

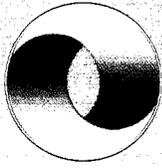


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GENELABS  
TECHNOLOGIES, INC.

## Dear Shareholders

I want to extend my thanks to all of the Genelabs' shareholders for your dedication and support as we continue to make progress on our corporate goals of both discovering and developing new pharmaceutical products that have the potential to improve human health.

During 2005, our drug discovery team again demonstrated progress seeking to discover new compounds designed to combat infection with the hepatitis C virus (HCV). Of our three distinct HCV programs, two target the HCV polymerase and one targets a different HCV protein that is also essential for viral replication, known as HCV NS5a. We believe that compounds that directly stop the virus from replicating, as an alternative to current treatments that enhance immune response, can be effective treatments for the infection in people with the virus. We further believe that future treatment of HCV infections will likely involve combinations of antiviral drugs that are safer and more potent than the drugs available today, to improve patient response and to overcome potential resistance that may be encountered in treating HCV. As a consequence, our three programs have the potential to be complementary in a multi-drug treatment regimen.

Throughout the year our scientists continued to work with Gilead Sciences, Inc., under our collaboration on nucleoside compounds that function through the HCV polymerase, becoming incorporated into the HCV genome in a manner that prevents completion of its replication. Outside of this collaboration, we advanced within preclinical development two non-nucleoside compounds, which function by directly binding to the HCV polymerase, preventing it from replicating the HCV genome in our in vitro assays. These two non-nucleoside compounds come from distinct chemical classes, so they both have separate potential to treat infection with the virus, and we are in the process of scale-up manufacturing to make GMP-grade material that would enable us to conduct the studies needed to file an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA). In our more recently initiated HCV discovery program directed at synthesizing compounds that function by interacting with an HCV protein called NS5a, we have identified a number of compounds with potent inhibition of HCV replication in our cell-based assays. We are in the process of optimizing these small molecule compounds to minimize the toxicity, increase the oral bioavailability, and increase the circulatory half-life, as we have done with our non-nucleoside compounds.

Hepatitis C causes serious, chronic liver disease and is the most common cause of liver transplantation in the United States. Worldwide, it is estimated that 170 million people have been infected with HCV. There is a tremendous and urgent need for improved drugs to treat HCV and we at Genelabs are extremely proud of the progress that has been made in our programs targeting this virus.

In addition to our drug discovery efforts, Genelabs has been dedicated to the development of an investigational new drug for lupus. Lupus is a severe and debilitating disease for which new treatments are clearly needed. Our goal is to develop Prestara™ as a broadly-applicable, oral treatment for women suffering from the effects of lupus. In 2005 we completed an open-label study of Prestara in which we saw a beneficial effect on lupus patients' bone mineral density for the group of patients receiving 200 mg per day of Prestara. We subsequently met with the FDA to discuss the results of this open-label clinical trial, along with our earlier double-blind trial measuring bone mineral density which did not show statistical significance in favor of Prestara. The FDA indicated that an additional, adequate, well-controlled phase III clinical trial would be necessary to support an indication for the treatment of the signs and symptoms of lupus. Please remember we already have one positive, adequate, well-controlled clinical trial of Prestara in lupus, Study 95-02, which measured stabilization or improvement in certain patients with mild-to-moderate systemic lupus erythematosus. Following the recent FDA meeting, we have concluded that the most viable path forward for Prestara would be to focus on lupus signs and symptoms rather than bone mineral density in patients with lupus. We are nearing completion of the design of the additional trial the FDA is requiring, and are simultaneously evaluating funding alternatives for the trial, as we only plan to conduct the trial if sufficient project-based funding is available from a third party.

Finally, I'd like to acknowledge with pride the dedicated employees at Genelabs, all of whom are focused on our goals of discovering and developing new drugs to combat serious diseases.



**James A. D. Smith**  
President and Chief Executive Officer  
April 28, 2006

NOTE: This letter contains forward-looking statements regarding the progress of our HCV programs and the development of Prestara, which are subject to uncertainties and risks that could cause actual results to differ materially from the statements made. Please read the information in our enclosed Annual Report on Form 10-K, and our other filings with the Securities and Exchange Commission, for further information on these uncertainties and risks.

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

Form 10-K

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

For the fiscal year ended December 31, 2005

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 0-19222

**Genelabs Technologies, Inc.**

(Exact name of registrant as specified in its charter)

California  
(State or other jurisdiction of  
incorporation or organization)

94-3010150  
(I.R.S. Employer  
Identification No.)

505 Penobscot Drive,  
Redwood City, California  
(Address of principal executive offices)

94063  
(Zip Code)

Registrant's telephone number, including area code  
(650) 369-9500

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:  
Common Stock  
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):  
Large accelerated filer  Accelerated filer  Non-accelerated filer

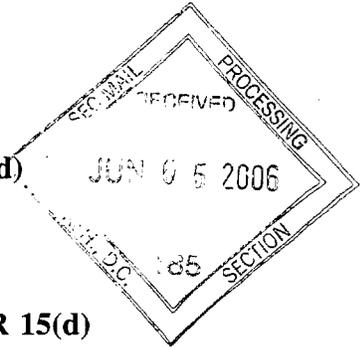
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

Aggregate market value of Common Stock held by non-affiliates of the registrant, as of June 30, 2005: \$43,950,000 based on the last reported sales price on the Nasdaq National Market.

Number of shares of registrant's Common Stock outstanding on March 15, 2006: 17,817,649

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement for its 2006 Annual Meeting of Shareholders to be held on June 16, 2006 are incorporated by reference into Part III (Items 10, 11, 12, 13 and 14) hereof.



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## FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains certain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, referred to as the Exchange Act, which are subject to the “safe harbor” created therein, including those statements which use any of the words “may,” “will,” “anticipates,” “estimates,” “intends,” “believes,” “expects,” “plans,” “potential,” “seeks,” “goal,” “objective,” and similar expressions. These forward-looking statements include, among others, statements regarding:

- our ability to secure sufficient funds to continue as a going concern;
- estimates that existing cash resources will be adequate to provide liquidity for our regular operations to approximately the beginning of the fourth quarter of 2006;
- our future cash resources, expenditures and our ability to obtain additional funding for our business plans; and
- plans, programs, progress, and potential success regarding our research efforts, including our ability to identify compounds for preclinical development and the success of any such preclinical development efforts in our hepatitis C and other research programs;
- plans, programs, progress, and potential success regarding our collaborators and licensees, including Gilead Sciences, Inc. for nucleoside compounds against hepatitis C virus, GlaxoSmithKline for hepatitis E vaccine, and, for Prestara, Watson Pharmaceuticals, Inc., Genovate Biotechnology Co., Ltd., and Tanabe Seiyaku Co., Ltd.;
- our ability, or our collaborators’ ability, to achieve any of the milestones contained in our agreements;
- further actions or developments relating to Prestara™ (prasterone), our investigational drug for lupus, and its New Drug Application;
- the securing and defense of intellectual property rights important to our business.

All statements in this annual report on Form 10-K that are not historical are forward-looking statements and are subject to risks and uncertainties, including those set forth in the Risk Factors section in Item 1A. Among these are the risks that we may not be able to raise sufficient funds to continue operations, that we may be delisted from the Nasdaq Capital Market, that problems with our manufacturers or collaborators may negatively impact their or our research, clinical trials or product manufacture, development or marketing, that our research programs may fail, that our attempts to license our technologies to others may fail and that clinical trials of Prestara™ or similar formulations of prasterone are abandoned, delayed, or have results that are negative, inconclusive or not usable to support regulatory approval, that the FDA and foreign authorities may delay or deny approval of Prestara™. These as well as other factors may also cause actual results to differ materially from those projected and expressed or implied in these statements. We assume no obligation to update any such forward-looking statement for subsequent events. The risks and uncertainties under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained herein, among other things, should be considered in evaluating our prospects and future financial performance. All forward-looking statements included in this annual report on Form 10-K are made as of the date hereof.

### **Corporate History, Headquarters and Website Information**

We were incorporated in California in 1985. Our principal executive offices are located at 505 Penobscot Drive, Redwood City, California 94063, and our main telephone number is (650) 369-9500. Investors can obtain access to this annual report on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K and all amendments to these reports, free of charge, on our website at [www.genelabs.com](http://www.genelabs.com) as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

We also make available on our website our Code of Business Ethics and Conduct, the charters of the Audit Committee, Compensation Committee and Nominating Committee of our Board of Directors, our policy on Shareholder Communications to the Board of Directors and our whistleblower procedures. The information contained on our website, or on other websites linked from our website, is not part of this report.

## PART I

### Item 1. *Business.*

#### Overview

Genelabs Technologies, Inc., referred to as Genelabs or the Company, is a biopharmaceutical company engaged in the discovery and development of pharmaceutical products to improve human health. Our business objective is to develop a competitive advantage by focusing on drug targets for which we can rapidly optimize lead compounds, with the goal of developing drugs with significant market potential. In our drug discovery programs, which are presently concentrated on new treatments for infection with the hepatitis C virus, or HCV, we seek to identify compounds that have a distinct advantage over potential competitive compounds in potency, safety, and/or pharmacokinetic properties, with a goal of achieving "best-in-class" status. In addition, two separate development-stage projects have the potential to achieve "first-in-class" status: Prestara™ (prasterone), an investigational drug for systemic lupus erythematosus, referred to as SLE or lupus, and an investigational vaccine for hepatitis E virus, or HEV, that is being developed by GlaxoSmithKline under a license from us.

The goal of our current drug discovery programs is to discover novel antiviral compounds for treatment of HCV, a disease which chronically infects 2.7 million people in the United States and for which there is a major need for new treatments. Beginning in early 2002, Genelabs initiated work on two projects directed at inhibiting HCV infections by targeting the viral specific enzyme, HCV RNA-dependent RNA polymerase, also known as NS5b or HCV polymerase. In one of these projects we have employed a class of compounds known as nucleoside analogues that can interfere with HCV polymerase activity so that the polymerase makes incomplete copies of the HCV virus genome. The second polymerase project uses a different class of chemicals, referred to as non-nucleosides, designed to directly bind to the HCV polymerase and prevent the polymerase from properly functioning. During 2005, Genelabs continued drug discovery and development work on compounds from both projects and discovered a new class of non-nucleoside compounds that demonstrated an even greater level of potency in cell-based models than a preclinical development compound that we identified earlier. We conduct our work in the nucleoside program under a research collaboration and license agreement with Gilead Sciences, Inc. that we entered into in 2004. Gilead currently funds Genelabs' HCV polymerase nucleoside discovery research and is responsible for preclinical development activities on the nucleoside project. Genelabs currently is conducting discovery and preclinical development activities on its HCV non-nucleoside polymerase project without a corporate partner, although we may ultimately enter into a collaboration with another company that has more resources than Genelabs. In 2005, we initiated a project to screen and optimize compounds directed against another HCV target, NS5a.

Genelabs also has pursued regulatory approval of an investigational drug for women with systemic lupus erythematosus. This compound is a form of prasterone which we call Prestara™. No new drug has been approved in the United States for treatment of SLE in well over 40 years and current therapies are not adequate. Although the most recent of Genelabs' Phase III clinical trials of Prestara did not meet its primary endpoint, the U.S. Food and Drug Administration, or FDA, has indicated that they may review a New Drug Application, or NDA, for treating the signs and symptoms of lupus based on an additional, positive phase III clinical trial that meets their criteria.

In addition to these primary programs focused on drug discovery and development, we have established a portfolio of patents and patent applications based on inventions arising from our other research and development activities. We have granted licenses to third parties under our intellectual property portfolio, including under patents covering the hepatitis E virus, hepatitis G virus and a nucleic acid amplification technology known as LADA, and we may seek to grant additional licenses under these or other patents we own.

On March 15, 2006, Genelabs had cash, cash equivalents and restricted cash of approximately \$8.3 million, which we expect can sustain existing operations only into the beginning of the fourth quarter of 2006. As a result, there is substantial doubt as to the ability of Genelabs to continue as a going concern absent a substantial increase in cash from a new corporate partnership or sale of equity securities. In addition, Genelabs does not currently satisfy the listing requirements of the Nasdaq Capital Market, requiring a minimum shareholder's equity balance and/or market capitalization level, which could result in the delisting of Genelabs from that exchange.

## Drug Discovery Research

Genelabs' core research capabilities include medicinal chemistry, combinatorial chemistry, computational modeling, molecular biology, assay development and high-throughput screening, drug metabolism and pharmacokinetics. For the past several years, HCV has been the primary focus of our drug discovery efforts. In the future we may seek to expand our drug discovery efforts to encompass additional targets. Genelabs' research concentrates on small molecules, which can be administered orally and which generally are relatively simpler to manufacture than larger biological molecules such as peptides, antibodies or proteins.

*Drug Discovery Process.* Genelabs' drug discovery strategy focuses on screening for compounds that affect biological targets which previously have been shown to be useful in controlling disease activity, and then optimizing the pharmacologic properties of those compounds by systematically making changes in the original compound and testing for improved properties. We choose targets for diseases where there is a large unmet medical need which can be addressed by the kinds of chemical compounds with which we have experience. These targets generally are for infectious disease, such as the hepatitis C virus, where we have substantial prior experience, but future targets may involve other diseases.

Generally, we begin by establishing tests, or assays, to screen potential drug candidates that may have activity against the target. Thousands of compounds may be evaluated using high-throughput screening techniques to identify suitable starting compounds. Using these starting compounds, a systematic process is then conducted to optimize the compounds to develop lead compounds which have the potency, pharmacokinetic properties, toxicity profile, manufacturability, patentability and other characteristics to be good drug candidates. The optimization process is tasked to a team of scientists comprised of both chemists and biologists. This team is focused on synthesizing variations of the starting compounds, testing them in assays, and analyzing the resulting data. The analysis adds to our understanding of structure-activity relationships, which are used to strategize further modifications to the compounds. This cycle then is repeated. During this process, we benchmark our compounds against known competitors with the objective of optimizing our compounds so they have an advantage in potency, safety and/or other pharmaceutical properties.

If the optimization program is successful in synthesizing a compound meeting our pre-determined criteria, it is advanced into early pre-clinical development to develop further data on pharmacokinetics and toxicity, and to further optimize the process of synthesizing the compound. If such data are positive, Genelabs may continue development into the formal pre-clinical phase which involves tests meeting Good Laboratory Practices, or GLP, standards of the FDA. If this data is positive, Genelabs may seek to file an Investigational New Drug Application, or IND, and begin human clinical trials. Because the risk is high that a compound may fail in pre-clinical or clinical testing, Genelabs continues the optimization process in order to discover and develop additional compounds that may meet the pre-determined criteria. At any stage of development, Genelabs may seek to out-license the compound, or the program under which it has been developed, to a pharmaceutical or larger biotechnology company, which could then take over the development process. Alternatively, Genelabs may elect to retain development of promising compounds in order to seek to realize additional value, although further development involves risk that the compounds may fail due to toxicity, lack of efficacy or other reasons.

*Hepatitis C Virus.* HCV is an infectious and potentially fatal virus that can be contracted through blood and bodily fluid contact. The virus attacks the liver and can cause liver inflammation, and eventually liver scarring, liver failure and liver cancer. In most cases, the body is not able to fight off the infection and the infected individual becomes a chronic carrier of HCV. Most people with chronic HCV infection have no symptoms for many years and are unaware that they carry this potentially deadly virus. Because they are asymptomatic carriers, these infected people can unknowingly infect others. According to the World Health Organization, as many as 170 million people worldwide have chronic HCV infection, of which 5 to 10 million are in Europe. The United States Centers for Disease Control and Prevention, or CDC, estimates that approximately 2.7 million people in the U.S. are chronically infected with HCV. According to the CDC, each year in the United States approximately 25,000 people become newly infected with HCV and approximately 8,000 to 10,000 people die from complications of hepatitis C. Liver failure resulting from chronic HCV infection is now recognized as the leading cause of liver transplantation in the United States.

Currently, there is no approved vaccine to prevent hepatitis C. The standard of care for treatment of HCV is a combination of interferon alfa-2 and the nucleoside analogue ribavirin, typically given over a number of months, with interferon injected once weekly and ribavirin given orally once daily. This treatment regimen is only effective in approximately half of the patients infected with HCV genotype 1, the genotype most prevalent in the United States. The interferon/ribavirin treatment has significant toxicities, most importantly severe anemia and psychiatric effects. There are no other drugs or biologics approved by the FDA for treatment of HCV. As a consequence, the pool of patients who are unresponsive to the currently approved treatment continues to grow each year.

Because a significant need exists for improved treatment options, Genelabs believes the future market for HCV drugs will be large. Because of the significant market potential and unmet medical need, Hoffmann La-Roche and Schering-Plough Corporation, who are manufacturers of currently approved HCV drugs, along with other pharmaceutical companies such as Merck & Co., Inc. and Boehringer Ingelheim GmbH, biotechnology companies such as Gilead Sciences, Inc., ViroPharma Incorporated, Idenix Pharmaceuticals, Inc. and Vertex Pharmaceuticals, Inc., among others, and academic and government organizations, are conducting research and development in competition with Genelabs for discovery and development of various other compounds to treat HCV infection. These companies generally have greater resources than Genelabs and, in some cases, have product candidates that are in a more advanced stage of development than Genelabs' drug candidates.

Because HCV rapidly mutates, we believe future therapy may consist of multiple drugs that function by different mechanisms, in an attempt to overcome the emergence of HCV strains that are resistant to treatment. This is similar to the treatment paradigm currently employed in the management of patients with HIV infection, another chronic viral infection. As a consequence, Genelabs has initiated multiple projects in the HCV area, seeking to discover orally-active drugs that function by distinct mechanisms, which we believe eventually may be given in combination to patients with HCV infection.

Our HCV programs have focused on different mechanisms of inhibiting the replication of the HCV virus. Two of these approaches target a viral-specific enzyme which is called the HCV NS5b RNA-dependent RNA polymerase. This enzyme is directly involved in HCV replication. We believe the NS5b enzyme is an attractive target for creating HCV-specific drugs because: (1) a proper functioning of the polymerase is required for HCV replication; (2) human cells do not use this viral polymerase for their own replication; and (3) drugs that target viral polymerases have proven to be effective for treating other viral infections, such as HIV. In one project we have employed a class of compounds known as nucleoside analogues that cause the HCV polymerase to make incomplete copies of the HCV genome, thereby curtailing viral replication. Another separate project uses a different class of chemicals that bind directly to the HCV polymerase and prevent it from properly functioning, which also curtails viral replication. Since initiating our HCV discovery programs, we have:

- established a high-throughput cell-free enzyme assay for HCV RNA polymerase;
- established a cell-based assay which measures replication of an engineered HCV (known as a replicon);
- synthesized a large number of compounds and tested them for activity;
- identified compounds that show potent inhibition of the HCV polymerase in our assays and that satisfy our toxicity limits when used in human cells;
- written and submitted multiple patent applications claiming compounds with activity against HCV;
- initiated preclinical studies in both HCV polymerase research projects;
- selected two of the non-nucleoside compounds for advancement into IND-enabling preclinical development in advance of potential human testing; and
- entered into a contract with an outside supplier to enable production of a sufficient quantity of preclinical compounds under current Good Manufacturing Practice (cGMP) conditions, to enable us to undertake IND-enabling preclinical studies.

