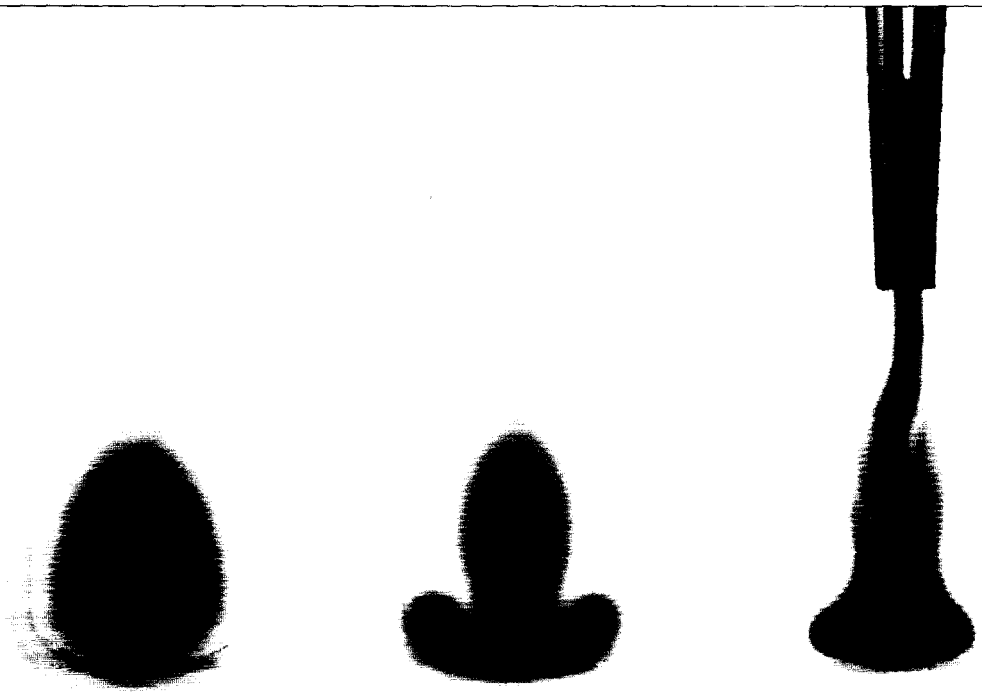


GENELABS
TECHNOLOGIES, IN

2004 ANNUAL REPORT

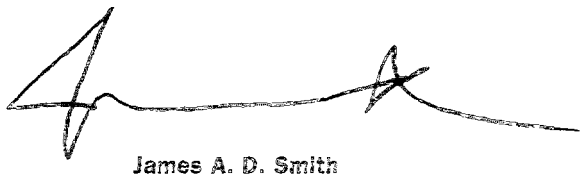
DEAR SHAREHOLDERS > Our team and I are grateful for your support and dedication as we continue to pursue our goals of discovering and developing new pharmaceutical products to improve human health.

The year 2004 was, in many respects, very successful in many different areas of our business. Unfortunately, much of this success was overshadowed when our Phase III clinical trial of Prestara™ for lupus did not achieve its primary endpoint. Our drug discovery team performed tremendously during 2004, advancing compounds into preclinical development in two distinct drug discovery programs for the hepatitis C virus (HCV) infection. We also signed a license agreement with Tanabe Seiyaku for Japanese rights to Prestara, completed the divestment of our diagnostics subsidiary and entered into a worldwide license and research collaboration with Gilead Sciences covering one of our HCV programs. We also continued to generate value from our legacy technologies: our licensee GlaxoSmithKline made a milestone payment to us relating to a clinical trial result for an investigational hepatitis E vaccine and we modified a non-exclusive license to our Linker-aided DNA amplification technology previously granted to Affymetrix to accelerate royalty payments into 2004.

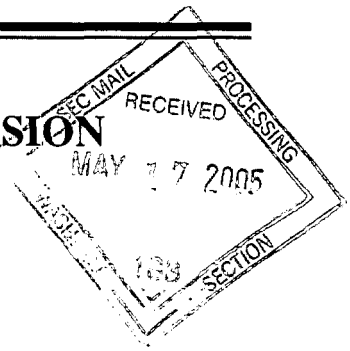
In addition to our drug discovery efforts, Genelabs has been dedicated to the development of our investigational drug Prestara, with the goal of improving care for women with lupus, a debilitating disease for which new treatments are clearly needed. Despite the recent clinical trial results, we have accrued a large amount of data in support of the safety and efficacy of Prestara. The FDA has issued an approvable letter for our Prestara New Drug Application, largely based on the strength of the previously conducted Study GL95-02, which showed an improvement in the overall signs and symptoms of women with lupus and, separately, an improvement in the bone mineral density of women with lupus. In the approvable letter, FDA asked that we confirm these positive findings in bone mineral density as the key contingency to approval. Based on the preliminary analyses the recently completed clinical trials did not achieve this goal. As our analyses complete and we meet with the FDA, we will be able to better determine our next steps for Prestara.

As this work continues, our efforts at discovering new HCV drugs continue. We are particularly excited by a new series of non-nucleoside compounds discovered by our scientists that target the HCV RNA-dependent RNA polymerase with current laboratory data showing exceptional potency and good pharmacokinetic properties. Based on the evidence to date, we believe these compounds may fulfill our target "best-in-class" profile.

Again, I thank you for your support as a shareholder and for your interest in Genelabs Technologies. I also want to acknowledge with pride our Genelabs employees, all of whom are dedicated to our goals of discovering and developing new drugs to combat serious diseases.



James A. D. Smith
President and Chief Executive Officer
March 2005



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, 2004

OR

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

For the transition period from to

Commission file number 0-19222

Genelabs Technologies, Inc.

(Exact Name of Registrant as Specified in Its Charter)

California	**94-3010150**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification Number)*

505 Penobscot Drive
Redwood City, California 94063
(Address of Principal Executive Offices, Including Zip Code)

(650) 369-9500
(Registrant's Telephone Number, Including Area Code)

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

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

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 an accelerated filer (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, 2004: $201,877,000 based on the last reported sales price on the Nasdaq Stock Market.

