on pages 83 through 84 are incorporated herein by reference.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Redwood City, State of California, on March 16, 2005.

### GENITOPE CORPORATION

By: /s/ Dan W. Denney, Jr.

Dan W. Denney, Jr.  
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints DAN W. DENNEY JR., PH.D. AND JOHN M. VUKO, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, 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 report on Form 10-K, 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 in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K has been signed by the following persons on behalf of the Registrant and of the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Dan W. Denney, Jr.</u> Dan W. Denney, Jr.	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 16, 2005
<u>/s/ John M. Vuko</u> John M. Vuko	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	March 16, 2005
<u>/s/ Gordon D. Denney</u> Gordon D. Denney	Director	March 16, 2005
<u>/s/ Gregory Ennis</u> Gregory Ennis	Director	March 16, 2005
<u>/s/ Stanford C. Finney</u> Stanford C. Finney	Director	March 16, 2005
<u>/s/ Ronald Goode</u> Ronald Goode	Director	March 16, 2005
<u>/s/ William A. Hasler</u> William A. Hasler	Director	March 16, 2005

## INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of Genitope Corporation.(1)
3.2	Amended and Restated Bylaws of Genitope Corporation.(1)
4.1	Specimen Common Stock Certificate.(1)
4.2	Investor Rights Agreement, dated August 29, 2003, by and among Registrant and certain investors named therein.(1)
4.3	Series F Warrant, dated August 29, 2003, between the Registrant and Stanford C. Finney.(1)
10.1	Form of Indemnity Agreement entered into by Registrant with each of its directors and certain executive officers.(1)
10.2*	1996 Stock Option Plan and form of related agreements.(1)
10.3*	2003 Equity Incentive Plan and Form of Stock Option Agreement under the 2003 Equity Incentive Plan.(1)
10.4*	2003 Non-Employee Directors' Stock Option Plan and Form of Nonstatutory Stock Option Agreement under the 2003 Non-Employee Directors' Stock Option Plan.(1)
10.5*	2003 Employee Stock Purchase Plan and Form of 2003 Employee Stock Purchase Plan Offering.(1)
10.6	Sublease, dated August 3, 1999, between Regen Biologics, Inc. and the Registrant.(1)
10.7	Second Amendment to Sublease, dated October 1, 2000, between Regen Biologics, Inc. and the Registrant.(1)
10.8	Third Amendment to Sublease, dated May 16, 2003, between Regen Biologics, Inc. and the Registrant.(1)
10.9	Lease, dated April 10, 1996, between Metropolitan Life Insurance Company and Regen Biologics, Inc.(1)
10.10	Sublease, dated July 7, 2001, between Openwave Systems, Inc. and the Registrant.(1)
10.11	First Amendment to Sublease, dated January 1, 2003, between Openwave Systems, Inc. and the Registrant.(1)
10.12	Lease, dated January 21, 2000, between Phone.com, Inc. and Metropolitan Life Insurance Company.(1)
10.13	Sublease, dated as of June 22, 1997, between Genelabs Technologies, Inc. and the Registrant.(1)
10.14	Fourth Amendment to Sublease Agreement, dated November 1, 2002, between Genelabs Technologies, Inc. and the Registrant.(1)
10.15	Industrial Net Lease, dated July 29, 1986, between Lincoln Property Company N.C., Inc. and Genelabs Technologies, Inc.(1)
10.16**	Supply Agreement, dated December 9, 1998, between the Registrant and biosyn Arzneimittel GmbH, and Amendment to Supply Agreement, dated March 25, 2000.(1)
10.17	Loan Agreements, dated July 28, 2003, by and among the Registrant, Stanford C. Fiancy and Bank One. N.A., as amended by Omnibus Addendum to Promissary Notes and Related Agreements, dated August 1, 2003,(1)
10.18*	Salary Information for Executive Officers
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (contained on signature page).
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification by the Chief Executive Officer and the Chief Financial Officer of Genitope Corporation, as required by Rule 13a-14(b) or 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.1350)

---

\* Management contract or compensatory plan.

\*\* Confidential treatment granted for certain omitted portions of this exhibit.