We also continue to synthesize additional compounds to serve as potential follow-up candidates for preclinical development for HCV.

In addition to the HCV NS5b polymerase as a target, in early 2005 Genelabs began a research project involving a different HCV target that is known as HCV NS5a. HCV NS5a is a different protein that is believed to be essential for HCV viral replication, although its exact function is not known. Our initial screening process identified starting compounds which were suitable for our optimization process, and we have since synthesized hundreds of compounds designed for this target, a number of which have demonstrated nanomolar-level activity in an HCV replicon cell-based model. We have recently begun evaluating these compounds for their drug metabolism and pharmacokinetic properties as we seek to determine whether they are eligible for advancement into preclinical development.

Genelabs continues to evaluate other HCV targets as well as targets for other diseases. We may choose to implement programs with other drug targets in addition to or instead of our existing programs.

*Licensing of HCV Nucleosides.* In September 2004, we signed an agreement with Gilead Sciences, Inc. to collaborate in the research, development and commercialization of nucleoside inhibitors of the HCV polymerase. We are leading the research efforts and Gilead will lead development and commercialization efforts. Gilead paid us a nonrefundable \$8 million upfront payment and is providing research funding of approximately \$11 million over a three-year research term, which commenced in October 2004. We have agreed to devote a specified number of scientists to this program and have provided Gilead exclusive worldwide access to certain compounds developed in the program. Gilead has the option to continue funding the collaboration for one additional year after completion of the initial three-year research term. We are entitled to milestone payments of up to \$38 million for each compound that is developed by Gilead under the agreement and royalties on any net sales of products developed under the collaboration.

### **Development of Prestara for Systemic Lupus Erythematosus**

Our clinical development efforts have been concentrated on Prestara™ (prasterone), an investigational drug for systemic lupus erythematosus. Lupus is a life-long autoimmune disease that causes the immune system to attack the body's own tissues and organs. In August 2002, we received an approvable letter for Prestara, also referred to as GL701, Aslera™ and Anastar™, from the U.S. Food and Drug Administration, or FDA, but to date we have not met the primary contingency contained in the letter, requiring additional positive phase III clinical trial data on the effects of Prestara on bone mineral density, or BMD. In December 2005, we met with the FDA to discuss our potential development options for Prestara. This meeting was held after we received the results of three clinical trials, two double-blind phase III studies and one open-label follow-on study, that were conducted measuring BMD in women with lupus who were taking glucocorticoids. The meeting with the FDA was held to enable Genelabs to determine the potential paths forward for Prestara, including 1) pursuit of an indication for the treatment of the signs and symptoms of lupus and 2) pursuit of an indication for the prevention of loss of BMD in lupus patients taking glucocorticoids. We had pursued the BMD indication with the FDA since receiving an approvable letter in 2002, although we remained interested in an indication for treating the signs and symptoms of lupus, due to its potentially broader application. As a result of the meeting, the FDA indicated that at least one additional, adequate, well-controlled phase III clinical trial would be necessary to support an indication for the treatment of the signs and symptoms of lupus. The FDA further indicated that Genelabs should refer to the FDA's draft guidance for developing drugs for SLE, which was published earlier in 2005, and that it would be willing to work with Genelabs in designing such a study. Genelabs currently believes that pursuing an indication for the treatment of the signs and symptoms of lupus is a more viable route forward than continuing to pursue an indication for prevention of bone mineral density loss in patients with lupus.

*Lupus and the Clinical Rationale Behind Prestara™* According to various published estimates, lupus affects approximately 200,000 patients in the United States, and Genelabs believes that there are at least one million patients worldwide. Lupus is a severe, chronic and frequently debilitating autoimmune disease that primarily affects women, who generally are diagnosed while of childbearing age. Lupus is characterized by alternating periods of active disease symptoms, or flares, and periods of quiescence, and it can cause significant morbidity and disruption of daily activities. Inflammation occurs in nearly all patients, and symptoms can include irreversible damage to almost every organ system, including the musculoskeletal, renal, pulmonary, neurological, cardiovascular, and cutaneous systems, as well as depression and severe fatigue. In the United States, there have been no new drugs

approved by the FDA for the treatment of lupus in more than 40 years. Existing treatments for lupus are often inadequate, due to limited benefits and severe adverse side effects.

Prestara is a pharmaceutical formulation for oral administration that contains highly purified prasterone, the synthetic equivalent of dehydroepiandrosterone, or DHEA, a naturally occurring hormone and the most abundant adrenal hormone in humans, as the active ingredient. Lupus patients generally have abnormally low levels of DHEA, approximately 50% of normal, and it is believed that hormonal influences may play a role in the development and progression of the disease.

*Background of Prestara's Development.* Genelabs obtained an exclusive license to the rights to Prestara for use in SLE from Stanford University in 1993, and we have since completed three double-blind randomized placebo controlled clinical trials of Prestara in women with lupus.

The first of these clinical trials, designated Study GL94-01, was completed in 1997 and evaluated Prestara's ability to reduce the glucocorticoid, or steroid, dose in women with mild to moderate lupus who were dependent on steroids to prevent their disease from exacerbating. The study's objective was to reduce the steroid dose in these women while simultaneously maintaining or improving the patients' lupus disease activity. Prior to initiating treatment in the study, all 191 women with SLE in this trial previously required glucocorticoids at doses of 10 to 30 mg per day in order to stabilize their disease. During the study period, patients in the trial received daily doses of 200 mg of Prestara, 100 mg of Prestara or placebo for seven to nine months. The primary endpoint of this trial was a sustained reduction in each patients' glucocorticoid dose to 7.5 mg per day or less, which are levels approximately equivalent to those normally produced by the adrenal glands. Data from the trial showed that patients who received the 200 mg daily doses of Prestara had a higher response rate than patients who received placebo, particularly for those patients with active disease at baseline. The results of this study were published in the July 2002 issue of *Arthritis and Rheumatism*.

A second phase III clinical trial, Study GL95-02, was completed in 1999 and evaluated Prestara's ability to improve or stabilize clinical outcome and disease symptoms in women with mild to moderate lupus. The 381 women with SLE enrolled in this trial were randomized to receive either an oral dose of 200 mg of Prestara or placebo once a day for 12 months. All placebo and Prestara patients were allowed to continue taking their existing medications for the full course of this trial. The primary endpoint of the trial was "responder", and responders were patients who experienced no clinical deterioration while demonstrating simultaneous improvement or stabilization over the duration of the study across two disease activity measures, the SLE Disease Activity Index (SLEDAI) and Systemic Lupus Activity Measure (SLAM), and two quality of life measures, the patient global assessment and the Krupp Fatigue Severity Scale (KFSS). In other words, in order for a patient in the trial to be considered a "responder", over a one-year term they had to be stable or improved in four separate measures without any additional medications (besides the study medication) or disease worsening. In an intent-to-treat analysis of patients with active disease at baseline, Prestara-treated patients showed a 31% greater rate of response than the placebo group: 59% of Prestara patients responded to treatment compared to 45% of placebo patients. This improvement in response was statistically significant ( $p=0.017$ ). In late 2002 the FDA advised Genelabs that it considers Study GL95-02 to be a positive, adequate and well-controlled study. The results of this study were published in the September 2004 issue of *Arthritis and Rheumatism*.

Because the most common organ damage in patients with lupus is musculoskeletal, nested within Study GL95-02 was a study conducted at eight of the investigator sites to assess BMD in patients who were required to have been taking glucocorticoids for at least six months prior to entering the trial. These patients had BMD measurements taken by Dual X-ray Absorptiometry (DEXA) at the beginning and end of the trial. An analysis of the results including all patients who had baseline and post-treatment bone mineral density measurements showed that the group of patients receiving Prestara had significantly increased bone mineral density, compared to a decrease in bone density for the group of patients on placebo. Between the Prestara and placebo treatment groups, the differences were statistically significant (measured by mean percentage change; 55 patients,  $p=0.003$  at the lumbar spine and 53 patients,  $p=0.013$  at the hip). Lupus patients are at risk for the long-term complication of osteoporosis both because loss of bone density is a common manifestation of the disease and because a significant side effect of current lupus therapies is decreased bone density.

*Prestara NDA.* Upon completion of GL95-02, Genelabs prepared a New Drug Application, or NDA, for Prestara to treat women with lupus, which was submitted to the FDA on a rolling basis under fast-track designation in 2000. We subsequently received priority review designation from the FDA.

The FDA Arthritis Advisory Committee reviewed the NDA on April 19, 2001, but did not vote on whether to recommend approval of Prestara. On June 26, 2001, the FDA sent us a letter stating that the Prestara NDA was not approvable, listing deficiencies that must be addressed before the NDA can be approved. As a result of various meetings with us, the FDA sent us a letter in January 2002 suggesting exploration of additional data and analyses regarding Prestara's positive effect on BMD, that was observed in Study GL95-02. We submitted the requested information to the FDA in February 2002. On August 28, 2002, we received an approvable letter from the FDA. The approvable letter indicated that approval of the NDA was primarily contingent upon the successful completion of an additional clinical trial providing sufficient evidence to confirm the positive effect on BMD that was observed in women with SLE while on glucocorticoids in Genelabs' Study GL95-02. To address this requirement, Genelabs designed and completed an additional multi-center, randomized, placebo-controlled, double-blind clinical trial, designated Study GL02-01. The primary endpoint in this study was BMD at the lumbar spine and 155 women with SLE receiving glucocorticoids were enrolled and treated with either 200 mg per day Prestara or placebo at 26 sites. Study GL02-01, in which the treatment duration was six months, did not meet its primary objective of showing improvement in BMD, although there was a trend in favor of Prestara. Patients completing Study GL02-01 were eligible to enroll in Study GL03-01, a one-year open-label follow-on study. Study GL03-01 met its primary objective of maintaining BMD for the patients taking 200 mg per day of Prestara. In the combined studies GL02-01 and GL03-01, patients taking 200 mg per day of Prestara for 12 to 18 months increased their BMD.

A separate nine month clinical trial of prasterone measuring BMD was conducted by Genovate Biotechnology Co., Ltd., referred to as Genovate, a Taiwan-based company that has a license from us for Prestara in Asian countries, except Japan. The Genovate study also did not demonstrate a statistically significant increase in the BMD of women with lupus taking glucocorticoids.

Following the clinical trials measuring BMD, Genelabs met with the FDA to discuss future development options for Prestara for lupus. Genelabs and the FDA discussed development for two different possible indications — 1) treatment of the signs and symptoms of lupus and 2) prevention of loss of BMD for women with lupus on glucocorticoids. For both indications the FDA indicated that additional positive clinical trial data would be needed before the FDA would review a New Drug Application for approval. For the treatment of the signs and symptoms of lupus, the FDA indicated that one additional positive clinical trial could be sufficient. Genelabs currently believes that pursuit of an indication for treating the signs and symptoms of lupus is a more viable route forward for Prestara than pursuit of an indication for BMD, which we had pursued since receipt of the approvable letter in 2002. The Company plans to meet with the FDA and obtain agreement on a protocol for an additional study of Prestara for lupus, with treatment of signs and symptoms of the disease as the objective of the study, although Genelabs presently does not have the funds to conduct the trial on its own.

*International Regulatory Applications.* Independent of the United States regulatory process, Genelabs filed and subsequently withdrew a Marketing Authorization Application, or MAA, seeking approval of Prestara for the treatment of SLE in Europe. We retain the option to file an application for approval again at a later date. In Japan, our licensee, Tanabe Seiyaku, Co., Ltd., or Tanabe, is responsible for pursuing approval of Prestara and for conducting and funding any associated studies that may be required, however, they have indicated that their development plans for Prestara will be determined after there has been further clarity regarding the development of Prestara in the United States.

*Market Position and Competition.* Genelabs has exclusive rights under U.S. patents granted to Stanford for the use of DHEA to treat SLE. Because DHEA is a long-known naturally occurring hormone, Genelabs believes there are no composition-of-matter patents on generic DHEA, although the company has submitted patent applications pertaining to the specific polymorphic form of DHEA used in its most recent clinical trials. Genelabs has received a Notice of Allowance for a U.S. patent application claiming a high-purity composition of that DHEA polymorphic form. In addition to the patents licensed from Stanford, two U.S. patents were issued to Genelabs during 2003, one of which relates to the measurement of patients' response to treatment of SLE with DHEA and the other to the use of DHEA for treating subnormal bone mineral density. The FDA has granted orphan drug status to

Prestara for the treatment of SLE disease in women, which, if Prestara were to be approved for marketing with that indication, would provide up to seven years of U.S. marketing exclusivity. We are pursuing additional patent applications relating to DHEA or its use in treating SLE both in the United States and internationally. We do not have issued patents on DHEA, or its use, in Europe or Japan.

Currently, products containing DHEA are available as dietary supplements in the United States. Genelabs believes that the government should regulate DHEA as a drug and has submitted a petition and supporting documentation to the FDA seeking DHEA's removal from the market as a dietary supplement. The FDA has not taken any action on our petition.

If Prestara were approved to for treatment of lupus, we believe Prestara would compete against existing and future drugs that are used to treat SLE, such as hydroxychloroquine sold by Sanofi-Aventis and others.

*Licensing of Prestara™.* We licensed exclusive rights to Prestara for North America to Watson Pharmaceuticals, Inc., under an agreement which would provide Genelabs with milestone payments and a significant royalty percentage on product sales if the FDA approves the Prestara NDA for SLE. The agreement provides for milestone payments for approval of Prestara by the FDA for each of two indications, treatment of lupus and reduction of steroids. Currently, we are not seeking approval for steroid reduction. Exclusive rights for Japan have been licensed to Tanabe in exchange for milestone payments and royalties on any net sales of Prestara in Japan. Exclusive rights for Asia (excluding Japan), Australia and New Zealand have been licensed to Genovate Biotechnology Co., Ltd., referred to as Genovate, in exchange for an equity position in Genovate. Genelabs also has licensed rights to Teva Pharmaceutical Industries Ltd. to market Prestara in Israel, Gaza and the West Bank and, if Prestara is approved in the U.S. and Israel, Genelabs will receive milestone payments and royalties from Teva. We intend to continue to pursue licensing the European marketing rights.

*Genovate Biotechnology Co., Ltd.* Genelabs holds approximately 8% of the equity in Genovate, a Taiwan-based company, which was formerly called Genelabs Biotechnology Co., Ltd. Genovate develops, manufactures and distributes pharmaceutical products in Asia and holds the rights to market Prestara™ in Asia (except Japan), Australia and New Zealand. In addition to our clinical trials, Genovate has conducted two Phase III clinical trials of prasterone in Taiwan. Since the founding of Genovate, we periodically have sold portions of our equity in Genovate, and we may sell additional portions of our equity in Genovate as regulations in Taiwan and market conditions permit. The chairman of our board of directors, Irene A. Chow, Ph.D., also serves on the board of directors of Genovate.

## **Hepatitis E Vaccine**

*Background.* Infection with the hepatitis E virus, or HEV, can cause severe and prolonged illness, with symptoms similar to hepatitis A including fever, jaundice and nausea, although HEV is generally more severe than hepatitis A. HEV is transmitted through contaminated water or food. The World Health Organization estimates that the overall mortality rate from HEV infection ranges between 0.5% to 4% and states that when fulminant hepatitis E occurs in pregnancy it regularly induces a mortality rate of 20% among pregnant women in the 3rd trimester. Large outbreaks have occurred in developing countries but cases in the U.S. are rare and usually associated with travel to developing countries. There is neither a specific treatment nor an approved vaccine for the prevention of HEV.

HEV was first isolated and cloned by Genelabs scientists working in conjunction with researchers from the U.S. Centers for Disease Control and Prevention. U.S. and foreign patents that broadly claim HEV genomes, DNA fragments and their encoded proteins have been issued to Genelabs.

*HEV Licenses.* In 1992 Genelabs granted GlaxoSmithKline, or GSK, an exclusive worldwide royalty-bearing license to make, use and sell HEV vaccines. GSK is developing an HEV vaccine candidate and has completed two Phase I trials and one Phase II trial. The Phase I trials were conducted in the U.S. and in Nepal, enrolling 88 and 44 volunteers, respectively. Both of these trials demonstrated that the investigational HEV vaccine appeared to be safe at various doses to normal human volunteers and generated an antibody response to the vaccine antigen. The Phase II trial was conducted by the Walter Reed Army Institute of Research, or WRAIR, in collaboration with the Medical Department of the Royal Nepal Army, the U.S. National Institutes of Health and GSK. It enrolled approximately 2,000 adults in Nepal who received three doses of either HEV vaccine or placebo

over a six month period, with a follow-up period of 18 months after the last dose. Based on the results of this trial GlaxoSmithKline made a milestone payment to Genelabs in November 2004.

In December 2005, scientists from WRAIR presented the results of the HEV vaccine phase II trial for the first time at an annual meeting of the American Society of Tropical Medicine and Hygiene. The presentation indicated that the clinical trial showed a 96% effectiveness of the vaccine in preventing disease caused by the hepatitis E virus. There were a total of 69 cases of HEV during the course of the trial after all three doses of the vaccine or placebo had been administered, and 66 of these cases were in the placebo group compared to 3 in the vaccine group. In addition, the data presented indicated that the vaccine was well tolerated, with no significant adverse safety events attributed to the vaccine during the course of the study.

In addition to GlaxoSmithKline's vaccine license, Genelabs has granted non-exclusive royalty-bearing licenses to develop and commercialize diagnostic products for HEV to Abbott Laboratories and to MP Biomedicals Asia Pacific Pte. Ltd., a former subsidiary of ours that used to be named Genelabs Diagnostics Pte. Ltd.

## Legacy Technologies

*Linker-Aided DNA Amplification.* In 2000 the United States Patent and Trademark Office granted Genelabs a patent covering a fundamental nucleic acid amplification technique developed by our scientists. This technology is a method of amplifying nucleic acids by attaching oligonucleotide linkers to the ends of target DNA sequences (Linker-Aided DNA Amplification, or LADA). In LADA, linkers of known sequences are added to the ends of target DNA sequences, thereby providing a known primer sequence that is complementary to the attached linkers. The primers are then used to amplify the target DNA, the precise sequence of which need not be known. In 2002 we non-exclusively licensed the LADA technology to Affymetrix, Inc. for upfront and annual fees, and royalties. In December 2004, the license was amended to provide Affymetrix with a paid-up license in return for a lump sum payment of \$1.25 million. Genelabs currently does not utilize the LADA technology and our goal is to monetize the value of the LADA patents through licensing or other means.

*Hepatitis G Virus.* Scientific publications have shown that patients infected with both the human immunodeficiency virus, HIV, and GB virus C, also known as hepatitis G virus, or HGV, have a reduced mortality rate compared to those only infected with HIV. Genelabs scientists first discovered HGV, which is transmitted by blood and other bodily fluids, while seeking to identify what was then an unknown hepatitis virus. Patents covering the HGV genome, peptides and their uses have issued to Genelabs. We have granted non-exclusive research licenses to academic institutions to facilitate their continuing research on the interaction between HGV and HIV, although we retain commercial rights to HGV, such as vaccine or therapeutic applications of the virus. We have also granted Roche Diagnostics, Chiron Corporation and Ortho Diagnostic Systems royalty-bearing license agreements for diagnostic applications of HGV. To date, royalties received under these HGV agreements have not been significant, and we do not foresee receiving significant royalties in the near future. Although the presence of HGV has been detected in blood samples contained in the U.S., Europe, Japan and elsewhere, to date there are no known diseases specifically caused by HGV and no assays developed for screening the blood bank supply.