Number of shares of Registrant's Common Stock outstanding on March 1, 2005: 88,503,779

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2005 Annual Meeting of Shareholders to be held on June 14, 2005 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:

- further actions or developments relating to Prestara™ (prasterone), our investigational drug, its recent Phase III clinical trial in the United States and its follow-on open label clinical trial;
- the clinical trial of prasterone being conducted by a licensee in Taiwan, including our present expectation that results will be available before the end of the second quarter of 2005;
- possible actions, if any, we or the U.S. Food and Drug Administration, or FDA, may take relating to our New Drug Application, or NDA, for Prestara™, filed with the FDA;
- 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;
- our ability to achieve any milestones in our agreements with Gilead Sciences, Inc. or other collaborators;
- 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.;
- estimates relating to our cash resources, expenditures and our ability to obtain additional funding for our business plans;
- estimates that cash resources will be adequate to provide liquidity into approximately mid-2006; and
- 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 at the end of Item 1. Among these are the risks 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™, that we may not be able to raise sufficient funds to continue operations, that we may be delisted from the Nasdaq National 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 and that our attempts to license our technologies to others may fail. 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 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. The Company's objective is to develop a competitive advantage by maintaining a tight focus on selected high-value research targets for which it can rapidly optimize lead compounds, with the goal of developing novel, potent drug candidates. Genelabs seeks to maintain a balanced pipeline of clinical development and discovery projects. Two projects currently at the development stage have the potential to achieve "first-in-class" status: Prestara™ (prasterone), an investigational drug we are developing for systemic lupus erythematosus ("SLE" or "lupus") and an investigational vaccine for hepatitis E virus ("HEV") being developed by GlaxoSmithKline under a license from us. In its drug discovery programs, the Company seeks to identify compounds that have a distinct advantage over potential competitive compounds in potency, safety, or pharmacokinetic properties, with a goal of achieving "best-in-class" status.

The Company has pursued this strategy in its drug discovery programs in seeking to discover novel antiviral compounds for treatment of infections by the hepatitis C virus, or HCV. Beginning in late 2001, 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 ("nucleosides") that we believe interfere with HCV polymerase activity so that the polymerase makes incomplete copies of the HCV virus genome. The second project uses a different class of chemicals ("non-nucleosides") designed to directly bind to the HCV polymerase and prevent the polymerase from properly functioning. During 2004, Genelabs initiated preclinical development work on compounds from both projects and entered into a research collaboration and license agreement with Gilead Sciences, Inc. for the nucleoside project. Gilead Sciences assumed preclinical development activities on the nucleoside project and has agreed to fund Genelabs' HCV polymerase nucleoside discovery research for three years. Genelabs is continuing both discovery and preclinical development activities on its HCV non-nucleoside polymerase project and plans to continue this effort into human clinical trials.

Genelabs also has sought to achieve value for shareholders by pursuing regulatory approval of an investigational drug for women with systemic lupus erythematosus, or SLE. 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 the past 40 years and current therapies are not adequate. Unfortunately, the latest Genelabs Phase III clinical trial of Prestara did not meet its primary endpoint in a clinical trial to assess bone mineral density in women with SLE taking glucocorticoids. A licensee of Genelabs, Genovate Biotechnology Co., Ltd., has completed treatment in a clinical trial of prasterone in Taiwan, which is of similar design to the Genelabs trial, and we presently expect the results of the Taiwan trial to be available before the end of the second quarter of 2005.

In addition to our primary programs focused on drug discovery and development, we have established a portfolio of patents and patent applications based on inventions arising from our 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.

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 (ingested by swallowing instead of administered through a needle or catheter) and which generally are easier to manufacture than larger biological molecules such as peptides, antibodies or proteins.

Drug Discovery Process. Genelabs' drug discovery strategy focuses on screening for, and optimizing, compounds that affect biological targets which previously have been shown by others to be useful in controlling disease activity. 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, 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 laborious process must be 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 or other pharmaceutical properties.

If the optimization program is successful in synthesizing a compound meeting our pre-determined criteria, it would be advanced into early pre-clinical development to develop further data on pharmacokinetics and toxicity, and to further optimize the process of synthesizing (making) the compound. If such data are positive, Genelabs may continue development into the formal pre-clinical phase (involving tests meeting Good Laboratory Practices, or GLP, standards of the U.S. Food and Drug Administration), and, if the further data is positive, seek to begin human clinical trials. Because the risk is high that a compound may fail in pre-clinical or clinical testing, we also would continue the optimization process to develop back-up compounds. At any stage of development, Genelabs may seek to out-license the compound to a pharmaceutical or larger biotechnology company, which may themselves take over the development process. Alternatively, we may elect to retain development of promising compounds in order to realize additional value, although further development involves further risk that the compounds will fail due to toxicity, lack of efficacy or other reasons.

Hepatitis C Virus. Hepatitis C virus, or 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, liver scarring, liver failure and liver cancer. However, most people infected with HCV 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. In most cases, the body is not able to fight off the infection and the infected individual becomes a chronic carrier of HCV. 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, approximately 25,000 people become newly infected and approximately 8,000 to 10,000 people die from complications of hepatitis C each year in the United States. 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 pegylated interferon alpha 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 effective only in approximately 50% of patients infected with HCV genotype 1, the genotype most prevalent in the United States. This regimen is more effective in patients infected with genotypes 2 and 3 which are less common in the U.S. 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 pegylated interferon alpha and ribavirin, along with other pharmaceutical companies such as Merck & Co., Inc. and Boehringer Ingelheim GmbH, biotechnology companies such as Gilead Sciences, Inc., Idenix Pharmaceuticals, Inc. and Vertex Pharmaceuticals, Inc., among others, and academic and government organizations, are conducting research and development in competition with Genelabs for nucleoside and 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.

To date our HCV program has focused on two distinct mechanisms of inhibiting the replication of the HCV virus. We have targeted 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 ("nucleosides") that cause the HCV polymerase to make incomplete copies of the HCV genome, thereby curtailing viral replication. Our second 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; and,
- initiated preclinical studies in both HCV research projects.

We have advanced compounds in the HCV programs to preclinical status, the stage at which the pharmaceutical properties and potential toxicity of candidate compounds are more thoroughly evaluated in advance of potential human testing. Simultaneously, we continue to synthesize additional compounds to serve as potential follow-up candidates for preclinical development for HCV.

In addition to HCV NS5b polymerase as a target, Genelabs has begun a research project involving a different HCV target. Our initial screening process has identified a starting compound which we believe may be suitable for our optimization process. We are recruiting additional chemistry and biology personnel to staff this optimization team. Genelabs continues to evaluate other HCV targets and targets for other diseases. We may choose to implement programs against another target in addition to our third program or in substitution for our third program.

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 are concentrated on Prestara™ (prasterone), an investigational drug for systemic lupus erythematosus, referred to as lupus or SLE. 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. Approval is contingent upon, among other things, the successful completion of an additional clinical trial providing sufficient evidence to confirm the positive effect of Prestara on bone mineral density of women with lupus on glucocorticoids and the emergence of no significant and new safety issues. We therefore conducted an additional Phase III clinical trial with bone mineral density as its primary endpoint. On October 5, 2004, we announced that this clinical trial, Study GL02-01, did not meet its primary endpoint. Separately, 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. We are continuing our analysis of the data and are evaluating our development options for Prestara.