- (1) Filed as an Exhibit to Genitope Corporation's Registration Statement on Form S-1 (File No. 333-107719), as filed with the Securities and Exchange Commission on August 6, 2003, as amended, and incorporated herein by reference.

# Corporate and Stockholder Information

## Management Team

Dan W. Denney, Jr., Ph.D.  
*Founder, Chairman and Chief Executive Officer*

Mike Buckley, Ph.D.  
*Vice President, Manufacturing*

Steve Chamow, Ph.D.  
*Vice President, Process Sciences*

Bonnie Charpentier, Ph.D.  
*Vice President, Regulatory Affairs*

Thomas DeZao  
*Vice President, Strategic Marketing and Sales*

Diane Ingolia, J.D., Ph.D.  
*Vice President, Technical Development and Intellectual Property Counsel*

Claude Miller  
*Vice President, Quality*

David Miller  
*Vice President, Information Technology*

Thomas Theriault, Ph.D.  
*Vice President, Research and Development*

John Yuko  
*Vice President, Finance and Chief Financial Officer*

Laura Randall Woodhead  
*Vice President, Legal Affairs and Secretary*

## Board of Directors

Dan W. Denney, Jr., Ph.D.  
*Founder, Chairman and Chief Executive Officer*

Gordon D. Denney  
*Director, Head of Special Projects and Internal Audits for the Board of Directors, Tom James Company*

Gregory Ennis  
*Director, Managing Director of Peninsula Equity Partners, LLC.*

Stanford C. Finney  
*Director, Chief Executive Officer of Spyglass Trading, L.P.*

Ronald Goode, Ph.D.  
*Director, Retired Pharmaceutical Executive*

William A. Hasler  
*Director, Retired Executive and Dean Emeritus*

## Legal Counsel

Cooley Godward LLP  
Five Palo Alto Square  
3000 El Camino Real  
Palo Alto, CA 94306

## Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP  
10 Almaden Boulevard  
Suite 1600  
San Jose, CA 95113

## Corporate Headquarters

Genitope Corporation  
525 Penobscot Drive  
Redwood City, CA 94063  
T: 650.482.2000  
F: 650.482.2002  
www.genitope.com

## Transfer Agent & Registrar

Mellon Investor Services LLC  
P.O. Box 3315  
South Hackensack, NJ 07606  
T: 1.800.301.3485  
T-International: 1.201.329.8660  
www.melloninvestor.com/isd

## Investor Relations

Genitope Corporation welcomes inquiries from stockholders and other interested investors. Additional copies of this report can be obtained by contacting Investor Relations.  
T: 650.482.2000  
ir@genitope.com  
ir.genitope.com

## Annual Meeting

All stockholders are cordially invited to attend the Annual Meeting of Stockholders, held on June 6, 2005 at 1:00 pm at our corporate headquarters.

## Stock Listing

The NASDAQ Stock Market®  
Ticker Symbol: GTOP

## Forward Looking Statements

This annual report contains "forward-looking" statements, including without limitation all statements related to the progress of our clinical trials and research programs, the leasing of a commercial manufacturing and corporate headquarters facility, the sufficiency of our cash resources, the timing of the immunization of the last patient registered in the Phase 3 clinical trial and the timing of the initiation of the first and second interim analyses of the data from our Phase 3 clinical trial. These forward-looking statements are generally identified by words such as "believes," "anticipates," "plans," "expects," "will," "intends" and other similar words and expressions. These forward-looking statements are based upon our current expectations. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the progress, timing and results of our clinical trials, difficulties or delays in obtaining regulatory approval, manufacturing of MyVax® Personalized Immunotherapy, intellectual property matters, competition from other pharmaceutical or biotechnology companies, risks of growth and dependence on key personnel and other risks detailed in our filing with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2004. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward looking statements are qualified in their entirety by this cautionary statement, and Genitope undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.



**Genitope Corporation**  
**525 Penobscot Drive**  
**Redwood City, CA 94063**  
**T 650.482.2000**  
**F 650.482.2002**  
**[www.genitope.com](http://www.genitope.com)**