*HCV Diagnostic Licenses.* After its discovery of certain polypeptide regions of HCV, Genelabs entered into a royalty-bearing license agreement with Pasteur Sanofi Diagnostics, which was acquired by Bio-Rad Laboratories, Inc. in 1999. We have also granted certain rights to our HCV patents to Chiron Corporation and Ortho Diagnostic Systems. The agreements with Chiron and Ortho do not provide for royalties and we receive royalties from Bio-Rad pursuant to the terms of the Pasteur Sanofi license.

*Antimicrobial Drug Discovery.* Our earlier drug discovery efforts initially explored DNA as a target for drug intervention. Under this program we identified a number of small molecule lead compounds that showed activity against pathogenic fungi and bacteria, and promoted one lead compound with potent activity against *Aspergillus fumigatus* to preclinical status. However, we have been unable to license this compound and no longer are devoting resources to seeking further development of this or other DNA-binding compounds. In early 2005 we began a small exploration program on a potential antibacterial target, but have since redirected the resources from this program to our HCV NS5a drug discovery program.

## Patents

Genelabs seeks patent protection for its proprietary technologies and potential products in the U.S. and internationally. We own over 50 issued U.S. patents; these patents cover our novel drug discovery technologies, Prestara, our HEV and HGV discoveries, and other proprietary technologies. We also own corresponding international patents that cover similar claims to our U.S. patents. Genelabs also has exclusive and non-exclusive licenses under a number of patents and patent applications owned by third parties. In addition, we possess many pending patent applications covering our novel chemistries and drug discovery technologies and other proprietary technologies, but cannot estimate how many of these pending patent applications, if any, will be granted as patents.

Genelabs® and the Genelabs logo are registered trademarks, and Prestara™, Anastar™ and Aslera™ are trademarks of Genelabs Technologies, Inc. This Annual Report on Form 10-K also includes trade names and trademarks of companies other than Genelabs.

## Government Regulation

The research and development, preclinical testing and clinical trials, manufacture, distribution, marketing and sales of human pharmaceutical and medical device products are subject to regulation by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, research and development activities and the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of the products that we are developing.

*Research and Development.* Our research and development programs involve the use of hazardous chemical, radiological and biological materials, such as infectious disease agents. Accordingly, our present and future business is subject to regulations under state and federal laws regarding work force safety, environmental protection and hazardous substance control and to other present and possible future local, state and federal regulations.

*Pre-Clinical Testing.* In the U.S., prior to the testing of a new drug in human subjects, the FDA requires the submission of an Investigational New Drug application, or IND, which consists of, among other things, results of preclinical laboratory and animal tests, information on the chemical compositions, manufacturing and controls of the products, a protocol, an investigator's brochure and a proposed clinical program. Preclinical tests include laboratory evaluation of the product and animal studies to assess the potential safety and efficacy of the product and its formulation. Unless the FDA objects, the IND becomes effective 30 days after receipt by the FDA. FDA objection to the initiation of clinical trials is not uncommon, and the FDA may request additional data, clarification or validation of data submitted, or modification of a proposed clinical trial design.

*Clinical Trials.* Clinical trials are conducted in accordance with protocols that detail the objectives and designs of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Each clinical study is conducted under the auspices of an Institutional Review Board, or IRB. The IRB will consider, among other things, ethical factors, the informed consent and the safety of human subjects and the possible liability of the institution. Clinical trials are typically conducted in three sequential phases, although the phases may overlap. In Phase I, the initial introduction of the drug into human subjects, the product is tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. Phase II involves studies in a limited patient population to (i) determine the efficacy of the product for specific, targeted indications, (ii) determine dosage tolerance and optimal dosage and (iii) identify the common short-term adverse effects and safety risks. When Phase II evaluations indicate that a product is effective and has an acceptable safety profile, two Phase III trials are normally required to further test for safety and efficacy within an expanded patient population at multiple clinical sites.

*Manufacturing.* Each manufacturing establishment must be determined to be adequate by the FDA before approval of product manufacturing. Manufacturing establishments are subject to inspections by the FDA for compliance with current Good Manufacturing Practices and licensing specifications before and after an NDA has been approved, and international manufacturing facilities are subject to periodic FDA inspections or inspections by the international regulatory authorities.

*Marketing and Distribution.* The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of the NDA for approval of the marketing and commercial shipment of a new drug. The

FDA may deny approval if applicable regulatory criteria are not satisfied or may require additional clinical or other testing. Even if additional testing data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval or it may limit the scope of any approval it does grant. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur or are first discovered after the product reaches the market. The FDA may also require post-approval testing and surveillance programs to monitor the effect of products that have been commercialized and has the power to prevent or limit further marketing of the product based on the results of these post-marketing programs.

*Sales.* Sales of medicinal products outside the U.S. are subject to regulatory requirements governing human clinical trials and marketing for drugs and biological products. The requirements vary widely from country to country. The process of obtaining government approval for a new human drug or biological product usually takes a number of years and involves the expenditure of substantial resources.

### **Sale of Diagnostic Business**

*Genelabs Diagnostics Pte. Ltd.* In April 2004, we sold our diagnostics business, Genelabs Diagnostics Pte. Ltd. and its immediate parent company, Genelabs Asia Pte. Ltd., to MP Biomedicals, LLC, and received proceeds from the sale of \$3.0 million. Prior to the sale, we accounted for our diagnostics business as a discontinued operation.

### **Employees**

As of December 31, 2005, Genelabs and its subsidiaries had approximately 66 full-time equivalent employees, of whom 50 were involved in research and development and 16 were in administration. Our employees are not represented by any collective bargaining agreements, and we have never experienced a work stoppage due to a labor dispute.

### **Item 1A. Risk Factors**

There are a number of risk factors that should be considered by Genelabs' shareholders and prospective investors. It is not possible to comprehensively address all risks that exist, but the following risks in particular should be considered, in addition to other information in this Annual Report on Form 10-K.

#### **Risks Related to Genelabs**

*We will need to raise additional capital within the next several months, and if we are unable to timely secure adequate funds on acceptable terms, we will be required to cease our operations and will not be able to continue as a going concern.*

On March 15, 2006, Genelabs had cash and cash equivalents totaling approximately \$8.3 million, which we presently estimate can sustain our existing operations only until the beginning of the fourth quarter of 2006. We will need to raise additional capital in order to execute our business plans, provide adequate working capital to satisfy our obligations and continue as a going concern. While we are in the process of seeking additional funds, including entering into a new collaboration for our hepatitis C virus drug discovery program, selling equity, renegotiating an existing corporate collaboration, and/or other arrangements, it is possible that none of these efforts to seek additional funds will be successful. If these efforts are not successful we will need to terminate operations and you may lose your entire investment. If one or more of these efforts are successful, the amount of funds we raise may still not be sufficient for us to sustain operations as planned or at all. As of the date of this filing, there is substantial doubt about the Company's ability to continue as a going concern due to its historical negative cash flow and because the Company does not currently have sufficient committed capital to meet its projected operating needs for at least the next twelve months. Additionally, our financial condition may lead our vendors and suppliers to require advance payments or security deposits, further draining our resources, and may result in loss of some of our employees who seek employment elsewhere.

If we raise additional funds through the issuance of equity, or securities convertible into equity, we may be required to do so at a price per share below then-current trading prices, thereby diluting our current shareholders.

We may not be able to obtain additional funds on acceptable terms, or at all. Other sources of capital, such as a collaboration or strategic alliance, may require us to grant third parties rights to our intellectual property assets, or require us to adversely renegotiate the terms of one or more of our existing collaborations. We may also need to change our operating plans. Although we are currently discussing with third parties a collaboration for our HCV non-nucleoside drug discovery program, we may fail to enter into any agreement on acceptable terms, if at all. We also may be unable to find buyers willing to purchase our equity or to license other products or technology on commercially favorable terms, if at all. If additional funds are not available we may be required to cease operations.

In order to maintain its license to use radioactive research materials, Genelabs has established a \$150,000 standby letter of credit in favor of the Radiologic Health Branch of the California Department of Health Services. If we are unable to raise additional funds, the letter of credit may be terminated and the radioactive materials license may be suspended or revoked.

***Because we may not continue to qualify for listing on the Nasdaq quotation system, the value of your investment in Genelabs may substantially decrease.***

To remain listed on the Nasdaq Capital Market we must have at least \$2.5 million in shareholders' equity or a market value of at least \$35 million. Our shareholders' equity as of December 31, 2005 was \$2.3 million and as of March 15, 2006 the Company's market value was approximately \$34 million. We currently do not comply with the minimum shareholder's equity requirement, and will not be able to comply with this requirement unless we are able to increase our shareholders' equity through a financing or other means. We may not be able to maintain compliance with the market capitalization requirement.

To remain listed on the Nasdaq Capital Market the closing bid price of our stock must be at least \$1.00 per share. We may not be able to maintain compliance with the minimum closing bid price requirement.

If Genelabs is unable to meet or maintain compliance with all of the Nasdaq listing requirements, it will be delisted from the Nasdaq Capital Market. If delisted from the Nasdaq Capital Market, Genelabs might apply for listing on the American Stock Exchange. Genelabs may fail to meet the requirements for initial listing or may fail to maintain compliance with the continued listing requirements of the American Stock Exchange. Delisting from the Nasdaq Capital Market would adversely affect the trading price of our common stock, significantly limit the liquidity of our common stock and impair our ability to raise additional funds.

***We may not be profitable in the near future or at all and in order to carry out our business plans we will require additional funds which may not be available.***

We have incurred losses each year since our inception and have accumulated approximately \$229 million in net losses through December 31, 2005, including a net loss of \$10.8 million for the year ended December 31, 2005. We may never be profitable and our revenues may never be sufficient to fund operations.

We presently estimate that our current cash resources are adequate to fund our current operations to approximately the beginning of the fourth quarter of 2006. We will require additional capital to carry out our business plans. The following are illustrations of potential impediments to our ability to successfully secure sufficient additional funds:

- the current trading price of our stock will materially and adversely affect our ability to raise funds through the issuance of stock;
- the amount of stock we may sell and capital we may raise privately without a shareholder vote is limited, and we may be unable to secure capital on a timely basis with acceptable terms if we must submit such a transaction to our shareholders for approval;
- the listing of our stock on the Nasdaq Capital Market may materially and adversely affect our ability to raise funds through the issuance of stock because of factors such as reduced liquidity and the requirement to comply with state securities laws;
- if we are unable to maintain compliance with the Nasdaq's listing requirements, our ability to successfully obtain additional equity financing will be negatively impacted;

- since our research programs are in an early stage, there are fewer opportunities to enter into collaborations with other companies and up-front payments for early-stage pharmaceutical research collaborations are generally smaller for projects that are further from potential marketability;
- biotechnology research and development projects have a high risk of failure and the failure of our research-stage drug candidates or those of other companies could discourage funding sources from providing us with financing; and
- discussions with the Food and Drug Administration have indicated that the Company will need to conduct at least one additional Phase III clinical trial of Prestara in order to qualify for approval, and the Company does not have the funds to conduct the trial.

Additional funds for our research and development activities may not be available on acceptable terms, if at all. The unavailability of additional funds could delay or prevent the development of some or all of our products and technologies, which would have a material adverse effect on our business, financial condition and results of operations.

***The results of our clinical trial of Prestara™, Genelabs' drug candidate for systemic lupus erythematosus, were not positive, substantially decreasing the probability that Prestara will ever be approved for marketing and diminishing our business prospects.***

In order to satisfy conditions set by the U.S. Food and Drug Administration, or FDA, we conducted a Phase III clinical trial of Prestara on women with lupus taking glucocorticoids using BMD as the trial's primary endpoint. Prestara is a pharmaceutical formulation containing highly purified prasterone, the synthetic equivalent of dehydroepiandrosterone or DHEA, a naturally occurring hormone. This clinical trial did not demonstrate a statistically significant difference between the bone mineral density of the group of patients taking Prestara and the group taking placebo. Additionally, the trial was not powered to demonstrate, and in fact did not demonstrate, a statistically significant benefit in secondary endpoints such as amelioration of lupus symptoms. While we believe we have identified most probable causes for the failure of this study to reach its primary endpoint, we may never know with certainty what the cause or causes of this failure were.

A clinical trial of prasterone (the active ingredient in Prestara) was conducted by Genovate Biotechnology Co., Ltd., or Genovate, a Taiwan-based company that has a license from us for Prestara in most Asian countries. In April 2005 we announced that this clinical trial did not meet its primary endpoint, bone mineral density at the lumbar spine. Because both our and Genovate's clinical trials did not meet their primary endpoints, the FDA will not approve Prestara without another Phase III clinical trial. It may not be possible to design and implement a trial that would successfully provide results sufficient to obtain FDA approval for Prestara, and Genelabs currently does not have the funds to conduct such a trial.

***Our research programs are in an early stage and may not successfully produce commercial products.***

Pharmaceutical discovery research is inherently high-risk because of the high failure rate of projects. To date, our pharmaceutical research has been focused on a limited number of targets for which no or few commercial drugs have been successfully developed. Our projects may fail if, among other reasons, the compounds being developed fail to meet criteria for potency, toxicity, pharmacokinetics, manufacturability, intellectual property protection and freedom from infringement, or other criteria; if others develop competing therapies; or if we fail to make progress due to lack of resources or access to enabling technologies. Genelabs' product candidates, other than Prestara, are in an early stage of research. All of our research projects may fail to produce commercial products.

If Genelabs discovers compounds that have the potential to be drugs, public information about our research success may lead other companies with greater resources to focus more efforts in areas similar to ours. Genelabs has limited human and financial resources. Creation of the type of compounds we seek to discover requires sophisticated and expensive lab equipment and facilities, a team of scientists with advanced scientific knowledge in many disciplines such as chemistry, biochemistry and biology, and time and effort. Large pharmaceutical companies have access to the latest equipment and have many more personnel available to focus on solving particular research

problems, including those that Genelabs is investigating. Therefore, even if our research programs are successful, we may have a competitive disadvantage.

***Our collaborations may fail.***

We have entered into collaborations with Gilead, GSK, Watson, Tanabe and other companies and we may enter into future collaborations with these or other companies. Our collaborators may breach their contracts, or our collaborators may not diligently and successfully develop and commercialize the results of the research. Alternatively, our collaborators may elect not to extend or augment the collaborations. In this regard, Gilead may not continue to fund our research beyond its obligation in the research contract and GSK may choose not to continue developing the HEV vaccine. We are dependent on our collaborators to successfully carry out preclinical and clinical development, to obtain regulatory approvals, and/or to market and sell any products arising from the research and/or development conducted by the company or the collaborator. Factors which may cause our collaborators to fail in these efforts include: problems with toxicity, bioavailability or efficacy of the product candidate, difficulties in manufacture, problems in satisfying regulatory requirements, emergence of competitive product candidates developed by the collaborator or by others, insufficient commercial opportunity, problems the collaborators may have with their own contractors, lack of patent protection for our product candidate or claims by others that it infringes their patents or other intellectual property rights. Collaboration on a project also may result in disputes with the collaborator over the efforts of the Company and/or the collaborator or rights to intellectual property. If we are unable to obtain the funds to ensure the continuance of our business or fail to perform all of our obligations, our collaborators may withhold further funding, seek to seize control over our intellectual property and other assets, and/or assert claims for damages against us. In the course of the collaboration our collaborator may obtain know-how which enables it to compete with us in the same area of research and/or development. Because research and development results are unpredictable, we and our collaborators may not achieve any of the milestones in the collaboration agreements.

***We do not have the resources to conduct preclinical development.***

We do not have the personnel or facilities to conduct the formal preclinical development of our hepatitis C compounds as necessary to file an application to conduct clinical trials in humans. Our experience in conducting preclinical development, including formal toxicology studies, is limited. We will need to outsource this activity and may need to retain more experienced personnel. Outsourcing is expensive, time-consuming and requires reliance on the performance of third parties. Because of our financial condition, stock performance and setbacks in our Prestara™ program, we may have difficulty hiring specialized personnel.

***We may be unable to attract or retain key personnel.***

Our ability to develop our business depends in part upon our attracting and retaining qualified management and scientific personnel. As the number of qualified personnel is limited, competition for such staff is intense. We may not be able to continue to attract or retain such people on acceptable terms, given the competition for those with similar qualifications among biotechnology, pharmaceutical and healthcare companies, universities and nonprofit research institutions. Furthermore, the negative results from the most recent clinical trials of Prestara™ and the ensuing drop in our stock price, as well as the Company's declining cash position, have significantly diminished our future business prospects, thus making it more difficult to retain existing employees and to recruit new employees. Since the announcement of the results of our Phase III trial of Prestara in October 2004, substantially all of our clinical development staff have left the Company. The loss of our key personnel or the failure to recruit additional key personnel could significantly impede attainment of our objectives and harm our financial condition and operating results. Additionally, recent and proposed laws, rules and regulations increasing the liability of directors and officers may make it more difficult to retain incumbents and to recruit for these positions.

***If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our product candidates.***

As part of our process of conducting drug discovery research and clinical trials we rely on third parties such as medical institutions, pre-clinical and clinical investigators, contract laboratories and contract research

organizations to participate in the conduct of our clinical trials. We depend on Gilead for nucleoside compounds for treatment of hepatitis C infections, and on GSK for the hepatitis E vaccine, to conduct preclinical and clinical development, to obtain regulatory approval and to manufacture and commercialize. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

***If our Japanese marketing partner for Prestara™ does not obtain approval to market Prestara in Japan, our business prospects will suffer because we do not have capabilities to develop Prestara for Japan ourselves and we would lose a significant source of potential revenue.***

Our licensee in Japan, Tanabe, has not conducted clinical trials for Prestara in Japan. Given the most recent negative results in the clinical trials of Prestara and the similar formulation used in Taiwan, Tanabe may not proceed with clinical trials, or if it does, the results from such trials may not be positive.

***Our outside suppliers and manufacturers for Prestara™ and our hepatitis C compounds are subject to regulation, including by the FDA, and if they do not meet their commitments, we would have to find substitute suppliers or manufacturers which could delay supply of product to the market.***

Regulatory requirements applicable to pharmaceutical products tend to make the substitution of suppliers and manufacturers costly and time consuming. We rely on a single supplier of prasterone, the active ingredient in Prestara, and we rely on a single finished product manufacturer, Patheon Inc., for production of Prestara capsules and for packaging. We rely on another manufacturer for the scale up and production of our hepatitis C compounds. The disqualification of these suppliers and manufacturers through their failure to comply with regulatory requirements could negatively impact our business because of delays and costs in obtaining and qualifying alternate suppliers. We have no internal manufacturing capabilities for pharmaceutical products and are entirely dependent on contract manufacturers and suppliers for the manufacture of our drug candidates. Genelabs and our North American collaborator, Watson, previously arranged for the manufacture of quantities of Prestara and its active ingredient in anticipation of possible marketing approval. This inventory has exceeded its initial expiration date, although the expiration date of the active ingredient may be extended if it successfully passes re-testing.