There is a separate clinical trial of prasterone being 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 is a double-blind, placebo-controlled clinical trial similar in design to our Study GL02-01, with bone mineral density as its primary endpoint. The Genovate trial has a longer treatment duration of nine months, compared to six months for our study GL02-01. While the Genovate trial is not being conducted under a U.S. Investigational New Drug application, commonly referred to as an IND, we believe it is designed to comply with Good Clinical Practices, or GCPs, under the International Conference on Harmonization. The Genovate trial enrolled 89 patients and the last patient visit occurred in January 2005. We have entered into an agreement with

Genovate to share clinical trial data relating to Prestara™ and prasterone, including the data from their current Phase III trial in Taiwan. We cannot predict whether the Genovate trial will be positive. If the results of the Genovate trial are positive, we intend to submit them to the FDA to support our New Drug Application for Prestara, however, we cannot predict whether the FDA would consider such data or whether the data would be sufficient to obtain FDA approval.

If the Genovate trial does not demonstrate a statistically significant benefit on bone mineral density with acceptable side effects, or if the data are positive but not accepted by the FDA as sufficient to support approval of Prestara, or if FDA review is delayed, our business prospects would be substantially and adversely affected. In such event, we cannot predict whether another clinical trial which would satisfy the requirements of the FDA could feasibly be designed and executed. We do not have sufficient funds to pay for an additional Phase III clinical trial and raising additional funds to finance another clinical trial would be difficult since all the Phase III clinical trials heretofore conducted by us and Genovate have not been sufficient to produce FDA approval. Furthermore, an additional clinical trial would delay possible FDA approval by years and changes in the lupus market may diminish the prospects for Prestara, which also would affect our ability to raise funds for an additional clinical trial.

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 can affect the musculoskeletal and nervous systems as well as the lungs, heart, kidneys, skin and joints. Scientific publications have reported that the most common form of organ damage among lupus patients, musculoskeletal damage, occurs in 22% of patients, followed by neuropsychiatric disorders in 20% of lupus patients and renal disease in 15%. 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. To develop this drug candidate, we have built internal clinical development capabilities including clinical trial design, monitoring, analysis and reporting, regulatory affairs and quality control and assurance, all of which may be used to support the development of additional indications for Prestara and for other investigational drugs.

Genelabs has focused its clinical trials of Prestara on women. A small Phase III clinical trial in men with SLE was closed due to enrollment difficulties because so few men develop systemic lupus erythematosus, however the study did not indicate any serious adverse events associated with Prestara in this population.

Genelabs completed three double-blind randomized placebo controlled clinical trials of Prestara in women with lupus. The first of these trials, designated GL94-01, was completed in 1997 and evaluated Prestara's ability to reduce the glucocorticoid dose in steroid-dependent women with mild to moderate lupus while maintaining stable or improved SLE disease activity. 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. 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 study was a sustained reduction in glucocorticoid dose to 7.5 mg per day or less, which are levels approximately equivalent to those normally produced by the

adrenal glands. Data presented to the American College of Rheumatology on behalf of Genelabs 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 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. 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 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 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 bone mineral density in patients who were required to have been taking glucocorticoids for at least six months prior to entering the trial. These patients had bone mineral density 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 bone mineral density 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 is contingent upon, among other things, the successful completion of an additional clinical trial providing sufficient evidence to confirm the positive effect on bone mineral density that was observed in women with SLE while on glucocorticoids in Genelabs' Study GL95-02. To address this requirement, Genelabs designed and completed a multi-center, randomized, placebo-controlled, double-blind clinical trial, designated Study GL02-01. The primary endpoint in this study was bone mineral density at the

lumbar spine and 155 women with SLE receiving glucocorticoids were enrolled and treated for six months with either 200 mg per day Prestara or placebo at 26 sites. As noted above, GL02-01 did not meet its primary endpoint and was not powered to, and did not, meet its secondary endpoints.

All patients who completed Study GL02-01 were eligible to enroll into a one-year open-label follow-on study, which we have designated Study GL03-01. GL03-01 is designed to dose all patients with Prestara and all patients are scheduled to have additional bone mineral density scans six months and twelve months after their last scan under Study GL02-01. A total of 115 patients from Study GL02-01 elected to enroll into Study GL03-01. This study is ongoing and, unless we terminate it earlier, is scheduled to end in August 2005. We cannot predict whether the data from GL03-01 will be positive or will have any positive effect on our Prestara NDA.

Genelabs is also addressing other issues cited in the approvable letter, including, among other things, compiling data for submission regarding qualification of a manufacturing site. There were no major safety concerns raised by the clinical trials, however, results from the Genovate trial have not been analyzed and GL03-01 is not completed.

International Regulatory Applications. Independent of the United States regulatory process, Genelabs filed a Marketing Authorization Application, or MAA, seeking approval of Prestara for the treatment of SLE in Europe under the centralized procedure of the European Agency for Evaluation of Medicinal Products, or EMEA. Approval by the EMEA is required prior to commercialization of Prestara in the European Union. In June 2004 we withdrew the application after the EMEA indicated that questions they had raised during their review of the MAA remained unresolved and we concluded that we could not resolve the remaining issues within the timelines set for EMEA's review of the MAA. We retain the option to file again at a later date. In Japan, our licensee, Tanabe Seiyaku, Co., Ltd., 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 in the U.S. development of Prestara.

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 DHEA. In addition, 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 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. Because our clinical trials of Prestara have changed to focus on bone mineral density in women with SLE on glucocorticoids, it is not clear whether the orphan drug designation would continue to apply if Prestara is approved for marketing. We are pursuing additional patent applications relating to DHEA and 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 prevent loss of bone mineral density in women with SLE, 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, and existing and future drugs used to treat or prevent bone loss, such as bisphosphonates sold by Merck & Co., Inc. and Proctor & Gamble, among 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, and if both were approved the milestone would total $45 million. Currently, we are not seeking approval for steroid reduction and we do not know what the approved indication would encompass if our current NDA is approved by the FDA based on our bone mineral density endpoint. Exclusive rights for Japan have been licensed to Tanabe Seiyaku Co., Ltd., or Tanabe, under an agreement which would provide Genelabs up to $10 million in milestone payments upon the achievement of certain pre-determined development and regulatory goals and royalties on 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, however, we do not believe we can obtain acceptable value for a license to Prestara in Europe without positive clinical trial results.

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. Several years ago, Genovate conducted a 119-patient Phase III clinical trial of prasterone in Taiwan in accordance with U.S. Good Clinical Practices and data from this trial were included in the NDA for Prestara submitted by Genelabs as supportive data from a foreign source. More recently, as described above, Genovate completed a clinical trial of the effect of prasterone on bone mineral density in women with lupus, the results of which are not yet available.

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., is also chairman of 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. 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 an exclusive worldwide royalty-bearing license to make, use and sell HEV vaccines. GlaxoSmithKline is developing an HEV vaccine candidate and has completed two Phase I trials — one in the U.S. and one 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. In 2001, the Walter Reed Army Institute of Research initiated a Phase II clinical trial of GlaxoSmithKline's vaccine candidate in collaboration with the Medical Department of the Royal Nepal Army, the U.S. National Institutes of Health and GlaxoSmithKline. The trial 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, which have not yet been published, GlaxoSmithKline paid Genelabs a milestone payment in November 2004. GlaxoSmithKline has not announced its plans for future development, if any, of the hepatitis E vaccine candidate. We are not aware of any other vaccine against hepatitis E currently being evaluated in clinical trials. In addition to GlaxoSmithKline's vaccine license, Genelabs has granted Abbott Laboratories and Genelabs Diagnostics Pte. Ltd., a wholly-owned subsidiary of MP Biomedicals, LLC and former Genelabs subsidiary, royalty-bearing, non-exclusive worldwide licenses to develop and commercialize diagnostic products for HEV.

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 its 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.

Antifungal 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.

Patents

Genelabs seeks patent protection for its proprietary technologies and potential products in the U.S. and internationally. We own over 40 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., or GLD, 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 GLD as a discontinued operation.

Employees

As of December 31, 2004, Genelabs and its subsidiaries had 69 full-time equivalent employees, of whom 51 were involved in research and development and 18 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.

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

The results of our confirmatory 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.

Genelabs has focused its development efforts to date on conducting clinical trials for an investigational new drug, Prestara™ (prasterone), also referred to as GL701, Aslera™ and Anastar™, for the treatment of women with systemic lupus erythematosus, or lupus. Lupus is a severe, chronic and debilitating autoimmune disease that can affect the musculoskeletal and nervous systems, lungs, heart, kidneys, skin and joints. Prestara is a pharmaceutical formulation containing highly purified prasterone, the synthetic equivalent of dehydroepiandrosterone or DHEA, a naturally occurring hormone.

In order to satisfy conditions set by the U.S. Food and Drug Administration, or FDA, we recently conducted a Phase III clinical trial of Prestara on women with lupus taking glucocorticoids using bone mineral density as the trial's primary endpoint. 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. We are continuing to analyze the data in an attempt to determine the reasons why the trial did not achieve statistical significance at its primary or secondary endpoints, however, it is not likely that the cause or causes of this failure can be identified with certainty.

A clinical trial of prasterone has been conducted by Genovate Biotechnology Co., Ltd., referred to as Genovate, a Taiwan-based company that has a license from us for Prestara in most Asian countries. The Genovate trial enrolled 89 patients of which 88 received study medication and the last patient visit occurred in January 2005. We do not know if the outcome of this trial will be positive. Even if the results are positive, the study may not be useful for our development of Prestara in the United States or elsewhere.

Moreover, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. Genelabs' business plans depend on FDA approval of Prestara in the United States, and if we are not able to obtain FDA approval for Prestara in a timely manner, or if significant and new safety issues emerge, our business would suffer because we would not be entitled to a milestone payment from Watson, we would not receive royalties from Prestara sales in the United States, which are our most significant near-term source of potential revenue, and the prospects for Prestara in other countries would be substantially diminished.

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 maintain its listing on the Nasdaq National Market, Genelabs is required, among other things, to either maintain stockholders' equity of at least $10 million or a market value of at least $50 million, as well as to maintain a closing bid price of at least $1.00 per share of common stock.

When we announced our negative clinical trial results on October 5, 2004 our closing bid price fell below $1.00. On November 16, 2004, Nasdaq notified us that we were out of compliance with the $1.00

closing bid price requirement and provided us their standard grace period to regain compliance. On January 7, 2005 Nasdaq notified us that we had regained compliance because the bid price of our stock had closed above $1.00 for more than ten consecutive trading days. Since then, however, the closing bid price of our stock has fallen below $1.00 and we may be unable to regain compliance with the closing bid price requirement.

If Genelabs is unable to meet or maintain compliance with all of the Nasdaq listing requirements, it may be delisted from the National Market System. If delisted from the Nasdaq National Market, Genelabs might apply for listing on the Nasdaq SmallCap Market or the American Stock Exchange. Both the Nasdaq SmallCap Market and American Stock Exchange, however, also have listing requirements, which Genelabs may fail to meet for initial listing or with which Genelabs may fail to maintain compliance. Delisting from the National Market System could adversely affect the trading price of our common stock, and delisting from the Nasdaq SmallCap Market or the American Stock Exchange could significantly limit the liquidity of our common stock and adversely affect its trading price.

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 $218 million in net losses through December 31, 2004, including a net loss of $13.5 million for the year ended December 31, 2004. 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 until approximately mid-2006. However, we will still 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 number of shares of common stock that we are currently authorized to issue is limited, and when combined with the low 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;
- we may fail to meet Nasdaq's listing requirements and our ability to successfully complete an additional equity financing will be negatively impacted should we become unable to regain and maintain compliance with Nasdaq's listing requirements in a timely manner;
- 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; and
- our latest Phase III clinical trial for our investigational lupus drug, Prestara, did not meet its primary and secondary endpoints.

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.

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 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 Sciences, Inc., or Gilead, GlaxoSmithKline, or GSK, and other companies and we may enter into future collaborations with Gilead, GSK or other companies. There can be no assurance that our collaborators will not breach their contracts, or that our collaborators will diligently and successfully develop and commercialize the results of the research. Gilead may not continue to fund our research beyond its obligation in the research contract. We are dependent on our collaborators to successfully carry out preclinical and clinical development, to obtain regulatory approvals, and to market and sell any products arising from the research. 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 rights to intellectual property or may result in the collaborator obtaining know-how which enables it to compete with us in the same area of research. Because research and development results are unpredictable, we and our collaborators may not achieve any of the milestones in the collaboration agreements.

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 personnel is intense. We may not be able to continue to attract or retain such people on acceptable terms, given the competition for such personnel among biotechnology, pharmaceutical and healthcare companies, universities and nonprofit research institutions. Furthermore, the negative results from our United States clinical trials of Prestara™ and the ensuing drop in our stock price have significantly diminished our future business prospects, thus making it more difficult to retain existing employees and to recruit new employees. 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, new 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.

In our geographic area and industry, stock options are an important component of compensation. If we are unable to offer stock options comparable to other biotechnology companies we will be at a disadvantage in retaining and recruiting personnel. As of February 28, 2005, we have less than 700,000 shares available to issue as stock options and we will need shareholder approval to increase this number. If we are unable to obtain authorization to increase the number of shares available for issuance under our stock option plans it will be more difficult to attract, retain and motivate employees.

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 clinical trials we rely on third parties such as medical institutions, clinical investigators, contract laboratories and contract research organizations to participate in the conduct of our clinical trials. Additionally, the Taiwan clinical trial is conducted by another company, Genovate Biotechnology Co., Ltd., and we do not have control over the conduct of that trial. We depend on Gilead Sciences, Inc. for nucleoside compounds for treatment of hepatitis C infections, and GlaxoSmithKline, plc for 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 we are unable to find a European marketing partner for Prestara™ our business prospects will suffer because we do not have capabilities to obtain regulatory approval for Prestara in Europe or to market Prestara there ourselves and we would lose a significant source of potential revenue.