The following could harm our ability to manufacture Prestara or our hepatitis C compounds:

- the unavailability at reasonable prices of adequate quantities of the active ingredient or intermediates;
- the loss of a supplier's or manufacturer's regulatory approval;
- the failure of a supplier or manufacturer to meet regulatory agency pre-approval inspection requirements;
- the failure of a supplier or manufacturer to maintain compliance with ongoing regulatory agency requirements;
- the inability to develop alternative sources in a timely manner or at all;
- inability or refusal of the manufacturers to meet our needs for any reason, such as loss or damage to facilities or labor disputes;
- manufacture of product that is defective in any manner;
- competing demands on the contract manufacturer's capacity, for example, shifting manufacturing priorities to their own products or more profitable products for other customers; and
- complications in the scale-up or large-scale manufacturing of our hepatitis C compounds.

***We may be unable to obtain patents or protect our intellectual property rights, or others could assert their patents against us.***

Agency or court proceedings could invalidate our current patents, or patents that issue on pending applications. Our business would suffer if we do not successfully defend or enforce our patents, which would result in loss of proprietary protection for our technologies and products. Patent litigation may be necessary to enforce patents to determine the scope and validity of our proprietary rights or the proprietary rights of another.

The active ingredient in Prestara is prasterone, more commonly known as dehydroepiandrosterone, or DHEA. DHEA is a compound that has been in the public domain for many years. Although the specific polymorphic form of DHEA we have used may be patentable, we do not believe it is possible to obtain patent protection for the base chemical compound anywhere in the world. Genelabs licensed two United States patents covering uses of DHEA in treating lupus from Stanford University in 1993. The Stanford patents expire in 2012 and 2013, and the license expires when the patents expire. In addition, we have filed patent applications covering additional uses for Prestara and various pharmaceutical formulations and intend to file additional applications as appropriate. We have filed patent applications covering compounds from our HCV drug discovery programs; however, no patents are currently issued. A number of patents have issued to Genelabs covering our drug discovery technologies and methods related to selective regulation of gene expression and the control of viral infections. A number of patent applications are pending.

If another company successfully brings legal action against us claiming our activities violate, or infringe, their patents, a court may require us to pay significant damages and prevent us from using or selling products or technologies covered by those patents. Others could independently develop the same or similar discoveries and may have priority over any patent applications Genelabs has filed on these discoveries. Prosecuting patent priority proceedings and defending litigation claims can be very expensive and time-consuming for management. In addition, intellectual property that is important for advancing our drug discovery efforts or for uses for the active ingredient in Prestara owned by others might exist now or in the future. We might not be able to obtain licenses to a necessary product or technology on commercially reasonable terms, or at all, and therefore, we may not pursue research, development or commercialization of promising products.

***The lease for our facilities expires in November and we may not have the facilities to continue our operations.***

The lease for the facilities housing nearly all of our operations expires in November 2006. We may be unable to obtain an extension or renewal of the lease on acceptable terms, or at all. If we are unable to remain on our current premises, we may be unable to obtain alternative facilities due to our financial condition or for other reasons, and we may be unable to fully relocate our operations before termination of our current lease, thereby incurring a significant interruption in our business operations. Any relocation would result in substantial disruption of our operations and diversion of management and staff away from our core business activities. The terms for the existing or any new premises may require higher rent, advance payments, deposits or other terms disadvantageous to us. We sublease a portion of our premises to Genitope Corp. for approximately \$150,000 per year and there is no assurance that the sublease will continue on favorable terms, or at all, or that we would be able to remove the space from any extension of our lease.

***Our facilities in California are located near an earthquake fault, and an earthquake could disrupt our operations and adversely effect results.***

Almost all of our operations are conducted in a single facility built on landfill in an area of California near active geologic faults which historically have caused major earthquakes from time to time. The office park where the facility is located is approximately at sea level behind levees sheltering the buildings from the San Francisco Bay. In the event of a significant earthquake, we could experience significant damage and business interruption. The Company currently has insurance coverage for earthquake and flood damage, including business interruption coverage due to those events, with limits of \$5 million and subject to a deductible which currently is approximately \$1.6 million. There is no assurance that earthquake or flood insurance will continue to be available at a cost that is acceptable to the Company or that such insurance will be adequate to reimburse our losses.

## **Industry Risks**

***Our activities involve hazardous materials and improper handling of these materials by our employees or agents could expose us to significant legal and financial penalties.***

Our research and development activities involve the controlled use of hazardous materials, including infectious agents, chemicals and various radioactive compounds. Our organic chemists use solvents, such as chloroform, isopropyl alcohol and ethanol, corrosives such as hydrochloric acid and other highly flammable materials, some of which are pressurized, such as hydrogen. We use radioactive compounds in small quantities under license from the State of California, including Carbon(14), Cesium(137), Chromium(51), Hydrogen(3), Iodine(125), Phosphorus(32), Phosphorus(33) and Sulfur(35). Our biologists use biohazardous materials, such as bacteria, fungi, parasites, viruses and blood and tissue products. We also handle chemical, medical and radioactive waste, byproducts of our research, through licensed contractors. As a consequence, we are subject to numerous environmental and safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Federal, state and local governments may adopt additional laws and regulations affecting us in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, current or future laws or regulations.

Although we believe that our safety procedures for using, handling, storing and disposing of hazardous materials comply with the standards prescribed by state and federal regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and we could be liable for any civil damages that result, the cost of which could be substantial. Further, any failure by us to control the use, disposal, removal or storage of, or to adequately restrict the discharge of, or assist in the cleanup of, hazardous chemicals or hazardous, infectious or toxic substances could subject us to significant liabilities, including joint and several liability under state or federal statutes. We do not specifically insure against environmental liabilities or risks regarding our handling of hazardous materials. Additionally, an accident could damage, or force us to shut down, our research facilities and operations.

***We may not be able to obtain or maintain sufficient insurance on commercially reasonable terms or with adequate coverage against potential liabilities in order to protect ourselves against product liability claims.***

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We may become subject to product liability claims if someone alleges that the use of our products injured subjects or patients. This risk exists for products tested in human clinical trials as well as products that are sold commercially. Although we currently have insurance coverage in amounts that we believe are customary for companies of our size and in our industry and sufficient for risks we typically face, including general liability insurance of \$6 million, we may not be able to maintain this type of insurance in a sufficient amount. We currently maintain \$5 million of product liability insurance for claims arising from the use of our products in clinical trials. In addition, product liability insurance is becoming increasingly expensive. As a result, we may not be able to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities which could harm our business by requiring us to use our resources to pay potential claims.

## **Market Risks**

***Because our stock is volatile, the value of your investment in Genelabs may substantially decrease.***

The market price of our common stock, like the stock prices of many publicly traded biopharmaceutical companies, has been and will probably continue to be highly volatile. Between January 1, 2005 and December 31, 2005, the price of our common stock fluctuated between \$1.70 and \$6.15 per share, as adjusted for the reverse-split. Between January 1, 2006 and February 28, 2006, the price of our common stock fluctuated between \$1.73 and \$2.30 per share. In addition to the factors discussed in this Risk Factors section, a variety of events can impact the stock price, including the low percentage of institutional ownership of our stock, which contributes to lack of stability for the stock price. The availability of a large block of stock for sale in relation to our normal trading volume could also result in a decline in the market price of our common stock. In the event we do not obtain the

capital necessary to continue as a going concern, we may be required to discontinue operations, which could result in the complete loss of investment to our shareholders.

In addition, numerous events occurring outside of our control may also impact the price of our common stock, including general market conditions or those related to the biopharmaceutical industry. Other companies have defended themselves against securities class action lawsuits following periods of volatility in the market price of their common stock. If a party brings this type of lawsuit against us, it could result in substantial costs and diversion of management's time.

**Item 2. *Properties.***

We lease our principal research, clinical development and office facilities under an operating lease expiring in November 2006. This location encompasses approximately 50,000 square feet located in Redwood City, California, with a current annual base rent of approximately \$1,343,000. We may seek an extension of our existing lease, enter into a new lease for all or a portion of the facilities we currently occupy, or enter into a new lease at a different location. Genelabs believes that its present facility is adequate for its current needs and that suitable additional or substitute space is available if we choose to relocate our operations.

**Item 3. *Legal Proceedings.***

We are not currently subject to any pending material legal proceedings.

**Item 4. *Submission of Matters to a Vote of Security Holders.***

None.

## PART II

### Item 5. *Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.*

The Common Stock of Genelabs began trading publicly on The Nasdaq National Market on June 13, 1991 under the symbol "GNLB." On October 13, 2005, the Company transferred the listing of its common stock from The Nasdaq National Market to the Nasdaq Capital Market, where it is also traded under the symbol "GNLB". The following table sets forth for the periods indicated the high and low sale prices of the Company's common stock as reported by The Nasdaq National Market or the Nasdaq Capital Market. On December 19, 2005, the Company implemented a one-for-five reverse split of its outstanding common stock, and the prices per share listed below have been adjusted to give effect to this reverse split.

	<u>High</u>	<u>Low</u>
<b>2004</b>		
1st Quarter . . . . .	\$16.25	\$10.05
2nd Quarter . . . . .	16.00	10.00
3rd Quarter . . . . .	14.60	8.80
4th Quarter . . . . .	13.40	2.40
<b>2005</b>		
1st Quarter . . . . .	\$ 6.15	\$ 2.95
2nd Quarter . . . . .	3.55	1.80
3rd Quarter . . . . .	3.35	2.35
4th Quarter . . . . .	3.30	1.70

As of February 28, 2006, there were approximately 676 holders of record of Genelabs Common Stock.

Genelabs has never declared or paid any cash dividends on its capital stock. We currently intend to retain any earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

The following table represents certain information with respect to our equity compensation plans as of December 31, 2005, including our 1995 Stock Option Plan, our 2001 Stock Option Plan and our 2001 Employee Stock Purchase Plan.

### Equity Compensation Plan Information

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders:			
Stock Option Plans . . . . .	1,746,000	\$9.73	844,000
Stock Purchase Plan . . . . .	<u>—</u>	<u>—</u>	<u>408,000</u>
Equity compensation plans not approved by security holders . . .	<u>—</u>	<u>—</u>	<u>—</u>
Total . . . . .	<u>1,746,000</u>	<u>\$9.73</u>	<u>1,252,000</u>

Genelabs' equity compensation plans do not contain evergreen provisions.

**Item 6. Selected Financial Data.**

The selected financial data presented below summarize certain financial information from the consolidated financial statements. The information below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes thereto included in Item 8 of this Annual Report on Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

	Years Ended December 31,				
	2005	2004	2003	2002	2001
	(In thousands, except per share amounts)				
<b>Statement of Operations Data:</b>					
Total revenue	\$ 6,849	\$ 5,556	\$ 2,916	\$ 3,645	\$ 4,769
Research and development expenses	12,205	15,113	16,838	13,987	12,736
General and administrative expenses	5,958	6,505	6,484	6,079	6,966
Loss from continuing operations	(10,842)	(15,793)	(20,322)	(16,080)	(13,287)
Net loss	(10,842)	(13,511)	(19,807)	(15,950)	(13,000)
Loss per common share from continuing operations	(0.61)	(0.90)	(1.59)	(1.56)	(1.34)
Net loss per common share	(0.61)	(0.77)	(1.55)	(1.55)	(1.31)

	December 31,				
	2005	2004	2003	2002	2001
	(In thousands)				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents, restricted cash and short-term investments	\$10,211	\$26,508	\$26,530	\$6,570	\$19,000
Working capital	5,458	18,999	22,379	2,684	13,646
Total assets	12,661	29,383	29,866	9,765	22,100
Shareholders' equity	2,347	12,947	22,815	2,714	11,900

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*All statements in Management's Discussion and Analysis of Financial Condition and Results of Operations that are not historical are forward-looking statements. All estimates for 2006 and later periods of costs, expenses, revenue, savings, future amortization periods and other items are forward-looking statements. Statements regarding possible actions or decisions in 2006 and later periods by Genelabs and other parties, including collaborators and regulatory authorities, are forward-looking statements. Actual results may differ from the forward-looking statements due to a number of risks and uncertainties that are discussed under "Risk Factors" in Item 1A and elsewhere in this Annual Report on Form 10-K. Shareholders and prospective investors in the Company should carefully consider these risk factors. We disclaim any obligation to update these statements for subsequent events.*

Genelabs Technologies, Inc., referred to as Genelabs or the Company, is a biopharmaceutical company focused on the discovery and development of pharmaceutical products to improve human health. The Company has built drug discovery capabilities that can support various research and development projects. The Company is currently concentrating these capabilities on discovering novel compounds that selectively inhibit replication of the hepatitis C virus, or HCV, and advancing preclinical development of compounds from this hepatitis C virus drug discovery program, while also exploring options for development of a late-stage product for lupus.

A number of key events impacted the business of Genelabs during 2005. Beginning with drug discovery, we expanded our research capacity and capability by hiring additional scientists. We have focused our hiring activities on our HCV polymerase non-nucleoside drug discovery program and a separate effort focused on a target encoded by the NS5a region of the HCV genome. In addition, we continued our work on the HCV nucleoside program in collaboration with Gilead Sciences, Inc., or Gilead. In the non-nucleoside program we completed one and seven day toxicology studies in two rodent species on two different non-nucleoside compounds from separate chemical families. Based on the results of these studies, we contracted with an outside manufacturer to perform scale-up synthesis and production of additional quantities of the compounds which would enable further toxicology and other studies necessary to file an Investigational New Drug, or IND, application in the United States. Depending on resource constraints and test results, the Company may proceed with scale-up manufacturing of one, both or neither of the preclinical compounds. If the manufacturing proceeds smoothly and the requisite tests are conducted efficiently with positive results, the Company believes that it may file an IND or similar application during 2007. There can be no assurance that manufacturing and testing will be successful or that the Company will file an IND within such time frame.

In drug development, we focused on defining possible paths forward for our investigational drug for women with lupus, Prestara™. Patients who completed our phase III clinical trial, designated Study GL02-01, were eligible to enroll in a 12-month open-label continuation study which was designated Study GL03-01. This follow-on trial assessed the effect of Prestara on bone mineral density of the Study GL02-01 participants over an additional 12 months. Preliminary results of Study GL03-01 indicated that patients who received 200 mg of Prestara per day increased their bone mineral density, or BMD, at the lumbar spine by approximately 0.9% during the 12 months they were enrolled in Study GL03-01. Results of Study GL03-01 also indicated that patients who received a lower dose of Prestara, 100 mg per day, did not increase their BMD during the clinical trial, and in fact lost a measurable amount of BMD at the lumbar spine over the 12-month period of Study GL03-01. The safety profile for Prestara in this study was consistent with that seen in previous clinical studies. After learning these results, we had a meeting with the FDA for the purpose of determining the future development path for Prestara. In the meeting the FDA informed us that we would need additional positive clinical trial data before they would consider reviewing a New Drug Application for Prestara, and they indicated that one additional, positive clinical trial could suffice for an indication of treating the signs and symptoms of lupus. Going forward, we intend to pursue an indication for treating the signs and symptoms of lupus rather than the bone density indication we had pursued since 2002. We are presently in the process of designing a prospective clinical trial of Prestara for lupus, measuring the signs and symptoms of lupus, although we presently do not have the resources to conduct this trial on our own, and we may decide to discontinue further development of Prestara.

Effective October 13, 2005, our common stock trading was transferred from The Nasdaq National Market to the Nasdaq Capital Market, which was formerly known as the Nasdaq SmallCap Market. On December 19, 2005 we

implemented a one-for-five reverse split of our common stock, and on January 6, 2006, Nasdaq sent us notification that we had re-gained compliance with their \$1.00 minimum closing bid price requirement.

On March 15, 2006, Genelabs had cash, cash equivalents and restricted cash of approximately \$8.3 million, which we expect can sustain existing operations only into the beginning of the fourth quarter of 2006. As a result, there is substantial doubt as to the ability of Genelabs to continue as a going concern absent a substantial increase in cash from a new corporate partnership or sale of equity securities. In addition, Genelabs does not currently satisfy the listing requirements of the Nasdaq Capital Market, requiring a minimum shareholder's equity balance or market capitalization level, which could result in the delisting of Genelabs from that exchange.

### **Critical Accounting Policies**

The preparation of our financial statements in conformity with U.S. generally accepted accounting principles requires management to make judgments, assumptions and estimates that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. The following are critical accounting estimates which are important to understanding our financial condition and results of operations as presented in the financial statements.

*Revenue Recognition.* Revenue from non-refundable upfront license fees where we continue involvement through a collaboration or other obligation is referred to as "unearned contract revenue" and classified as a liability on the balance sheet. We amortize unearned contract revenue into "contract revenue" on the statement of operations over the research or development period instead of recognizing it into income immediately upon receipt. We base the amortization period for each agreement on our estimate of the period we have significant obligations under the contract. We continually review the basis for our estimates, and we may change the estimates if circumstances change. These changes can significantly increase or decrease the amount of revenue recognized in the financial statements. For arrangements with multiple deliverables, we allocate the revenue among the deliverables based on objective and reliable evidence of each deliverable's fair value. Unearned contract revenue at December 31, 2005 was from three different sources. Genelabs' management considers the amortization periods for each of the up-front payments as critical accounting estimates.

At December 31, 2005, the largest component of unearned contract revenue was related to an up-front payment from Gilead Sciences, Inc. under a research collaboration and license agreement we entered into in 2004. When the agreement was signed we received an up-front payment of \$8 million that we are amortizing over a four year period from the effective date of the collaboration. The four-year period is based on the initial three-year term of our research obligations to Gilead plus an additional one-year extension, which is at Gilead's sole option. As of December 31, 2005, \$5.5 million of unearned contract revenue was related to the up-front payment received from Gilead, of which \$2.0 million was classified as current. In addition to the up-front payment, Gilead is also obligated to pay us on-going research funding.

At December 31, 2005, Genelabs also has unearned contract revenue aggregating \$2.5 million related to two separate agreements for Prestara, Genelabs' investigational drug for lupus. We classified as current approximately \$1.2 million of the unearned contract revenue for these agreements. We amortize the two up-front payments we received over the estimated development terms for Prestara for the territories covered by each of the agreements. Genelabs' management believes that its significant obligations under the agreements extend to the time when regulatory decisions are made to approve Prestara in the key licensed territory, if Prestara were to be approved, or until further development of Prestara is terminated. For each of the agreements related to Prestara, Genelabs is amortizing the unearned contract revenue through December 31, 2008.

In all of the agreements for which we have recorded deferred revenue, the estimated period for amortization has an important impact on the revenue we recognize, and, in turn, on the net loss we report in our financial statements. For example, if longer terms were estimated our revenue would be lower and our net loss would be higher. Conversely, if a shorter amortization term were estimated, our revenue would be greater and the net loss lower. We regularly assess the remaining terms over which the up-front payments are being recognized into the statement of operations and, if appropriate, make changes based on updated information. For example, in 2004 we lengthened the amortization period for the unearned contract revenue related to the agreement with Watson Pharmaceuticals after our U.S. clinical trial, Study GL02-01, for Prestara did not succeed in meeting its clinical

endpoints. The failure of the clinical trial to meet its endpoints resulted in a longer period of time for us to potentially receive approval of Prestara, and our best current estimate is that it may now take until the end of 2008. Our estimate is based on the need for another clinical trial to obtain approval. However, because we have not completed the protocol and we have not received agreement from the FDA on the specific trial, the estimates are highly subjective and may change in the future once we have more information and are able to better determine our plans for future development of Prestara.