Because we have limited sales, marketing and distribution capabilities and no established presence in Europe, our business plans include licensing the European marketing rights to Prestara to a larger pharmaceutical or biotechnology company with established marketing capabilities in Europe and the regulatory expertise to assist us in obtaining regulatory approval for Prestara in Europe. If we are unable to find a European collaborator, we would not be able to launch Prestara in Europe in a timely manner, if at all, even if it is approved. Our business would suffer because we would not be able to generate near-term revenue from Prestara in Europe. Given that our United States clinical trial did not succeed in meeting its primary or secondary endpoints, it is unlikely that we will be able to secure a European marketing partner in the near term, if at all.

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 Seiyaku Co., Ltd. or Tanabe, has not conducted clinical trials for Prestara in Japan. Given the recent negative results in our United States clinical trial, there can be no assurance that Tanabe will proceed with clinical trials, or if it does, that the results from such trials will be positive.

If Prestara™ is approved for marketing in the United States, it may not have orphan drug status based on the approved use.

Orphan drug status can provide up to seven years of U.S. marketing exclusivity. The FDA granted orphan drug status to Prestara for treatment of systemic lupus erythematosus, or SLE, and for the reduction in the use of steroids in steroid-dependent SLE patients. Subsequently, the FDA's approvable letter required a clinical trial of Prestara on bone mineral density in women with SLE who are taking glucocorticoids (steroids). If Prestara is approved by the FDA, our current orphan drug status may not apply if the indication approved by the FDA is perceived different from the indication given orphan drug designation.

Our outside suppliers and manufacturers for Prestara™ 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. 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 Prestara as a finished product and for its active ingredient. Genelabs and our North American collaborator, Watson Pharmaceuticals, Inc., previously arranged for the manufacture of quantities of Prestara and its active ingredient in anticipation of possible marketing approval. This inventory will exceed its expiration date before any possible commercial launch, although the expiration date of the active ingredient may be extended if it successfully passes re-testing. The lead time for manufacturing large quantities of Prestara is many months, and depends on the availability of our contract suppliers. If Prestara were to be approved, we may not have sufficient quantities of finished product and the commercial launch of Prestara may be delayed.

Our manufacturing and supply agreement with Patheon for Prestara capsules has an initial term through December 31, 2008, and is renewable for three-year terms thereafter, unless either party provides the other with twelve months' notice prior to the end of the then-current term. The Patheon manufacturing supply agreement also provides for termination by either party upon failure of the other party to remedy a material breach within sixty days or upon bankruptcy of the other party; by us in the event of an action preventing us from importing, exporting, purchasing or selling the product; or by Patheon on six months' prior notice if we assign the agreement to an assignee that is not acceptable to Patheon. Our supply agreement for prasterone, the active ingredient in Prestara, has an initial term through May 29, 2005 and is automatically renewed for one-year periods unless either party provides the other with two years' notice. The supplier may not terminate without cause during the initial term. The active ingredient supply agreement also provides for termination by either party upon failure of the other party to remedy a material breach within sixty days or upon bankruptcy of the other party.

We believe that we are current in all material obligations under both of these agreements. In the event of termination or expiration of one or both of these agreements, we believe that we would be able to find alternative suppliers, however, we may not be able to secure these arrangements in a timely manner or on favorable terms and we would need to devote substantial time and expense to transfer the process of manufacture, and receiving regulatory qualifications.

The following could harm our ability to manufacture Prestara:

- the unavailability of adequate quantities of the active ingredient;

- 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; and
- competing demands on the contract manufacturer's capacity, for example, shifting manufacturing priorities to their own products or more profitable products for other customers.

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. We do not believe it is possible to obtain patent protection for the 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 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 covering Genelabs' 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 that we do not currently know about 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.

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, such as Prestara for lupus, if approved, 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, 2004 and December 31, 2004, the price of our common stock fluctuated between $0.48 and $3.25 per share. Between January 1, 2005 and March 1, 2005, the price of our common stock fluctuated between $0.77 and $1.23 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. The price of our stock fell considerably upon the announcement of our

negative clinical trial results for Prestara and the price may decline further if we are unable to demonstrate a reasonable probability of obtaining approval for Prestara.

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, and have an option to renew this lease for an additional four-year term following its expiration. This location encompasses approximately 50,000 square feet located in Redwood City, California, with a current annual base rent of approximately $1,308,000. Genelabs believes that this facility is adequate for its current needs and that suitable additional or substitute space will be available as needed to accommodate its operations.

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

Not applicable.

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

Not applicable.

PART II

Item 5. ***Market for Registrant's Common Equity and Related Shareholder Matters.***

The Common Stock of Genelabs began trading publicly on the Nasdaq Stock Market on June 13, 1991 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 Stock Market.

	High	Low
2003		
1st Quarter	1.88	1.12
2nd Quarter	2.10	1.26
3rd Quarter	1.86	1.38
4th Quarter	2.85	1.37
2004		
1st Quarter	3.25	2.01
2nd Quarter	3.20	2.00
3rd Quarter	2.92	1.76
4th Quarter	2.68	0.48

As of February 28, 2005, there were approximately 679 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, 2004.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	6,945,000	$2.76	2,004,000
Equity compensation plans not approved by security holders	—	—	—
Total	6,945,000	$2.76	2,004,000

Genelabs' equity compensation plans do not contain evergreen provisions.

On January 27, 2005, in connection with Genelabs' annual review process and practice of granting incentive stock options to its employees, the board of directors and its option committee granted options to purchase 1,461,000 shares of Genelabs' common stock at its then fair market value. After the issuance of these grants and other stock option activity, as of February 28, 2005 we had 8,279,000 options outstanding at a weighted-average exercise price of $2.43 per share, leaving 667,000 options

available for future issuance. All equity compensation plans currently in place at Genelabs have been approved by the shareholders.

Sale of Unregistered Securities. In January 2004, we sold 818,897 shares of our common stock to Tanabe Seiyaku Co., Ltd. at a price of $3.175 per share for gross and net proceeds of $2.6 million. These shares were issued in a private placement exempt from registration under the Securities Act of 1933, as amended, pursuant to Regulation D and/or Section 4(2) of the Act. The recipient represented its intention to acquire the shares for investment purposes only and not with a view to or for sale in connection with any distribution thereof. Appropriate restrictive legends were affixed to the share certificates.

Item 6. ***Selected Financial Data.***

The following selected consolidated financial information has been derived from the audited 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.

The following table summarizes quarterly financial data (unaudited).

	December 31	September 30	June 30	March 31
	(in thousands, except per share amounts)			
2004 Quarter Ended:				
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	(0.02)	(0.05)	(0.06)	(0.06)
Net loss per share	(0.02)	(0.05)	(0.03)	(0.05)

	December 31	September 30	June 30	March 31
	(in thousands, except per share amounts)			
2003 Quarter Ended:				
Total revenue	$ 715	$ 698	$ 776	$ 727
Research and development expenses	5,373	4,428	3,645	3,392
General and administrative expenses	2,069	1,244	1,615	1,556
Loss from continuing operations	(6,678)	(4,970)	(4,474)	(4,200)
Net loss	(6,490)	(4,837)	(4,280)	(4,200)
Loss per share from continuing operations	(0.08)	(0.08)	(0.08)	(0.08)
Net loss per share	(0.08)	(0.08)	(0.07)	(0.08)

In the second quarter of 2004, we made certain reclassifications in the statement of operations, decreasing research and development expenses and increasing general and administrative expenses, with no impact on total operating expenses or the net loss. These reclassifications are reflected in the table above, and amounted to $141,000, $145,000 and $165,000 for the first quarter of 2004 and the fourth and first quarters of 2003, respectively.