We have assessed the remaining term over which each of the up-front payments are being recognized into the statement of operations, and believe we are using the most appropriate terms based on the facts known to us as of the date of the filing of this Annual Report on Form 10-K. However, actions taken by the FDA, decisions made by our collaborators or other changes in circumstances after the filing of this Annual Report on Form 10-K may either reduce or lengthen the remaining period over which Genelabs records unearned contract revenue into the statement of operations.

*Accounting for Employee Stock Options.* As permitted by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," referred to as SFAS 123, we have elected to continue to apply the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for our employee stock option plans. Accordingly, to date we generally have accounted for employee stock options based on their intrinsic value and have not recognized compensation expense for employee options granted at fair market value or higher. In the notes to our financial statements we separately disclose the pro forma effects on reported net loss and loss per share as if compensation expense had been recognized based on the fair value method of accounting using the Black-Scholes option pricing model. In valuing our options for this disclosure, we make assumptions about risk-free interest rates, dividend yields, volatility and weighted average expected lives of the options. Genelabs management believes that these estimates are subjective, and notes that changes in any of these assumptions, particularly the volatility assumption, would increase or decrease the accounting value of the option and correspondingly increase or decrease the pro forma effect on the disclosures of reported net loss and loss per share under the fair value method.

In December 2004, the Financial Accounting Standards Board issued a revised Statement of Financial Accounting Standards No. 123, or SFAS 123R, superseding previous accounting rules covering stock options issued to employees. We are adopting SFAS 123R effective January 1, 2006. Under SFAS 123R, we will record compensation expense for stock options issued to employees based on an estimate of the fair value of the options when they are issued, and we are implementing this new standard using the modified-prospective transition method. The stock option valuation assumptions permitted under SFAS 123R are different than those contained in SFAS 123 and we are in the final stages of determining the assumptions that we will use for options we grant in 2006 and thereafter. SFAS 123R will materially increase our operating expenses and our net loss.

## **Results of Operations**

### ***Years Ended December 31, 2005 and 2004***

*Introduction.* Genelabs' net loss was \$10.8 million in 2005, a decrease of \$2.7 million from the \$13.5 million net loss in 2004. This decrease in net loss was primarily the result of lower research and development costs and higher contract revenue, partially offset by a 2004 gain on the sale of a discontinued operation. A more detailed discussion of the changes in Genelabs' statement of operations follows.

*Revenue.* Revenues were \$6.8 million in 2005 and \$5.6 million in 2004. The following table breaks down revenue by major source (in thousands):

	<u>2005</u>	<u>2004</u>
Contract revenue:		
HCV drug discovery research collaboration (Gilead Sciences, Inc.) . . . . .	\$5,600	\$1,400
Prestara collaborations (Watson Pharmaceuticals, Inc. and Tanabe Seiyaku Co., Ltd.) . . . . .	620	1,182
Linker-aided DNA amplification license fee (Affymetrix, Inc.) . . . . .	—	1,250
Hepatitis E vaccine milestone (GlaxoSmithKline) . . . . .	—	750
Data analysis services . . . . .	—	292
Total contract revenue . . . . .	<u>6,220</u>	<u>4,874</u>
Royalties . . . . .	<u>629</u>	<u>682</u>
Total revenue . . . . .	<u>\$6,849</u>	<u>\$5,556</u>

In 2005, our most significant source of revenue was from our collaboration with Gilead Sciences, Inc. The agreement with Gilead that we entered into during 2004 has a three-year initial research term, with Gilead having an option to extend for one additional year. Upon signing the agreement we received an \$8.0 million up-front payment, and we are entitled to receive quarterly payments aggregating approximately \$11 million over the initial three year term as we work with Gilead to discover additional nucleoside compounds that inhibit replication of HCV. If Gilead exercises its option to extend the research term by one year, additional payments would be due to Genelabs. We recognized contract revenue of \$5.6 million under the Gilead agreement in 2005, comprised of \$3.6 million in research funding and \$2.0 million for the pro-rata share of the up-front license fee. The revenue recognized during 2005 was greater than that recognized in 2004 because the agreement was in place for all of 2005 compared to only one quarter of 2004.

In 2005 we recognized \$0.6 million in revenue from our two collaborations for the development and commercialization of Prestara. These are with Watson Pharmaceuticals Inc. for North America and Tanabe Seiyaku Co., Ltd. for Japan. In 2005, our revenue related to Prestara decreased by \$0.6 million compared to 2004 primarily due to a lengthening of the term we estimate it could take us to potentially obtain approval of Prestara in the United States. Our lengthening of the estimated term to potentially receive approval in the United States was made based on negative clinical trial results received in 2004, and our determination that approval would not be possible by the previous time through which we were recognizing revenue. For both agreements related to Prestara, we presently are amortizing the up-front payments through the end of 2008. The amortization for both agreements could change in the future based on the clinical trial design, the status of our ability to initiate a clinical trial, and discussions with our corporate partners, among other things.

During 2005, we did not recognize revenue related to our linker-aided DNA amplification licenses or our hepatitis E vaccine agreement with GlaxoSmithKline because we did not receive any payments. In late 2004 we ceased providing data analysis services to other parties, and accordingly did not record or receive any revenue during 2005.

In addition, we receive royalties from other parties which aggregated approximately \$0.6 million in 2005, compared to \$0.7 million in 2004.

*Operating Expenses.* The following table breaks down operating expenses into the two major categories of costs in our financial statements (in thousands).

	<u>2005</u>	<u>2004</u>	<u>Change</u>
Research and development . . . . .	\$12,205	\$15,113	-19%
General and administrative . . . . .	<u>5,958</u>	<u>6,505</u>	-8%
Total operating expenses . . . . .	<u>\$18,163</u>	<u>\$21,618</u>	-16%

All operating expenses are related to Genelabs' business of discovering and developing pharmaceutical products. The two key decreases in operating expenses for 2005 compared to 2004 were lower costs resulting from our completion of all clinical work on Prestara for lupus and lower costs incurred for our employees' incentive bonuses, which were partially offset by increased costs on our hepatitis C virus drug discovery research. These are each explained in more detail below.

*Research and Development Expenses — Background*

We are in the business of drug discovery and development and have not developed any products that have been approved for sale. Because the majority of our costs are directly related to discovering and developing new drugs, we classify these costs as research and development and expense them as they are incurred. Research and development expenses include salaries and benefits for employees directly involved in these activities, supplies and chemicals used in laboratories, clinical trial and related clinical manufacturing costs, contract and outside service fees, and allocated facilities and overhead costs. Over the last several years the majority of Genelabs' research and development activities have been focused on two key areas — the discovery of entirely new drugs and the development of Prestara™ for lupus. Following a clinical trial that did not meet its endpoint in late 2004, the work related to Prestara decreased throughout 2005.

*Research and Development Expenses by Project*

In 2005, \$12.2 million of operating expenses were in research and development, compared to \$15.1 million in 2004, a decrease of \$2.9 million. The following table breaks down the research and development expenses by major category (in thousands):

	<u>2005</u>	<u>2004</u>	<u>Change</u>
Drug discovery (Hepatitis C virus, or HCV) . . . . .	\$ 5,880	\$ 4,715	+25%
Drug development (Prestara™) . . . . .	2,584	5,744	-55%
Support costs and other research and development . . . . .	<u>3,741</u>	<u>4,654</u>	<u>-20%</u>
Total research and development . . . . .	<u>\$12,205</u>	<u>\$15,113</u>	<u>-19%</u>

*Drug Discovery*

Costs for our drug discovery program increased to \$5.9 million in 2005 from \$4.7 million in 2004. Drug discovery costs were higher in 2005 than in 2004 due to our significant expansion of the program beginning in the latter half of 2004, which continued throughout 2005, with most of our hiring of new employees occurring during the fourth quarter of 2004 and the first quarter of 2005. As of December 31, 2005, our research headcount increased by 13% over the amount at the end of 2004. Costs increased as a result of increased personnel and a greater usage of chemicals and lab supplies used by the scientists. The percentage increase in costs in 2005 compared to 2004 was greater than the percentage increase in headcount during 2005 due to the timing of hiring in late 2004 combined with the hiring of more scientists with advanced degrees such as Ph.D's. In addition, since we do not have full preclinical development capabilities in our own laboratories, in 2005 we required additional outside lab services as our compounds advanced within preclinical development. The increase in HCV drug discovery costs in 2005 also included the addition of a new program, using HCV NS5a as a drug target, and further work on the programs targeting the HCV polymerase, including identification of additional potent compounds and the advancement of another one of these to preclinical development status. Since initiating our first drug discovery program in 1993, Genelabs has built medicinal chemistry, combinatorial chemistry, computational modeling, molecular biology, assay development and high-throughput screening, drug metabolism, pharmacokinetics and toxicology capabilities. Genelabs has incurred direct drug discovery costs of approximately \$45 million through December 31, 2005. Of this amount, \$16 million relates to our HCV drug discovery programs which began in early 2002. During 2005, substantially all of our drug discovery efforts were directed toward three separate hepatitis C virus research programs, which are concentrated on identifying a new drug to combat infection with HCV. Two of these programs target the HCV NS5b RNA-dependent RNA polymerase (the enzyme directly responsible for replication of the HCV genome), although through different mechanisms. We refer to one of these mechanisms as our nucleoside program and we refer to the other as the non-nucleoside program. Our third HCV drug discovery program targets

the HCV NS5a protein, a different viral enzyme that is also required for viral replication. Part of our drug discovery process includes continued testing of our preclinical drug candidates and identification of additional potential lead compounds:

Due to the nature of drug discovery research, we cannot reliably estimate the outcome of scientific experiments, many of which will impact the design and conduct of subsequent scientific experiments, and all of which provide additional information on both the direction of the research program and likelihood of its success. As such, the potential timing for key future events that may occur in our drug discovery programs cannot reliably be estimated and we cannot estimate whether a compound will advance to a later stage of development or when we may determine that a program is no longer viable for potentially producing a drug candidate. We also cannot reasonably predict the costs to reach these stages, and cannot predict whether any of our compounds will result in commercial products or lead to revenue for the Company. Going forward into 2006, we believe both of our HCV polymerase-targeted programs, nucleoside and non-nucleoside, are staffed at appropriate levels to address our objectives. We believe that, as we continue advancement of the preclinical candidates in the non-nucleoside program, our external costs will increase as we rely on outside sources to manufacture the drug material and conduct studies. In 2006, subject to receipt of additional funding, we also plan to expand work on our newest HCV drug discovery program, targeting the NS5a protein, and intend to explore other drug targets as potential programs, if our financial resources allow. However, the resources available to us, outcomes of current and planned scientific experiments and outcomes of corporate partnering discussions may cause us to revise this estimate. Management continually evaluates the status of our drug discovery research programs and expects to continue to devote resources toward these efforts, while at the same time managing the level of expenditures to balance limited cash resources and the various drug discovery and development opportunities.

#### *Drug Development (Prestara™)*

Costs for Prestara decreased to \$2.6 million in 2005 compared to \$5.7 million in 2004, a reduction of over 50% as we completed a Phase III clinical trial in the third quarter of 2004, completed a follow-on open-label trial in the third quarter of 2005 and significantly decreased the staff working on the program. Genelabs began developing Prestara™ for systemic lupus erythematosus in 1993 when Genelabs licensed exclusive rights to patents related to Prestara from Stanford University. To potentially develop this investigational new drug we have incurred direct costs of approximately \$50 million through December 31, 2005. In 2006 we currently expect the costs to be lower than the 2005 levels by at least 50%, as we have completed clinical work on the previous studies and have a significantly reduced staff. We expect to incur continued costs for the development of a clinical trial protocol and possibly other matters. Future development decisions and the future development of Prestara for lupus will depend on a number of factors, including discussions with and actions by the FDA, discussions with and actions by our Prestara collaborators and potential collaborators, and our financial resources. We may decide to discontinue development of Prestara in 2006, which may further reduce the costs from planned levels, depending on the timing of the decision.

### *Support Costs and Other Research and Development*

Support costs and other research and development is primarily comprised of costs necessary to maintain a research and development facility, such as rent, insurance, depreciation, support staff, utilities, maintenance and the incentive bonus, which are allocated based on the headcount ratio between research and development and general and administrative. Support costs and other research and development included within research and development were \$3.7 million in 2005 compared to \$4.7 million in 2004. The following table breaks down the major components of support costs and other research and development (in thousands):

	<u>2005</u>	<u>2004</u>
Facility rent, net of sublease income . . . . .	\$1,088	\$1,121
Salaries and benefits for lab and facility support personnel . . . . .	897	965
Insurance, depreciation and property taxes . . . . .	891	904
Utilities, maintenance and security . . . . .	736	677
Lab equipment, services and sundry supplies . . . . .	213	194
Allocation of incentive bonus compensation . . . . .	(153)	706
Other items . . . . .	<u>69</u>	<u>87</u>
Total support and other research and development costs . . . . .	<u>\$3,741</u>	<u>\$4,654</u>

The decrease in expenses during 2005 as compared to 2004 was primarily due to a reduction of the incentive bonus costs due to cash-balance contingencies our board of directors has established for the payment of any bonuses to employees. As of December 31, 2005, the contingency had not been met and accordingly no 2005 incentive bonus charge was recorded. The credit balance in the account for 2005 primarily represents the forfeiture of previous years' accruals by participants that had been in Genelabs' Long-Term Incentive Program. Other costs included in support costs and other research and development were generally comparable in 2005 and 2004, although utilities increased modestly due to higher usage and higher energy costs, and salaries for support personnel decreased as Genelabs consolidated operations that were no longer required. In 2006, we expect support costs and other research and development, other than employee incentive bonuses, to increase approximately 10% in order to support planned higher direct drug discovery research activities. In 2006, we expect costs for the incentive bonus program to be dependent on our meeting board-established contingency criteria and meeting our corporate objectives.

### *General and Administrative*

In 2005, general and administrative expenses decreased to \$6.0 million from \$6.5 million in 2004. General and administrative expenses consist primarily of personnel costs for executive management, finance, legal, business development, human resources and marketing departments, as well as professional expenses, such as legal and audit, and allocated facilities costs such as rent and insurance. During 2005, lower general and administrative costs were incurred for Prestara marketing activities, business development, human resources and reduced allocation of costs that are shared between research and development and general and administrative expenses, such as the employee incentive bonus. Management currently expects our 2006 general and administrative expenses, excluding the allocation of shared costs, to increase by approximately 5% compared to the 2004 general and administrative expenses if we maintain our same level of operations, primarily as a result of predicted inflationary increases in costs.

*Nonoperating Income.* Interest income was \$0.5 million in 2005 compared to \$0.3 million in 2004, an increase of \$0.2 million primarily due to higher average interest rates.

In 2004, we recorded \$2.3 million in a gain on sale of our discontinued operations and income from its operations. Because this transaction occurred during 2004, there was no comparable income during 2005.

### *Years Ended December 31, 2004 and 2003*

*Introduction.* Genelabs' net loss was \$13.5 million in 2004, a decrease of \$6.3 million from the \$19.8 million net loss in 2003. This decrease in net loss was primarily the result of higher contract revenue, lower research and

development costs and a gain on the sale of a discontinued operation. A more detailed discussion of the changes in Genelabs' statement of operations follows.

*Revenue.* Revenues were \$5.6 million in 2004 and \$2.9 million in 2003. The following table breaks down revenue by major source (in thousands):

	<u>2004</u>	<u>2003</u>
Contract revenue:		
HCV drug discovery research collaboration (Gilead Sciences, Inc.) . . . . .	\$1,400	\$ —
Linker-aided DNA amplification license fees (Affymetrix, Inc.) . . . . .	1,250	50
Prestara collaborations (Watson Pharmaceuticals, Inc. and Tanabe Seiyaku Co., Ltd.) . . . . .	1,182	1,841
Hepatitis E vaccine milestone (GlaxoSmithKline) . . . . .	750	—
Data analysis services . . . . .	<u>292</u>	<u>493</u>
Total contract revenue . . . . .	4,874	2,384
Royalties . . . . .	<u>682</u>	<u>532</u>
Total revenue . . . . .	<u>\$5,556</u>	<u>\$2,916</u>

Our research collaboration and license agreement with Gilead Sciences, Inc. provided \$1.4 million of revenue recognized in 2004. The agreement began in October 2004, and under the agreement we recognized \$0.5 million for the pro-rata share of an \$8.0 million up-front license fee and \$0.9 million in research funding for the fourth quarter of 2004. Because the agreement was signed during 2004, there was no comparable revenue for 2003.

In 2004, we received a license amendment fee of \$1.25 million for our linker-aided DNA amplification technology. This compares to license fees of \$50,000 in 2003. The increase in 2004 compared to 2003 occurred because our licensee, Affymetrix, Inc., made a one-time payment to us of \$1.25 million in exchange for receiving a fully paid-up license without future royalty obligations. We recognized the full amount we received as revenue because we have no significant future obligations to Affymetrix under the agreement.

In 2004, we recognized \$1.2 million in revenue from our two collaborations for development and commercialization of Prestara with Watson and Tanabe. In 2004, our revenue related to Prestara decreased by \$0.7 million compared to 2003 primarily due to a lengthening of the term we estimated it would take us to potentially obtain approval of Prestara in the United States. Our lengthening of the estimated term to potentially receive approval in the United States was made based on negative clinical trial results received in 2004, and our determination that approval would not be possible by the June 2005 time through which we were previously recognizing revenue. The decrease in contract revenue recognized under the agreement with Watson more than offset the incremental revenue recognized for the new agreement entered into during 2004 with Tanabe Seiyaku for Japan.

In 2004, GlaxoSmithKline, or GSK, paid us a \$0.75 million milestone based on the results of a clinical trial the Walter Reed Army Institute of Research conducted in collaboration with GSK for a hepatitis E virus vaccine that GSK is developing under license from Genelabs. We recognized as revenue the full amount of the milestone we received because we have no further significant obligations to GSK.

Revenue from data analysis services we have performed for other pharmaceutical companies declined to \$0.3 million in 2004 from \$0.5 million in 2003 because we chose to stop providing these services during the latter part of 2004.

In addition, we receive various royalties from other parties, which aggregated approximately \$0.7 million in 2004 and \$0.5 million in 2003. The increase in royalties primarily represents an increase in royalties from Affymetrix prior to their payment to us which eliminated future royalty obligations.

*Operating Expenses.* The following table breaks down operating expenses into the two major categories of costs in our financial statements ( in thousands).

	<u>2004</u>	<u>2003</u>	<u>Change</u>
Research and development . . . . .	\$15,113	\$16,838	-10%
General and administrative . . . . .	<u>6,505</u>	<u>6,484</u>	—
Total operating expenses . . . . .	<u>\$21,618</u>	<u>\$23,322</u>	<u>-7%</u>

All operating expenses are related to Genelabs' business of discovering and developing pharmaceutical products. The two key decreases in operating expenses for 2004 compared to 2003 were lower costs from conducting our clinical trial of Prestara for lupus and lower costs incurred for our employees' incentive bonuses. These are each explained in more detail below.

*Research and Development Expenses by Project*

In 2004, \$15.1 million of operating expenses were in research and development, compared to \$16.8 million in 2003, a decrease of \$1.7 million for 2004 as compared to 2003. The following table breaks down the research and development expenses by major project (in thousands):

	<u>2004</u>	<u>2003</u>	<u>Change</u>
Drug development (Prestara™) . . . . .	\$ 5,744	\$ 6,416	-10%
Drug discovery (HCV) . . . . .	4,715	4,513	+4%
Support costs and other research and development . . . . .	<u>4,654</u>	<u>5,909</u>	<u>-21%</u>
Total research and development . . . . .	<u>\$15,113</u>	<u>\$16,838</u>	<u>-10%</u>

*Drug Development (Prestara™)*

Costs for Prestara decreased to \$5.7 million in 2004 compared to \$6.4 million in 2003, primarily as a result of a decreased average number of patients under treatment in our Phase III clinical trial, which completed enrollment in February 2004. This decrease was partially offset by higher costs incurred for a 12-month open-label follow-on clinical trial for patients that elected to continue participation, although the per-patient costs in the open label trial were lower than in the Phase III clinical trial. Genelabs also incurred lower costs related to the qualification of a manufacturing site for Prestara.

*Drug Discovery*

Costs for our drug discovery program increased to \$4.7 million in 2004 from \$4.5 million in 2003. Drug discovery costs were modestly higher in 2004 compared to 2003 largely due to higher personnel costs and additional research materials used during 2004.

*Support Costs and Other Research and Development*

Support costs and other research and development is primarily comprised of costs necessary to maintain a research and development facility, such as rent, support staff, maintenance and utilities, and the incentive bonus, all allocated based on the headcount ratio between research and development and general and administrative. Support costs and other research and development were \$4.7 million in 2004 and \$5.9 million in 2003, a decrease of \$1.2 million. The decrease in costs during 2004 as compared to 2003 was primarily due to a reduction of the incentive bonus allocation in 2004 due to contingencies that were established for the payment of bonuses relating to the 2002 year, which were met in late 2003 and resulted in a higher charge for 2003 (approximately two years of incentive bonus charges). Other costs included in support costs and other research and development were generally comparable in 2004 and 2003.

### *General and Administrative*

In both 2004 and 2003, \$6.5 million of our operating expenses were general and administrative expenses. These expenses consist primarily of personnel costs for executive management, finance, legal, business development, human resources and marketing departments, as well as professional expenses, such as legal and audit, and allocated facilities costs such as rent and insurance. During 2004, higher general and administrative costs were incurred for audit and legal fees, mostly related to new regulations covering public companies and higher patent costs due to our filing more patent applications arising from our HCV drug discovery program. The increase in these audit and legal fees in 2004 offset decreases in the allocation of the incentive bonus to general and administrative expenses after contingencies were met during 2003, increasing the costs for 2003.

*Nonoperating Income.* Interest income was \$0.3 million in 2004, an increase of \$0.2 million from 2003 due to higher average cash balances during 2004 and higher average interest rates.

In 2004, we recorded \$2.3 million in a gain on sale of our discontinued operations and income from its operations compared to \$0.5 million in 2003 for income from its operations. Because the gain on sale was recorded during 2004, the income from discontinued operations was higher in 2004 than in 2003.

### **Liquidity and Capital Resources**

We assess liquidity primarily by the cash and cash equivalents available to fund our operations. Genelabs had cash, cash equivalents and restricted cash of \$10.2 million at December 31, 2005, which was a decrease of \$16.3 million from the cash, cash equivalents and restricted cash at December 31, 2004. The 2005 decrease in cash and cash equivalents was attributable to cash used in operations to fund our continued research on the discovery of new treatments for hepatitis C virus infection and development of Prestara.

Genelabs presently estimates that our current cash resources will be adequate to provide liquidity for our existing operations to approximately the beginning of the fourth quarter of 2006. We will require additional capital prior to this time to carry out our business plans in 2006 and expect to continue to rely on outside sources of financing to meet our capital needs.

The ability of the Company to continue as a going concern is dependent upon its ability to obtain additional capital from a collaboration, equity financing or other means. In order to satisfy its projected cash needs for at least the next twelve months, Genelabs is pursuing various alternatives, including licensing its non-nucleoside HCV polymerase program, renegotiating the terms of a collaboration and pursuing investments from third-parties. If any of these transactions are completed Genelabs expects they would provide additional cash to the Company, although the amounts are not determinable. Genelabs may be unable to complete any of these transactions as currently contemplated or at all, and the outcome of these matters cannot be predicted at this time. Further, there can be no assurance, assuming the Company successfully raises additional funds, that the Company will ever achieve positive cash flow. If the Company is not able to secure additional funding the Company will be required to scale back its research and development programs and general and administrative activities and may not be able to continue in business. These consolidated financial statements do not include any adjustments to the specific amounts and classifications of assets and liabilities, which might be necessary should the Company be unable to continue in business. The following are illustrations of potential impediments to our ability to successfully secure additional funds:

- our stock price and market capitalization are low, therefore the amount of capital we can raise through equity financings is limited;
- our ability to successfully complete an equity financing would be negatively impacted if we fail to meet Nasdaq's listing requirements; and
- our research programs are in an early stage, therefore there are fewer opportunities to enter into collaborations with other companies and up-front payments for early-stage pharmaceutical research collaborations are generally smaller than for projects that are closer to potential marketability.

Longer-term, if we succeed in securing sufficient capital to allow us to continue drug discovery research and complete an additional clinical trial for Prestara, Genelabs' liquidity and capital resources may be materially

impacted by success or failure in reaching milestones under corporate collaborations, the progress, if any, of the Company's other, unpartnered drug discovery programs and FDA actions with respect to our NDA for Prestara.

Since Genelabs' inception, the Company has operated at a loss and has funded operations primarily through public and private offerings of equity securities and, to a lesser extent, contract revenues. We expect to incur substantial additional costs, including research costs for drug discovery. The amount of additional costs in our business plans will depend on numerous factors including the progress of our research and development programs and the actions of corporate collaborators. To meet our capital needs we will require additional funding, but additional funds may not be available on acceptable terms, if at all. The unavailability of additional funds could delay or prevent the development, approval or marketing of some or all of our products and technologies, which would have a material adverse effect on our business, financial condition and results of operations.

*Other Contractual Arrangements.*

Genelabs' principal research, clinical development and office facilities are leased from third-parties under operating leases. As such, Genelabs expenses its facility rental costs over the terms of the respective leases as those costs are incurred. Other than the facility operating leases, Genelabs does not have any financial off-balance sheet arrangements.

All biotechnology companies in California that use radioactive materials must provide a means of assurance to the state that radioactive waste will be cleaned up in the event the facility is abandoned. Genelabs has provided this assurance by establishing a \$150,000 standby letter of credit in favor of the Radiologic Health Branch of the California Department of Health Services. The letter of credit is secured by a certificate of deposit of \$150,000 which is classified as restricted cash.

There are no contractual financial obligations that extend beyond the next five years. Our total contractual payment obligations for the next five years are as follows:

	<u>Less than One Year</u>	<u>One to Three Years</u>	<u>Three to Five Years</u>	<u>Total</u>
	(In thousands)			
Operating leases . . . . .	<u>\$1,231</u>	<u>—</u>	<u>—</u>	<u>\$1,231</u>

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

Genelabs' exposure to market risk for changes in interest rates relates primarily to the Company's cash equivalents. We consider the interest rate risk minimal as substantially all investments are in money market funds and we have not used derivative instruments. As of December 31, 2005, the overall average maturity of Genelabs' short-term investment portfolio was less than 90 days, leaving only a minimal exposure to changes in interest rates.

Genelabs' exposure to market risk for changes in foreign currency exchange rates relates primarily to the Company's investment in a Taiwan-based biopharmaceutical company, Genovate Biotechnology Co., Ltd., which is accounted for at cost, based on the lower of cost or market value method. This investment is the only item included in the balance sheet caption "Long-term investments." Genelabs may attempt to divest a portion of this investment, in which case changes in foreign currency exchange rates would impact the proceeds received upon sale of these shares. Because the book value of Genelabs' ownership percentage of Genovate is greater than our carrying cost, we currently do not believe that any foreign currency exchange rate changes would impact the value of this investment as reported in the financial statements unless the value of a Taiwan dollar depreciates by greater than 60% compared to the U.S. dollar, which, depending on other circumstances, might require Genelabs to record a non-cash charge to write-down the long-term investment. Genelabs has not entered into any transactions to mitigate its exposure to changes in the exchange rate for its long-term investment. The Genovate shares owned by Genelabs currently are not transferable and we cannot predict when or if the shares will be transferable and at what price, if any.

**Item 8. Consolidated Financial Statements and Supplementary Data.**

The Company's Consolidated Financial Statements are set forth in the "Genelabs Technologies, Inc. Index to Consolidated Financial Statements" on page F-1 of this Annual Report on Form 10-K.

The following table is a summary of the results of operations for the years ended December 31, 2005 and 2004. The information below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes thereto included in this Annual Report on Form 10-K in order to fully understand factors that may affect the comparability of the information presented below.

	<u>December 31</u>	<u>September 30</u>	<u>June 30</u>	<u>March 31</u>
	(In thousands, except per share amounts)			
<b>2005 Quarter Ended:</b>				
Total revenue . . . . .	\$ 1,719	\$ 1,698	\$ 1,710	\$ 1,722
Research and development expenses . . . . .	2,780	2,944	3,219	3,262
General and administrative expenses . . . . .	1,318	1,720	1,499	1,421
Loss from continuing operations . . . . .	(2,271)	(2,845)	(2,885)	(2,841)
Net loss . . . . .	(2,271)	(2,845)	(2,885)	(2,841)
Loss per share from continuing operations . . . . .	(0.13)	(0.16)	(0.16)	(0.16)
Net loss per share . . . . .	(0.13)	(0.16)	(0.16)	(0.16)
	<u>December 31</u>	<u>September 30</u>	<u>June 30</u>	<u>March 31</u>
	(In thousands, except per share amounts)			
<b>2004 Quarter Ended:</b>				
Total revenue . . . . .	\$ 3,801	\$ 399	\$ 667	\$ 689
Research and development expenses . . . . .	3,702	3,284	3,923	4,204
General and administrative expenses . . . . .	1,708	1,545	1,669	1,583
Loss from continuing operations . . . . .	(1,503)	(4,371)	(4,874)	(5,045)
Net loss . . . . .	(1,503)	(4,371)	(2,854)	(4,783)
Loss per share from continuing operations . . . . .	(0.09)	(0.25)	(0.28)	(0.29)
Net loss per share . . . . .	(0.09)	(0.25)	(0.16)	(0.27)

During the fourth quarter of 2004, an amendment to a license agreement with Affymetrix, Inc. for our linker-aided DNA amplification technology and a milestone payment received from GlaxoSmithKline for the hepatitis E virus vaccine together resulted in non-recurring revenue of \$2.0 million. In addition, during the fourth quarter of 2004 we commenced work under our license and research collaboration agreement with Gilead Sciences, Inc., under which we have recognized \$1.4 million as revenue per quarter beginning in the fourth quarter of 2004 and continuing throughout the four quarters of 2005.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not applicable.

**Item 9A. Controls and Procedures.**

(a) Disclosure Controls and Procedures. The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2005. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2005, the Company's disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act and are effective in ensuring that information required to be disclosed by the Company in the

reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

(b) **Internal Control Over Financial Reporting.** There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Item 9B. *Other Information.***

In December 2005, the Securities and Exchange Commission issued a release permitting an accelerated filer with an aggregate worldwide market value of voting and non-voting common equity held by non-affiliates of less than \$50 million to exit accelerated filer status at the end of the fiscal year in which it fails to meet that threshold as of the last business day of its second quarter. The aggregate worldwide market value of all equity held by non-affiliates of Genelabs Technologies, Inc. was less than \$50 million as of June 30, 2005, the last business day of our second fiscal quarter. Accordingly, Genelabs exited accelerated filer status as of December 31, 2005, and is therefore no longer subject to the rules and regulations applicable to accelerated filers, including those relating to internal controls over financial reporting and the filing of annual and periodic reports on an accelerated basis.

**PART III**

**Item 10. *Directors and Executive Officers of the Registrant.***

The information concerning the Company's directors required by Item 10 is incorporated herein by reference to the sections entitled "Proposal No. 1 — Election of Directors" and "Corporate Governance and Board of Directors Matters" of the definitive Proxy Statement for the Company's 2006 Annual Meeting of Shareholders (the "Proxy Statement"). The information concerning the Company's executive officers required by Item 10 is incorporated herein by reference to the section of the Proxy Statement entitled "Executive Officers." The information concerning compliance with Section 16 of the Securities Exchange Act of 1934, as amended, required by Item 10 is incorporated herein by reference to the section of the Proxy Statement entitled "Compliance With Section 16(a) of the Exchange Act."

In January 2004, the board of directors adopted a Code of Business Ethics and Conduct applicable to all employees, including the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the Code of Business Ethics and Conduct is available on our website at [www.genelabs.com](http://www.genelabs.com) under Investor Information, Corporate Governance and is also available free of charge upon written request to: Compliance Officer, Genelabs Technologies, Inc., 505 Penobscot Drive, Redwood City, California 94063. We intend to post any amendment to or waiver from our Code of Business Ethics and Conduct on our website.

**Item 11. *Executive Compensation.***

The information required by Item 11 is incorporated herein by reference to the sections of the Proxy Statement entitled "Executive Compensation," "Report of the Compensation Committee," "Performance Measurement Comparison," and "Proposal No. 1 — Election of Directors — Compensation of Directors."

**Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.***

The information required by Item 12 is incorporated herein by reference to the section of the Proxy Statement entitled "Security Ownership of Certain Beneficial Owners and Management."

**Item 13. *Certain Relationships and Related Transactions.***

The information required by Item 13 is incorporated herein by reference to the section of the Proxy Statement entitled "Certain Relationships and Related Transactions."

**Item 14. *Principal Accounting Fees and Services.***

Information required by Item 14 is incorporated herein by reference to the section of the Proxy Statement entitled "Proposal No. 2 — Ratification of Selection of Independent Registered Public Accounting Firm."

**PART IV**

**Item 15. *Exhibits, Financial Statement Schedules.***

(a)(1), (a)(2) and (c) *Financial Statements and Schedules.* Reference is made to "Genelabs Technologies, Inc. Index to Consolidated Financial Statements" on page F-1 of this Annual Report on Form 10-K.

All financial statement schedules have been omitted because the information required to be disclosed therein is not applicable or is included elsewhere in the Consolidated Financial Statements or notes thereto.

(a)(3) and (b) *Index to Exhibits.* The following documents are filed herewith or incorporated by reference herein.

<u>Exhibit No.</u>	<u>Exhibit Title</u>
3.01	Registrant's Amended and Restated Articles of Incorporation (incorporated herein by reference to Exhibit 3.01 to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2001).
3.02	Registrant's Certificate of Amendment of Articles of Incorporation (incorporated herein by reference to Exhibit 3.2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003).
3.03	Registrant's Certificate of Amendment of Articles of Incorporation dated December 14, 2005.
3.04	Registrant's Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.02 to Registrant's Annual Report on Form 10-K for the year ended December 31, 2000 (the "2000 Form 10-K")).
4.01	Specimen Certificate for Registrant's Common Stock.
10.01	Registrant's 1995 Stock Option Plan, as amended to date (incorporated herein by reference to Exhibit 10.07 of Registrant's Annual Report on Form 10-K for the year ended December 31, 1997).**
10.02	Registrant's 2001 Stock Option Plan, as amended December 19, 2005.**
10.03	Registrant's Amended and Renewed 1994 Annual and Long-Term Incentive Based Compensation Plan (incorporated herein by reference to Exhibit 10.04 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).**
10.04	Registrant's 2001 Employee Stock Purchase Plan as amended December 19, 2005.**
10.05	Form of Registrant's Indemnity Agreement entered into by Registrant with certain officers and directors (incorporated herein by reference to Exhibit 10.04 to Registrant's Registration Statement on Form S-1 filed with the Commission on April 29, 1991 (File No. 33-40120) (the "Form S-1")).**
10.06	Industrial Net Lease Agreement by and between Registrant and Lincoln Property Company N.C., Inc. dated July 29, 1986, as amended to date (incorporated herein by reference to Exhibit 10.06 to the Form S-1).
10.07	Amendment to Lease by and between Registrant and Metropolitan Life Insurance Company, successor to Lincoln Property Company N.C., dated as of September 25, 2002 (incorporated herein by reference to Exhibit 10.19 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 (the "Third Quarter 2002 Form 10-Q")).
10.08	Agreement, dated as of January 26, 1996, by and between Registrant and Dr. Edgar G. Engleman (incorporated herein by reference to Exhibit 10.15 to Registrant's Annual Report on Form 10-K for the year ended December 31, 1996 (the "1996 Form 10-K")).*
10.09	License Agreement, dated as of October 1, 1993, by and between Registrant and Stanford University (incorporated herein by reference to Exhibit 10.16 to the 1996 Form 10-K).*

<u>Exhibit No.</u>	<u>Exhibit Title</u>
10.10	Joint Investment Agreement for formation of Genelabs Biotechnology Co., Ltd., a company organized under the laws of Taiwan, Republic of China (incorporated herein by reference to Exhibit 10.28 to Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K").*
10.11	Technology Transfer Agreement, dated as of November 21, 1995, by and between Registrant and Genelabs Biotechnology Co., Ltd. (incorporated herein by reference to Exhibit 10.29 to the 1995 Form 10-K).*
10.12	Collaboration and License Agreement made as of November 12, 2000 by and between Registrant and Watson Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 10.17 to the 2000 Form 10-K).*
10.13	Agreement entered into by Registrant with Irene A. Chow, Ph.D., as of January 3, 2002 (incorporated herein by reference to Exhibit 10.17 of Registrant's Annual Report on Form 10-K for the year ended December 31, 2001).**
10.14	Form of Agreement entered into by Registrant with certain employees of Registrant (incorporated herein by reference to Exhibit 10.18 of the 2001 Form 10-K).**
10.15	Toll Manufacturing and Supply Agreement dated as of August 30, 2002 between Registrant and Patheon, Inc. (incorporated herein by reference to Exhibit 10.20 to the Third Quarter 2002 Form 10-Q).*
10.16	License and Collaboration Agreement made as of January 28, 2004 by and between Registrant and Tanabe Seiyaku Co., Ltd. (incorporated herein by reference to Exhibit 10.17 to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004).*
10.17	License and Research Collaboration Agreement entered into on September 29, 2004 by and between Registrant and Gilead Sciences, Inc. (incorporated herein by reference to Exhibit 10.18 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004).*
10.18	Heads of Agreement, dated August 27, 1992, by and between Registrant and SmithKline Beecham p.l.c. ("Heads of Agreement") (incorporated herein by reference to Exhibit 10.19 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1992).*
10.19	Second Amendment to Heads of Agreement (incorporated herein by reference to Exhibit 10.13 to Registrant's Annual Report on Form 10-K for the year ended December 31, 1998).*
10.20	Offer letter entered into between Registrant and Irene A. Chow, Ph.D., dated March 9, 2004 (incorporated herein by reference to Exhibit 10.21 to Registrant's Annual Report on Form 10-K for the year ended December 31, 2004).**
10.21	Discretionary incentive arrangement between Registrant and Irene A. Chow, Ph.D., as of January 27, 2005 described in Registrant's Current Report on Form 8-K filed February 2, 2005.**
21.01	List of Subsidiaries.
23.01	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Confidential treatment has been granted with respect to certain portions of this document.