An amendment to a license agreement with Affymetrix, Inc., for our linker-aided DNA amplification technology and a milestone payment by GlaxoSmithKline based on clinical trial results of an investigational vaccine for the hepatitis E virus together resulted in non-recurring revenue of $2.0 million during the fourth quarter of 2004. In addition, we commenced work under our license and

research collaboration agreement with Gilead Sciences, Inc., which resulted in further revenue of $1.4 million during the fourth quarter of 2004.

The higher costs recognized in the fourth quarter of 2003 offset lower costs recorded in the earlier quarters of 2003 as well as the fourth quarter of 2002. During the fourth quarter of 2003, Genelabs paid to its employees contingent bonuses that were not paid for the previous year. In addition, during the fourth quarter of 2003 additional accruals for the 2003 bonuses were made after key objectives for payment of the 2003 incentive bonuses were met. As a result of the contingency and key objectives both being met during the fourth quarter of 2003, the total charges incurred for the incentive bonus plan during that quarter were $1,986,000, of which $1,490,000 was included in research and development and $496,000 was included in general and administrative expenses. For reference, these charges are approximately double the incentive bonus charges for the full calendar year 2004.

The selected financial data presented below summarize certain financial information from the consolidated financial statements.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Total revenue	$ 5,556	$ 2,916	$ 3,645	$ 4,769	$ 7,075
Research and development expenses	15,113	16,838	13,987	12,736	14,306
General and administrative expenses	6,505	6,484	6,079	6,966	5,991
Loss from continuing operations	(15,793)	(20,322)	(16,080)	(13,287)	(12,282)
Net loss	(13,511)	(19,807)	(15,950)	(13,000)	(12,282)
Loss per common share from continuing operations	(0.18)	(0.32)	(0.31)	(0.27)	(0.28)
Net loss per common share	(0.15)	(0.31)	(0.31)	(0.26)	(0.28)

	December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$26,508	$26,530	$6,570	$19,000	$34,671
Working capital	18,999	22,379	2,684	13,646	28,758
Total assets	29,383	29,866	9,765	22,100	37,594
Shareholders' equity	12,947	22,815	2,714	11,900	24,000

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 2005 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 2005 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 1 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 and clinical development capabilities that can support

various research and development projects. The Company is currently concentrating its capabilities on developing a late-stage product for lupus, 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.

During 2004, the following were significant events for Genelabs: entering into the agreement with Tanabe Seiyaku Co., Ltd. for Prestara in Japan, the sale of our diagnostics business to MP Biomedicals, LLC, the withdrawal of our application for marketing authorization for Prestara in Europe, entering into the agreement with Gilead Sciences, Inc. for research and development of nucleoside compounds for hepatitis C infection, the results of our U.S. Phase III clinical trial for Prestara which did not meet its endpoints and the subsequent drop in our stock price. 2004 also saw a shift in emphasis and resources from clinical development of Prestara to drug discovery efforts in our hepatitis C program. We also experienced a management change when Irene A. Chow retired from her position as our Chief Executive Officer, remaining as Chairman, and James A.D. Smith, who had been President, was promoted to also serve as Chief Executive Officer.

Critical Accounting Policies and the Use of Estimates

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, 2004 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, 2004, 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. We received an up-front payment of $8 million that we are amortizing over the 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, 2004, $7.5 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. Before December 31, 2004, Gilead paid us $0.9 million for research to be performed in the first quarter of 2005, which we have classified as deferred revenue, all of which is current.

At December 31, 2004, Genelabs also has unearned contract revenue aggregating $3.1 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 for Prestara to did not succeed in meeting its clinical endpoints. The failure of the clinical trial to meet its endpoints will result 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 assumption that another clinical trial may be needed to obtain approval. However, because we have not met with the U.S. Food and Drug Administration, or FDA, to discuss the clinical trial results from our U.S. trial and we do not yet know the results from our open-label follow-on clinical trial or from a different clinical trial of prasterone that is being conducted by a licensee in Taiwan, we presently are unable to define the best course for future development of Prestara, or whether we should terminate further development. Therefore, the estimates are highly subjective and may change in the future once we have more information and 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, we generally account for employee stock options based on their intrinsic value and do not recognize 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, 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, which supercedes previous accounting rules covering stock options issued to employees. For Genelabs, SFAS 123R is scheduled to become effective with the quarterly reporting period beginning July 1, 2005. Under SFAS 123R, we will be required to record compensation expense for stock options issued to employees, based on an estimate of the fair value of the options when they are issued. Because the stock option valuation assumptions permitted

under SFAS 123R are different than those contained in SFAS 123, the stock option valuation disclosures contained in the footnotes to our financial statements may differ significantly from the valuations we record in the financial statements upon the adoption of SFAS 123R in the third quarter of 2005. We are currently evaluating which method we will use to adopt SFAS 123R. Regardless of the method we choose, we expect SFAS 123R to increase our operating expenses, which will have a material impact on our statement of operations.

Results of Operations

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 (dollars in thousands):

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

In 2004, our most significant single source of revenue was from our linker-aided DNA amplification technology, comprised of a license amendment fee of $1.25 million and royalties of $204,000, or a total of $1,454,000. This compares to license fees of $50,000 and royalties of $80,000, totaling $130,000, in 2003. The increase in 2004 compared to 2003 occurred primarily because our licensee, Affymetrix, Inc., paid us $1.25 million in December 2004 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. We do not expect to recognize any revenue from our agreement with Affymetrix during 2005 or thereafter.

Our research collaboration and license agreement with Gilead Sciences, Inc. provided the second most significant source of revenue for 2004. The agreement has a three-year research term, which Gilead has an option to extend for an additional year. We received an $8.0 million up-front payment upon signing the agreement, and are entitled to receive quarterly payments, in advance, aggregating approximately $11 million over the initial three year research 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. The agreement began in October 2004, and under the agreement we recognized contract revenue of $1.4 million for 2004, comprised of $0.5 million for the pro-rata share of the $8.0 million up-front license fee and $0.9 million in research funding for the fourth quarter of 2004.

In 2004 we also recognized $1.2 million in revenue from our two collaborations for development and commercialization of Prestara. These are with Watson Pharmaceuticals Inc. for North America and

Tanabe Seiyaku Co., Ltd. for Japan. In 2004, our revenue related to Prestara decreased by $0.7 million compared to 2003 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 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 a new agreement entered into during 2004 with Tanabe Seiyaku for the development and commercialization of Prestara in Japan. 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 based on further clinical trial results and possible discussions with the FDA.

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. We presently do not expect to recognize any additional revenue under the agreement with GSK until regulatory filings are made in specified countries.

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. We do not expect to recognize further revenues from data analysis services.

In addition, we receive various royalties from other parties, which, excluding the royalty from Affymetrix, aggregated approximately $0.5 million in both 2004 and 2003.

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

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

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 — Background

Because we are in the business of drug discovery and development and have not developed any products that have been approved for sale, we classify the majority of our costs as research and development and expense them as incurred. Research and development expenses include related salaries and benefits, clinical trial and related clinical manufacturing costs, contract and outside service fees, supplies and chemicals used in laboratories and allocated facilities and overhead costs. Over the last ten years, Genelabs directed the majority of its research and development toward two major projects — developing Prestara™ as an investigational new drug for lupus and discovery of entirely new drugs.

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 (dollars in thousands):

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

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 are lower than in the Phase III clinical trial. In addition, Genelabs incurred lower costs related to the qualification of a manufacturing site for Prestara. Genelabs began developing Prestara™ for systemic lupus erythematosus in 1993 when Genelabs licensed exclusive rights to patents related to Prestara from Stanford University. To develop this investigational new drug, we have built internal clinical development capabilities including clinical trial design, monitoring, analysis and reporting, regulatory affairs and quality control and assurance. Direct costs incurred to build these capabilities and advance Prestara to its current stage of development have been approximately $47 million through December 31, 2004. For 2005 we currently expect our costs for drug development to decrease by approximately $1.5 million, or 25%, compared to 2004 due to staff attrition and because the U.S. double-blind Phase III clinical trial completed in 2004. Future development of Prestara for lupus and the costs we incur will depend on a number of factors. These include the results of a clinical trial by a licensee in Taiwan, discussions with and actions by the FDA, actions involving regulatory authorities in Europe and other countries and actions by our Prestara collaborators. In the event we decide to discontinue development of Prestara in 2005, we do not expect to realize further significant savings for 2005 as we have agreements in place with our clinical investigators, service providers and consultants for services we expect to require even if Prestara development is terminated. Also, any savings from reducing clinical development staff would be partially offset by severance costs.

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. Since initiating its 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 $38 million through December 31, 2004. In 2004, substantially all of our drug discovery efforts were directed towards our two hepatitis C virus (HCV) research programs, both of which are concentrated on identifying a new drug to combat infection with HCV. The two current programs are both targeting the HCV RNA-dependent RNA polymerase, the enzyme directly responsible for replication of the HCV genome, although through different mechanisms. Part of our drug discovery process includes 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. During 2004, we entered into a license and research collaboration with Gilead that is currently providing a source of revenue to support the HCV nucleoside program we previously funded ourselves. The agreement requires us to commit a specified number of scientists to the HCV nucleoside program, at approximately the same level we had previously devoted to the program, so we do not expect costs in 2005 for that research program to increase appreciably as a result of the new agreement. However, we plan to expand work on our other existing HCV drug discovery program and introduce new drug discovery programs, and therefore presently estimate that drug discovery costs for 2005 will increase by over 20% compared to 2004, if we are able to hire the additional scientists required for such programs. 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 advancement of potential product candidates against Genelabs' limited cash resources and the potential cash requirements for development of Prestara.

Support Costs and Other R&D

Support costs and other R&D 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 R&D were $4.7 million in 2004 and $5.9 million in 2003, a decrease of $1.2 million. The following table breaks down by percentage the major components of support costs and other R&D:

	2004	2003
Facility rent	27%	21%
Insurance and depreciation	21%	16%
Incentive bonus allocation	17%	38%
Utilities, maintenance and security	14%	11%
Support staff	11%	10%
Other items	10%	4%
Total support and other R&D costs	100%	100%

The decrease in costs during 2004 as compared to 2003 was primarily due to a reduction of the incentive bonus allocation due to significant 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. Other costs included in support costs and other R&D were comparable in 2004 and 2003. In the table above, the 2004 percentage for items other than the incentive bonus allocation increases due to the decline in the 2004 incentive bonus percentage. In 2005, we expect support costs and other R&D to increase approximately 10% to 15% in order to support planned higher direct drug discovery research activities.

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. Requirements for future general and administrative expenses will vary based on future events that impact our business, such as the requirements for further development of Prestara, if any. Management currently expects our 2005 general and administrative expenses may increase by up to 15% compared to the 2004 general and administrative expenses, if the results of the Taiwan clinical trial are positive and the FDA agrees to review the data, as we may elect to expand marketing and business development activities related to Prestara. If we decide to discontinue development of Prestara, we expect that marketing and business development activities related to Prestara will be reduced but these savings may be offset by severance costs, legal costs and redirection of management to other corporate priorities such as increased emphasis on partnering our research programs.

Nonoperating Expenses. 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.

Years Ended December 31, 2003 and 2002

Introduction. Genelabs' net loss was $19.8 million in 2003, an increase of $3.8 million from the $16.0 million net loss in 2002. This increase in net loss is primarily the result of higher research and development costs during 2003. Research and development costs were higher in 2003 due to commencement of the clinical trial in women with lupus and also due to higher incentive bonus costs that were incurred as a result meeting contingencies established for payment of the incentives. Partially offsetting these increases were lower salary and benefit costs resulting from a reduction in workforce implemented in early 2003. A more detailed discussion of the changes in Genelabs' statement of operations follows.

Revenue. Revenues were $2.9 million in 2003, a decrease of $0.7 million from $3.6 million in revenues in 2002. The following table breaks down revenue by major source (dollars in thousands):

	2003	2002
Contract revenue:		
Prestara collaboration with Watson	$1,841	$2,525
License fees	50	125
Data analysis services	493	600
Total contract revenue	2,384	3,250
Royalties	532	395
Total revenue	$2,916	$3,645

In 2003, approximately 63% of revenue was the recognition into income of a previously received up-front license payment from Watson. In 2003, this source of revenue decreased from 2002 due to a revision we made to the estimate of time it would take us to obtain an answer from the FDA on approval of Prestara™ after our possible submission of a complete response to the approvable letter. As of December 31, 2003, Genelabs estimated that it would take until June 2005 for an FDA decision on the NDA based on the scheduled completion of the clinical trial conducted in the U.S. As noted above, in 2004 we changed this estimate to 2008.

Aside from the revenue recognized from Watson, other sources of revenue include royalties and license fees and data analysis services performed for larger pharmaceutical companies. Collectively, these other sources aggregated approximately $1.1 million in both 2003 and 2002.

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

	2003	2002	Change
Research and development	$16,838	$13,987	+20%
General and administrative	6,484	6,079	+7%
Total operating expenses	$23,322	$20,066	+16%

All operating expenses are related to Genelabs' business of discovering and developing pharmaceutical products. The two key increases in operating expenses for 2003 compared to 2002 were costs related to conducting our clinical trial of Prestara for lupus and costs incurred for our employees' incentive bonuses. These are each explained in more detail below.