\*\* Indicates management contract or compensatory plan, contract or arrangement.



**GENELABS TECHNOLOGIES, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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All schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders  
Genelabs Technologies, Inc.

We have audited the accompanying consolidated balance sheets of Genelabs Technologies, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genelabs Technologies, Inc. at December 31, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, the Company's recurring losses from operations, accumulated deficit and available funds for use in operations raise substantial doubt about its ability to continue as a going concern. Management's plans as to these matters are also discussed in Note 1. The 2005 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Palo Alto, California  
February 28, 2006

**GENELABS TECHNOLOGIES, INC.**  
**CONSOLIDATED BALANCE SHEETS**

**ASSETS**

	December 31,	
	2005	2004
	(In thousands)	
Current assets:		
Cash and cash equivalents . . . . .	\$ 10,061	\$ 26,358
Restricted cash . . . . .	150	150
Other current assets . . . . .	539	824
Total current assets . . . . .	10,750	27,332
Property and equipment, net . . . . .	951	1,091
Long-term investment . . . . .	960	960
	\$ 12,661	\$ 29,383

**LIABILITIES AND SHAREHOLDERS' EQUITY**

Current liabilities:		
Accounts payable and other accrued liabilities . . . . .	\$ 608	\$ 1,702
Accrued compensation and related expenses . . . . .	789	1,811
Accrued manufacturing costs . . . . .	675	700
Unearned contract revenue . . . . .	3,220	4,120
Total current liabilities . . . . .	5,292	8,333
Accrued compensation . . . . .	284	745
Unearned contract revenue . . . . .	4,738	7,358
Total liabilities . . . . .	10,314	16,436
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value, 4,990 shares authorized, none issued or outstanding at December 31, 2005 or 2004 . . . . .	—	—
Common stock, no par value, 125,000 shares authorized, 17,818 and 17,700 shares issued and outstanding at December 31, 2005 and 2004, respectively . . . . .	231,057	230,815
Accumulated deficit . . . . .	(228,710)	(217,868)
Total shareholders' equity . . . . .	2,347	12,947
	\$ 12,661	\$ 29,383

See accompanying notes.

**GENELABS TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Years Ended December 31,		
	2005	2004	2003
	(In thousands, except per share amounts)		
Revenue:			
Contract .....	\$ 6,220	\$ 4,874	\$ 2,384
Royalty .....	<u>629</u>	<u>682</u>	<u>532</u>
Total revenue .....	<u>6,849</u>	<u>5,556</u>	<u>2,916</u>
Operating expenses:			
Research and development .....	12,205	15,113	16,838
General and administrative .....	<u>5,958</u>	<u>6,505</u>	<u>6,484</u>
Total operating expenses .....	<u>18,163</u>	<u>21,618</u>	<u>23,322</u>
Operating loss .....	(11,314)	(16,062)	(20,406)
Interest income .....	485	284	99
Interest expense .....	<u>(13)</u>	<u>(15)</u>	<u>(15)</u>
Loss from continuing operations .....	(10,842)	(15,793)	(20,322)
Discontinued operations:			
Income from diagnostics business .....	—	262	515
Gain on sale of diagnostics business .....	<u>—</u>	<u>2,020</u>	<u>—</u>
Net loss .....	<u>\$(10,842)</u>	<u>\$(13,511)</u>	<u>\$(19,807)</u>
Loss per common share from continuing operations — basic and diluted ..	<u>\$ (0.61)</u>	<u>\$ (0.90)</u>	<u>\$ (1.59)</u>
Net loss per common share — basic and diluted .....	<u>\$ (0.61)</u>	<u>\$ (0.77)</u>	<u>\$ (1.55)</u>
Weighted average shares outstanding to calculate basic and diluted net loss per common share .....	<u>17,738</u>	<u>17,618</u>	<u>12,778</u>

See accompanying notes.

**GENELABS TECHNOLOGIES, INC.**

**CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY**

	Shares of Common Stock	Common Stock	Accumulated Deficit	Total Shareholders' Equity
	(In thousands)			
<b>Balance, December 31, 2002</b> .....	10,679	\$187,264	\$(184,550)	\$ 2,714
Net loss and comprehensive loss .....			(19,807)	(19,807)
Shares issued in private placements, net of issuance costs of \$1,104 .....	1,953	9,654	—	9,654
Shares issued upon exercise of warrants .....	72	529	—	529
Shares issued in public offering, net of issuance costs of \$2,345 .....	4,600	29,165	—	29,165
Shares issued under the employee stock purchase plan . . .	74	483	—	483
Shares issued under stock options .....	9	58	—	58
Stock-based compensation expense .....	—	19	—	19
<b>Balance, December 31, 2003</b> .....	17,387	227,172	(204,357)	22,815
Net loss and comprehensive loss .....	—	—	(13,511)	(13,511)
Shares issued upon exercise of warrants .....	34	254	—	254
Shares issued to Tanabe Seiyaku Co. Ltd., net of issuance costs of \$12 .....	164	2,588	—	2,588
Shares issued under the employee stock purchase plan . . .	91	550	—	550
Shares issued under stock options .....	24	215	—	215
Stock-based compensation expense .....	—	36	—	36
<b>Balance, December 31, 2004</b> .....	17,700	230,815	(217,868)	12,947
Net loss and comprehensive loss .....	—	—	(10,842)	(10,842)
Shares issued under the employee stock purchase plan . . .	117	234	—	234
Shares issued under stock options .....	1	3	—	3
Stock-based compensation expense .....	—	5	—	5
<b>Balance, December 31, 2005</b> .....	<u>17,818</u>	<u>\$231,057</u>	<u>\$(228,710)</u>	<u>\$ 2,347</u>

See accompanying notes.

**GENELABS TECHNOLOGIES, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2005	2004	2003
	(In thousands)		
Cash flows from operating activities:			
Net loss .....	\$(10,842)	\$(13,511)	\$(19,807)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense .....	406	408	493
Stock-based compensation expense .....	5	36	19
Gain on sale of discontinued diagnostics business .....	—	(2,020)	—
Income of discontinued diagnostics business .....	—	(262)	(515)
Changes in assets and liabilities:			
Other current assets .....	285	11	(362)
Accounts payable, accrued liabilities, and accrued compensation .....	(2,602)	161	1,841
Unearned contract revenue .....	(3,520)	9,219	(1,841)
Net cash used in operating activities .....	<u>(16,268)</u>	<u>(5,958)</u>	<u>(20,172)</u>
Cash flows from investing activities:			
Purchases of property and equipment .....	(266)	(579)	(107)
Net cash received from sale of discontinued diagnostics business .....	—	2,908	—
Restricted cash .....	—	(150)	—
Proceeds from sales and maturities of short-term investments .....	—	—	3,535
Remittances from discontinued diagnostics business .....	—	—	350
Net cash (used in)/provided by investing activities .....	<u>(266)</u>	<u>2,179</u>	<u>3,778</u>
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net .....	237	3,607	39,889
Net (decrease)/increase in cash and cash equivalents .....	(16,297)	(172)	23,495
Cash and cash equivalents, beginning of the period .....	26,358	26,530	3,035
Cash and cash equivalents, end of the period .....	<u>\$ 10,061</u>	<u>\$ 26,358</u>	<u>\$ 26,530</u>

See accompanying notes.

**GENELABS TECHNOLOGIES, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2005**  
**(tabular amounts in thousands, except per share data)**

**1. Significant Accounting Policies**

*Business Description*

Genelabs Technologies, Inc., referred to as Genelabs or the Company, is a biopharmaceutical company focused on the discovery and development of pharmaceutical products to improve human health. The Company has built drug discovery capabilities that can support various research and development projects. The Company is currently concentrating these capabilities on discovering novel compounds that selectively inhibit replication of the hepatitis C virus and advancing preclinical development of compounds from this hepatitis C virus drug discovery program, while also developing a late-stage product for lupus.

*Basis of Presentation*

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Accelerated Clinical Research Organization, Inc., Genelabs Diagnostic, Inc. and Genelabs Europe B.V. All intercompany accounts and transactions have been eliminated. Genelabs operates in one business segment, the discovery and development of pharmaceutical products. Prior to the disposition of the Company's diagnostics business in April 2004, Genelabs accounted for its diagnostics subsidiary as a discontinued operation.

The Company's consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business for the foreseeable future. The Company has incurred recurring operating losses and negative cash flows from operations, including a net loss of \$10,842,000 and cash used in operations of \$16,268,000 for the year ended December 31, 2005. As of December 31, 2005, the Company had working capital of \$5,458,000 and an accumulated deficit of \$228,710,000. These factors raise substantial doubt about the Company's ability to continue as a going concern. The ability of the Company to continue as a going concern is dependent upon its ability to obtain additional capital from a collaboration, equity financing or other means. In order to satisfy its projected cash needs for at least the next twelve months, Genelabs is pursuing various alternatives, including licensing its non-nucleoside HCV polymerase program, renegotiating the terms of a collaboration and pursuing investments from third-parties. If any of these transactions are completed Genelabs expects they would provide additional cash to the Company, although the amounts are not determinable. Genelabs may be unable to complete any of these transactions as currently contemplated or at all, and the outcome of these matters cannot be predicted at this time. Further, there can be no assurance, assuming the Company successfully raises additional funds, that the Company will ever achieve positive cash flow. If the Company is not able to secure additional funding the Company will be required to scale back its research and development programs and general and administrative activities and may not be able to continue in business. These consolidated financial statements do not include any adjustments to the specific amounts and classifications of assets and liabilities, which might be necessary should the Company be unable to continue in business.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts may differ from those estimates.

*Reverse Stock Split*

On December 19, 2005, the Company implemented a one-for-five reverse split of its outstanding common stock. All information regarding common stock, stock options, warrants and loss per share has been restated within the financial statements to reflect the reverse stock split.

GENELABS TECHNOLOGIES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

*Revenue Recognition*

Contract revenue for research and development is recorded as earned based on the performance requirements of the contract. Revenue from non-refundable upfront license fees where the Company continues involvement, such as through a collaboration, is recognized ratably over the research and development period. The Company bases the amortization period for each agreement on its estimate of the period over which the Company has significant obligations under the contract. Non-refundable contract fees for which no further performance obligations exist, and there is no continuing involvement by Genelabs, are recognized on the earlier of when the payments are received or when collection is assured. Revenue associated with development milestones is recognized based upon the achievement of the milestones, as defined in the respective agreements.

Advance payments received in excess of amounts earned are classified as deferred revenue.

Revenue received for arrangements with multiple deliverables is allocated among the deliverables based on objective and reliable evidence of each deliverable's fair value using available internal or third-party evidence.

Revenue associated with royalty payments based on third party sales is recognized as earned in accordance with contract terms, when third-party results are reliably measured and collectibility is reasonably assured.

In 2005 there was one significant source of revenue accounting for 82% of total revenue. In 2004 there were four significant sources of revenue accounting for 26%, 25%, 17% and 13% of total revenue. In 2003 there were two significant sources of revenue accounting for 63% and 16% of total revenue.

*Earnings per Share*

Net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. Had the Company been in a net income position, diluted earnings per share for 2005, 2004 and 2003 would have included an additional 8,000, 387,000 and 91,000 shares, respectively, related to the Company's outstanding stock options and warrants as determined under the treasury stock method. Net earnings per share, basic and diluted, from discontinued operations were \$0.00, \$0.13 and \$0.04 for 2005, 2004 and 2003, respectively.

**GENELABS TECHNOLOGIES, INC.**

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

***Stock-Based Compensation***

The Company applies APB Opinion No. 25 “Accounting for Stock Issued to Employees” in accounting for its employees’ stock based compensation plans. The Company grants employee stock options at an exercise price equal to or greater than the fair market value of the shares at the date of grant and, accordingly, recognizes no compensation expense for stock options granted to employees. The Company follows the disclosure only provisions of Statement of Financial Accounting Standards No. 123, “Accounting for Stock-Based Compensation” as amended by Statement of Financial Accounting Standards No. 148. The following table presents information showing the effects to the reported net loss and net loss per share as if Genelabs had accounted for employee stock-based compensation using the fair-value method:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net loss as reported . . . . .	\$(10,842)	\$(13,511)	\$(19,807)
Stock-based employee compensation cost:			
Included in net loss as reported. . . . .	—	—	—
Amount that would have been included in net loss if the Company had accounted for all stock-based employee compensation at its theoretical fair value . . . . .	<u>(1,095)</u>	<u>(1,878)</u>	<u>(1,895)</u>
Pro forma net loss . . . . .	<u>\$(11,937)</u>	<u>\$(15,389)</u>	<u>\$(21,702)</u>
Net loss per common share as reported, basic and diluted . . . . .	<u>\$ (0.61)</u>	<u>\$ (0.77)</u>	<u>\$ (1.55)</u>
Pro forma net loss per common share, basic and diluted . . . . .	<u>\$ (0.67)</u>	<u>\$ (0.87)</u>	<u>\$ (1.70)</u>

Compensation expense for options or warrants granted to non-employees is recorded at fair value of the consideration received or fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is remeasured and adjusted over the vesting term of the underlying options.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards 123 (revised 2004), “Share-Based Payment” (SFAS 123R), which the Company is required to implement effective January 1, 2006. SFAS 123R addresses the accounting for stock options issued to employees, and eliminates the ability to account for employee stock options using the intrinsic value method used by the Company in 2005 and previous years. Instead, SFAS 123R requires that these options be accounted for using a fair-value based method, and the Company will be required to recognize an expense based on estimates of the value of the stock options. The Company is adopting SFAS 123R using the modified-prospective transition method and is currently in the final stages of determining the assumptions that will be used for options granted in 2006 and thereafter. When SFAS 123R is adopted, the Company’s operating expenses will increase by the estimated fair value of the stock options issued to employees, which will have a material impact on the statement of operations, increasing both operating expenses and net loss.

***Cash, Cash Equivalents and Restricted Cash***

Cash and cash equivalents are held primarily in demand deposit, money market and custodial accounts with United States banks. Cash equivalents consist of financial investments with maturities of 90 days or less at acquisition that are readily convertible into cash and have insignificant interest rate risk. Restricted cash is a certificate of deposit that collateralizes a standby letter of credit in the same amount, and is renewable quarterly. At December 31, 2005 and 2004, all investments are in a single money market mutual fund which is classified as available for sale. Fair value approximates cost.

The Company invests funds that are not required for immediate operating needs in money market mutual funds, certificates of deposit or a diversified portfolio of debt securities. Management determines the appropriate

## GENELABS TECHNOLOGIES, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

classification of these marketable debt securities at the time of purchase and reevaluates such designation as of each balance sheet date.

#### *Property and Equipment*

Property and equipment are stated at cost. Depreciation on equipment is calculated on a straight-line basis over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the improvements. Amortization of assets under capital leases is included in depreciation expense.

#### *Long-Term Investment*

The Company uses the cost method of accounting for its equity investment in a private company, Genovate Biotechnology Co., Ltd., a Taiwan-based biopharmaceutical company in which Genelabs holds less than 10% of the outstanding shares.

#### *Impairment of Long-Lived Assets*

The Company reviews long-lived assets, including property and equipment and its long-term investment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. Impairment, if any, is assessed using discounted cash flows. Through December 31, 2005, there has been no such impairment.

#### *Research and Development Expenses*

The Company's research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, consulting costs, clinical trial costs and allocations of facility costs.

#### *Income Taxes*

The Company uses the liability method of accounting for income taxes, and determines deferred tax assets and liabilities based on differences between the financial reporting and the tax reporting basis of assets and liabilities. The Company measures these assets and liabilities using enacted tax rates and laws that are scheduled to be in effect when the differences are expected to reverse. Because the realization of deferred tax assets is dependent upon future earnings, if any, and the Company's future earnings are uncertain, all of the Company's net deferred tax assets have been fully offset by a valuation allowance.

**GENELABS TECHNOLOGIES, INC.**

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

**2. Property and Equipment**

The components of property and equipment are as follows:

	2005	2004
Laboratory equipment.....	\$ 5,788	\$ 5,529
Leasehold improvements.....	4,655	4,655
Office and other equipment.....	2,725	2,693
	13,168	12,877
Less accumulated depreciation and amortization .....	(12,217)	(11,786)
	\$ 951	\$ 1,091

There were no assets under capital lease at December 31, 2005. At December 31, 2004, an asset under capital lease is included in property and equipment at a cost of \$309,000 with accumulated amortization of \$144,000; this asset was purchased during 2005 pursuant to the lease agreement.

**3. Commitments and Contingencies**

The Company leases its primary office and laboratory facilities under a non-cancelable operating lease that has a term expiring in November 2006. The Company is required to pay certain maintenance expenses in addition to monthly rent. At December 31, 2005, future minimum lease payments under the single operating lease with an original term greater than one year are \$1,231,000, excluding sublease rentals, which is all due in 2006. Future minimum rental payments to be received by Genelabs under one noncancelable sublease agreement are \$130,000, which is also due in 2006. Total lease expense, net of sublease income, was \$1,443,000, \$1,470,000 and \$1,465,000 for 2005, 2004 and 2003, respectively.

To maintain its radioactive materials license, the Company has established a \$150,000 standby letter of credit in favor of the Radiologic Health Branch of the California Department of Health Services. The letter of credit is secured by a certificate of deposit which is classified as restricted cash.

The Company, as permitted under California law and in accordance with its Bylaws, has entered into agreements with its officers and directors to pay certain expenses, as incurred, and to indemnify them, subject to certain limits, if the officer or director becomes involved in a lawsuit or other proceeding arising from his or her service to the Company. There is no specified termination date for the agreements and the maximum amount of potential future indemnification is unlimited. The Company has a director and officer insurance policy that may enable the Company to recover a portion of any future amounts paid pursuant to the Company's indemnity obligations. The Company believes the fair value of its obligations under its indemnification commitments is minimal and at present no claims are being asserted against the Company for indemnification under these agreements. Accordingly, the Company has not recognized any liabilities relating to these agreements as of December 31, 2005.

The Company is subject to legal proceedings and claims that arise in the ordinary course of business. Management currently believes that the ultimate amount of liability, if any, with respect to any pending actions, either individually or in the aggregate, will not materially affect Genelabs' financial position or results of operations. However, the ultimate outcome of any litigation is uncertain. If an unfavorable outcome were to occur, the impact could be material. Furthermore, any litigation, regardless of the outcome, can have an adverse impact on the Company's results of operations as a result of defense costs, diversion of management resources, and other factors.

**GENELABS TECHNOLOGIES, INC.**

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

**4. Shareholders' Equity**

***Common Stock***

On January 28, 2004, Genelabs completed the sale of approximately 164,000 shares of its common stock to Tanabe Seiyaku Co. Ltd. at a price of \$15.88 per share for gross and net proceeds of \$2.6 million.

On October 22, 2003, Genelabs completed the sale of 4.6 million shares of its common stock in a public offering at a price of \$6.85 per share for gross proceeds of approximately \$31.5 million. Net proceeds from the offering were approximately \$29.2 million. In connection with the offering, Genelabs also issued to the underwriter warrants to purchase 92,000 shares of our common stock at an exercise price of \$7.10 per share.

On August 1, 2003, Genelabs completed the sale of approximately 333,000 shares of its common stock at a price of \$7.97 per share for gross proceeds of approximately \$2.7 million. In connection with the sale, Genelabs also issued warrants to purchase approximately 333,000 shares of Genelabs common stock at an exercise price of \$7.50 per share. Net proceeds from the placement were approximately \$2.4 million.

On May 2, 2003, Genelabs completed the sale of 1,620,000 shares of its common stock at a price of \$5.00 per share for gross proceeds of \$8.1 million. In connection with the sale, Genelabs also issued warrants to purchase an additional 486,000 shares of Genelabs common stock at an exercise price of \$7.50 per share. Net proceeds from the placement were approximately \$7.2 million. The exercise price of the warrants issued in this offering adjusted to \$7.35 per share after the public offering in October 2003.

The following table lists outstanding warrants to purchase common stock:

<u>Expiration Date</u>	<u>Number of Shares</u>	<u>Exercise Price</u>
May 2008 .....	380	\$7.35
October 2008 .....	92	7.10
August 2010 .....	<u>333</u>	7.50
Total and weighted average exercise price .....	<u>805</u>	\$7.38

At December 31, 2005, the Company had a total of 3,817,000 shares reserved for future stock issuances, which is comprised of the above warrants, 15,000 additional warrants which expired in January 2006 and shares authorized under employee stock purchase and option plans. At December 31, 2005, there were 103,365,000 authorized shares remaining available for future issuance.

**5. Stock-Based Compensation**

*Employee Stock Purchase Plan.* Employees who meet certain minimum requirements are eligible to participate in the Company's Employee Stock Purchase Plan. Eligible employees are entitled to purchase stock at 85% of the market value at the beginning or ending of six-month purchase periods, whichever is lower, and stock may be purchased at the same price for up to four periods. Employees can contribute up to 15% of total compensation, but purchases are limited to a maximum of \$25,000 per year. Through December 31, 2005, a cumulative total of 655,000 shares had been issued under the Stock Purchase Plan and a similar predecessor plan, with 408,000 shares remaining for future purchases.

*Stock Option Plan.* The Company's stock option plan provides for the issuance of incentive stock options and nonqualified stock options to employees, officers, directors and independent contractors. The number of stock options granted is determined by the Board of Directors or a committee designated by the Board of Directors, except for grants to directors, who receive options based on a formula. Stock options generally are not granted at prices lower than fair market value on the date of grant and vest over periods ranging up to four years, with expiration no later than ten years from the date of grant. At December 31, 2005, 844,000 shares were available for future grants.

**GENELABS TECHNOLOGIES, INC.**

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

Stock option transactions from 2003 through 2005 are summarized as follows:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2002 .....	1,091	\$16.21
Granted .....	280	8.09
Exercised .....	(9)	6.63
Canceled .....	(126)	16.92
Outstanding at December 31, 2003 .....	1,236	14.36
Granted .....	303	11.28
Exercised .....	(24)	9.00
Canceled .....	(126)	14.25
Outstanding at December 31, 2004 .....	1,389	13.79
Granted .....	684	3.33
Exercised .....	(1)	4.55
Canceled .....	(326)	13.64
Outstanding at December 31, 2005 .....	1,746	\$ 9.73

Additional information regarding stock options outstanding at December 31, 2005 is summarized as follows:

<b>Range of Exercise Prices</b>	<b>Number of Options Outstanding</b>	<b>Weighted Average Remaining Term</b>	<b>Weighted Average Exercise Price</b>	<b>Number of Options Exercisable</b>	<b>Weighted Average Exercise Price</b>
\$1.86-\$2.50 .....	369	9.9 years	\$ 2.34	12	\$ 2.20
\$2.51-\$5.00 .....	382	8.5 years	\$ 4.32	239	\$ 4.36
\$5.01-\$10.00 .....	309	6.6 years	\$ 8.05	270	\$ 8.11
\$10.01-\$20.00 .....	501	5.2 years	\$12.47	433	\$12.43
\$20.01-\$54.53 .....	185	3.3 years	\$31.03	185	\$31.03
\$1.86-\$54.53 .....	1,746	7.0 years	\$ 9.73	1,139	\$12.62

There were options for 1,025,000 and 889,000 shares exercisable at December 31, 2004 and 2003, respectively.

*Disclosure of Fair Value of Stock Options.* As disclosed in Note 1, Genelabs accounts for employee stock options using their intrinsic value at the time of grant. However, generally accepted accounting principles require companies that account for stock options under the intrinsic value method to also disclose the pro forma impact as if they had accounted for stock options using a fair value approach. Accordingly, for disclosure purposes, the fair value of stock options was estimated at the date of grant using a Black-Scholes option valuation model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. This model requires highly subjective assumptions regarding expected stock price volatility. The Company's stock options have characteristics significantly different from those of traded options and changes in the volatility assumptions can materially affect the fair value estimate. To determine the pro forma disclosure, the Company used the following weighted average assumptions for 2005, 2004 and 2003, respectively: dividend yields of zero; risk-free interest rates of 4.0%, 3.5% and 3.0%; volatility factors of 1.0; and a one year expected life of the options after vesting, which generally occurs over a four-year period. Based on these assumptions, the weighted-average fair value of options granted during 2005, 2004 and 2003 was \$1.85,

**GENELABS TECHNOLOGIES, INC.**

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

\$5.89 and \$4.34 per share, respectively. For purposes of pro forma disclosures, the estimated fair value of the options is expensed ratably over the options' vesting period.

Stock options are generally granted with an exercise price equal to the fair market value of the Company's common stock on the date of grant. During 2005 and 2003 all options were granted with an exercise price equal to the market value of the Company's stock on the date of grant. During 2004, certain options were granted with an exercise price that differed from the fair market value of the Company's common stock on the date of grant. The following table shows the weighted average exercise prices and fair values of stock options granted in 2004:

<u>Stock Options Granted with an Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Fair Value of Options</u>
Below market value of common stock . . . . .	—	—	—
At market value of common stock . . . . .	232	\$10.91	\$6.64
Above market value of common stock . . . . .	<u>71</u>	12.50	3.41
Stock option grants in 2004 . . . . .	<u>303</u>	\$11.28	\$5.89

**6. Collaborative Agreements**

The Company has the following collaborative agreements in place:

*Gilead Sciences, Inc.* In September 2004, the Company signed an agreement with Gilead Sciences, Inc. (Gilead) to collaborate in the research, development and commercialization of certain compounds that selectively inhibit replication of the hepatitis C virus. The agreement has an initial three-year research term, and Gilead has an option to extend the research term for one additional year. The Company received an \$8,000,000 non-refundable up-front payment upon signing the agreement, which is being recognized into revenue on a straight-line basis over the four-year term of Genelabs' potential obligations to Gilead. In addition, Genelabs receives payments from Gilead for Genelabs' scientists continuing work on this program. Contract revenue recognized under this agreement is comprised of the amortization of the up-front payment and the payments for Genelabs' on-going research. In 2005 and 2004, respectively, the Company recognized into revenue \$2,000,000 and \$500,000 from the up-front license fee and \$3,600,000 and \$900,000 from on-going research payments. At December 31, 2005, unearned contract revenue received from Gilead was \$5,500,000 comprised solely of the unamortized portion of the initial up-front payment.

*Tanabe Seiyaku Co., Ltd.* In January 2004, Genelabs signed an agreement with Tanabe Seiyaku Co., Ltd. (Tanabe), granting Tanabe an exclusive license to Prestara™ in Japan. The Company received a \$2,000,000 non-refundable payment upon signing the agreement which is being recognized into revenue as Genelabs fulfills its obligations to Tanabe. The Company considers the agreement with Tanabe a multiple element arrangement because Genelabs has obligations to supply specified quantities of development materials and obligations to share data relevant to the development of Prestara. These elements are accounted for separately. The obligation to supply Tanabe with development material is estimated to be approximately \$600,000, based on the cost of the material to be supplied, and will be recognized as revenue as the material is provided to Tanabe at their request. The amount related to the exclusive license of \$1,400,000 is being amortized into contract revenue on a straight-line basis over the estimated development term for Prestara in Japan, which is estimated to extend through December 31, 2008.

**GENELABS TECHNOLOGIES, INC.**

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

*Watson Pharmaceuticals, Inc.* In November 2000, Genelabs entered into an agreement with Watson Pharmaceuticals, Inc. (Watson), granting Watson an exclusive license to Prestara™ in North America. The Company received a \$10,000,000 non-refundable payment upon signing the agreement, which is being amortized into revenue over the term that Genelabs believes it has significant obligations to Watson, currently estimated to be through December 31, 2008. In 2003 the Company lengthened the amortization period based on the enrollment rate into a clinical trial. In 2004, after Genelabs' clinical trial did not meet its primary endpoint, the Company lengthened the amortization period for the unearned contract revenue from Watson because the Company concluded that it was probable another clinical trial would be required, resulting in a longer period of time before the Company can potentially receive approval of Prestara. The lengthening of the amortization period in each year decreased the amount of revenue the Company recognized into the statement of operations. Because the U.S. Food and Drug Administration has indicated that it will require an additional prospective clinical trial before approving the Company's New Drug Application for Prestara and the design of this prospective clinical has not been finalized, and may never be finalized, the Company may need to modify the amortization period as additional information becomes available.

Unearned contract revenue under the above collaborative agreements is as follows:

	At December 31,	
	2005	2004
Gilead Sciences, Inc. . . . .	\$5,500	\$ 8,400
Tanabe Seiyaku Co., Ltd. . . . .	1,454	1,739
Watson Pharmaceuticals, Inc. . . . .	1,004	1,339
Total unearned contract revenue . . . . .	7,958	11,478
Amount classified as current . . . . .	3,220	4,120
Amount classified as long-term . . . . .	\$4,738	\$ 7,358

Contract revenue recognized under the above collaborative agreements is as follows:

	For the Year Ended December 31,		
	2005	2004	2003
Gilead Sciences, Inc. . . . .	\$5,600	\$1,400	\$ —
Tanabe Seiyaku Co., Ltd. . . . .	285	261	—
Watson Pharmaceuticals, Inc. . . . .	335	921	1,841

**GENELABS TECHNOLOGIES, INC.**

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

**7. Sale of Discontinued Operation**

On April 21, 2004, the Company completed the sale of its diagnostics business, Genelabs Diagnostics Pte. Ltd., and its immediate parent, Genelabs Asia Pte. Ltd., receiving gross proceeds from the sale of \$3.0 million. Net proceeds after costs of disposition were \$2.9 million. The Company recorded a gain of \$2.0 million on the sale. Prior to the sale, Genelabs accounted for its diagnostics business as a discontinued operation. Summarized financial information for GLD prior to the date of sale in 2004 is as follows:

**Statements of Operations**

	<u>January 1 through April 20, 2004</u>	<u>Year Ended December 31, 2003</u>
Product sales .....	\$1,965	\$6,168
Cost of sales .....	<u>961</u>	<u>3,323</u>
Gross profit .....	1,004	2,845
Operating expenses .....	<u>742</u>	<u>2,330</u>
Income from discontinued operations .....	<u>\$ 262</u>	<u>\$ 515</u>

**Balance Sheet**

	<u>April 20, 2004</u>
Cash, cash equivalents and short-term investments .....	\$ 633
Accounts receivable .....	788
Inventories .....	<u>689</u>
Total assets .....	<u>\$2,110</u>
Current liabilities .....	\$1,266
Net equity of Genelabs Diagnostics Pte. Ltd. ....	<u>844</u>
Total liabilities and net equity .....	<u>\$2,110</u>

**GENELABS TECHNOLOGIES, INC.**

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

**8. Income Taxes**

There is no provision for income taxes because the Company has incurred operating losses.

Deferred tax assets and liabilities reflect the net tax effects of net operating loss and tax credit carryovers and 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 the Company's deferred tax assets as of December 31 are as follows:

	<b>2005</b>	<b>2004</b>
Deferred tax assets:		
Net operating loss carryforwards . . . . .	\$ 70,500	\$ 66,900
Deferred revenue . . . . .	3,200	4,600
Research credits . . . . .	3,900	3,700
Capitalized research expenditures . . . . .	3,900	2,400
Capital loss carryforwards . . . . .	1,200	900
Other individually immaterial items, net . . . . .	800	1,000
Total deferred tax assets . . . . .	83,500	79,500
Valuation allowance for deferred tax assets . . . . .	(83,500)	(79,500)
Net deferred tax assets . . . . .	\$ —	\$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. For 2005, 2004 and 2003, the valuation allowance increased by \$4.0 million, \$9.1 million and \$6.1 million respectively. Deferred tax assets at December 31, 2005 include approximately \$3.1 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to shareholder's equity.

At December 31, 2005, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$199 million which expire in the years 2006 through 2025 and federal research and development tax credits of approximately \$2.2 million which expire in the years 2006 through 2025. The Company's federal capital loss carryforwards of \$2.4 million expire in 2009. In addition, the Company had net operating loss carryforwards for state income tax purposes of approximately \$50 million which expire in the years 2006 through 2015 and state research and development tax credits of approximately \$2.5 million which do not expire.

Utilization of the Company's net operating loss and tax credit carryforwards may be subject to substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such an annual limitation could result in the expiration of the net operating loss and tax credits before utilization.

**9. 401(k) Savings Plan**

The Company maintains a 401(k) savings plan, which allows employees to contribute up to 50% of their pre-tax compensation into the plan. Employee contributions cannot exceed a statutory limit, which was \$14,000 in 2005, or \$18,000 for employees over 50 years old. Under the plan, each employee is fully vested in the contributions made to the plan. While the plan allows Genelabs to make discretionary and matching contributions, to date the Company has not made any contributions to the plan on behalf of employees.

CONFIDENTIAL

CONFIDENTIAL - SECURITY INFORMATION

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## Directors

**Irene A. Chow, Ph.D.**  
Chairman  
Genelabs Technologies, Inc.

**Arthur Gray, Jr.** <sup>(1) (2) (3)</sup>  
Senior Managing Director  
Carret and Company

**H. H. Haight** <sup>(1) (2) (3)</sup>  
President and Chief Executive Officer  
Argo Global Capital, Inc.

**Alan Y. Kwan** <sup>(1) (2) (3)</sup>  
Attorney  
Private Practice

**James A. D. Smith**  
President and Chief Executive Officer  
Genelabs Technologies, Inc.

<sup>(1)</sup> Member, Audit Committee

<sup>(2)</sup> Member, Nominating Committee

<sup>(3)</sup> Member, Compensation Committee

## Corporate Counsel

**Skadden, Arps, Slate  
Meagher & Flom LLP**  
Palo Alto, California

## Independent Registered Public Accounting Firm

**Ernst & Young LLP**  
Palo Alto, California

## Transfer Agent

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## Management Team

**James A. D. Smith**  
President and Chief Executive Officer

**Mumtaz Ahmed, M.D., Ph.D.**  
Vice President, Drug Development

**Adrian Arima**  
Vice President, General Counsel

**Ronald C. Griffith, Ph.D.**  
Chief Scientific Officer

**Heather Criss Keller**  
Senior Business Strategy Advisor & Secretary

**Matthew M. Loar**  
Chief Financial Officer

**Kenneth E. Schwartz, M.D.**  
Vice President, Medical Affairs

**Roy J. Wu**  
Vice President, Business Development

## Annual Meeting

The Annual Meeting of Shareholders will take place at 10:00 am Pacific Daylight Time on Friday, June 16, 2006 at the company's headquarters.

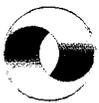
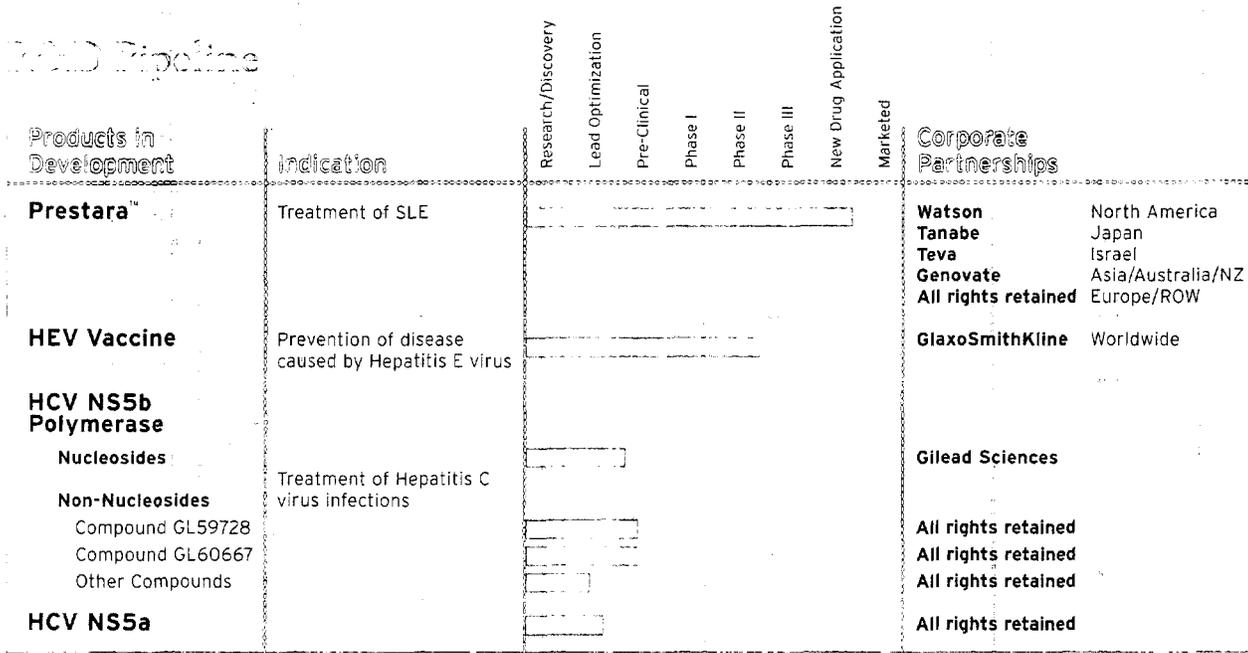
## Stock Information

As of April 21, 2006, there were approximately 683 shareholders of record of the company's common stock, with 17,817,649 shares outstanding. The common stock of the company is traded on the Nasdaq Capital Market System under the symbol GNLB. No dividends have been paid on the common stock since the company's inception.

The following table sets forth for the periods indicated the high and low prices of the company's common stock as reported by the Nasdaq National Market or the Nasdaq Capital Market. On December 19, 2005, the company implemented a one-for-five reverse split of its outstanding common stock, and prices per share listed below have been adjusted to give effect to this reverse split.

2005	High	Low	2004	High	Low	2003	High	Low
Q1	6.15	2.95	Q1	16.25	10.05	Q1	9.40	5.60
Q2	3.55	1.80	Q2	16.00	10.00	Q2	10.50	6.30
Q3	3.35	2.35	Q3	14.60	8.80	Q3	9.30	6.90
Q4	3.30	1.70	Q4	13.40	2.40	Q4	13.40	6.85

# R&D Pipeline



**GENELABS**  
TECHNOLOGIES, INC.

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