Research and Development Expenses by Project

The following table breaks down the research and development expenses by major project (dollars in thousands):

	2003	2002	Change
Drug development (Prestara™)	$ 6,416	$ 4,650	+38%
Drug discovery (HCV and DNA-binding)	4,513	5,273	-14%
Support costs and other R&D	5,909	4,064	+45%
Total research and development	$16,838	$13,987	+20%

Drug Development (Prestara™)

Costs for Prestara increased to $6.4 million in 2003 compared to $4.7 million in 2002 primarily as a result of our commencement of the Phase III clinical trial, which enrolled patients throughout 2003. In addition, Genelabs also incurred additional incremental costs in 2003 for qualification of a manufacturing site for Prestara.

Drug Discovery

Costs for our drug discovery program decreased to $4.5 million in 2003 from $5.3 million in 2002. Drug discovery costs were lower in 2003 compared to 2002 because of a reduction in the drug discovery workforce that was implemented in early 2003.

Support Costs and Other R&D

Support costs and other R&D were $5.9 million in 2003 and $4.1 million in 2002, an increase of $1.8 million. The following table breaks down by percentage the major components of support costs and other R&D:

	2003	2002
Facility rent	21%	17%
Insurance and depreciation	16%	34%
Incentive bonus allocation	38%	0%
Utilities, maintenance and security	11%	19%
Support staff	10%	17%
Other items	4%	13%
Total support and other R&D costs	100%	100%

The $1.8 million increase in costs during 2003 was primarily due to an increased incentive bonus allocation incurred in 2003 as compared to no incentive bonus allocation in 2002, under an incentive bonus plan in which all employees participate. No bonus charge was incurred in 2002 due to contingencies our board of directors established for the payment, which were not met until 2003. In addition, we modified our facility lease at the end of 2002, also increasing the support and other R&D costs approximately $0.4 million in 2003. Other costs included in support costs and other R&D decreased in 2003 as compared to 2002, both in total dollars and as a percentage of the total support and other R&D costs, as a result of facility improvements becoming fully depreciated at the end of 2002 and our reduction in workforce.

General and Administrative

In 2003, $6.5 million in operating expenses were general and administrative expenses, compared to $6.1 million in 2002, an increase of $0.4 million. During 2003, higher general and administrative costs were incurred due to recording of costs for incentive bonuses in 2003 compared to no charge in 2002, as during 2003 we met board-determined contingencies required prior to the payment of the incentive bonuses. Meeting these contingencies increased general and administrative costs by $0.5 million in 2003 compared to 2002. Offsetting this increase were lower salary costs as a result of the reduction in workforce implemented in early 2003.

Nonoperating Expenses. Interest income was $0.1 million in 2003, a decrease of $0.2 million from 2002. The decrease in interest income was due to lower average cash balances during 2003 than during 2002.

In 2003, we recorded $0.5 million in income from the discontinued operations of Genelabs Diagnostics Pte. Ltd., an increase of $0.4 million from $0.1 million in income for 2002. The increase in income from discontinued operations was primarily due to higher sales of diagnostics products.

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 $26.5 million at December 31, 2004, which was no change from the cash, cash equivalents and restricted cash at December 31, 2003. In 2004, our cash used in operations was $6.0 million, which funded our development of Prestara and our continued

research on the discovery of new treatments for hepatitis C virus infection. The cash used in operations during 2004 was reduced by the following nonrecurring events during the year:

- $8.0 million upfront payment received from Gilead Sciences, Inc. for a license and research collaboration agreement for discovery of new drugs for hepatitis C viral infections,
- $2.0 million upfront payment received from Tanabe Seiyaku for a license and collaboration agreement for the Japanese rights to Prestara,
- $1.25 million received from an amendment to a license agreement with Affymetrix for our linker-aided DNA amplification technology, and
- a milestone payment of $0.75 million received from GlaxoSmithKline based on the results of a Phase II clinical trial of their investigational vaccine for the hepatitis E virus.

During 2004, our $6.0 million cash used in operations and our $0.6 million in purchases of property and equipment were offset by $2.9 million in cash received from the sale of our diagnostics business, $2.6 million in cash received from the sale of common stock to our Japanese licensee for Prestara and $1.0 million in cash received from the exercise of stock options and warrants. Genelabs presently estimates that our current cash resources will be adequate to provide liquidity into approximately mid-2006. However, we will require additional capital 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 Company is considering entering into additional research collaborations, such as for our hepatitis C virus drug discovery program which is separate from our collaboration with Gilead. We are also evaluating the sale of non-core assets and exploring other potential partnerships as sources of funding. The Company may be unable to complete any of these transactions as currently contemplated or at all.

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 and development costs for Prestara. The amount of additional costs in our business plans will depend on numerous factors including the outcome of the clinical trial in Taiwan, whether the FDA will consider the data from Taiwan, any other FDA actions, 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.

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, although we have an option to extend our principal current operating lease for a four-year period beyond its current

expiration in November 2006. Our contractual payment obligations for the next five years are as follows:

	Less than One Year	One to Three Years	Three to Five Years	Total
		(in thousands)		
Operating leases	$1,308	$1,231	—	$2,539
Equipment loans	70	—	—	70
Total	$1,378	$1,231	—	$2,609

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 short-term investments. We consider the risk minimal as substantially all investments are in money market funds and we have not used derivative instruments. As of December 31, 2004, the overall average maturity of Genelabs' short-term investment portfolio was less than 90 days, leaving little 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. 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.

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, 2004. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2004, 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, 2004 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

(c) Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2004. In making this assessment, our management used the criteria set forth by The Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework. Our management has concluded that, as of December 31, 2004, our internal control over financial reporting was effective based on these criteria.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included in (e) below.

(d) Inherent Limitations on Effectiveness of Controls. Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in condition or that the degree of compliance with our policies or procedures may deteriorate. However, our internal controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our Chief Executive Officer and Chief Financial Officer have concluded that our internal controls are effective at that reasonable level.

(e) Report of Independent Registered Public Accounting Firm.

The Board of Directors and Shareholders
Genelabs Technologies, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Genelabs Technologies, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Genelabs Technologies, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that Genelabs Technologies, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Genelabs Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Genelabs Technologies, Inc. as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 of Genelabs Technologies, Inc. and our report dated March 8, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 8, 2005

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

Not applicable.

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 2005 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 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.

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" and "Proposal No. 1 — Election of Directors — Compensation of Directors."

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

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 Accountant 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 and Financial Statement Schedules.***

(a)(1), (a)(2) and (d) *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 they are not applicable or because the information is included elsewhere in the Consolidated Financial Statements or notes thereto.

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

Exhibit No.	Exhibit Title
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 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 (incorporated herein by reference to Exhibit 4.01 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")).
10.01	Registrant's 1985 Employee Stock Option Plan and related documents, as amended to date (incorporated herein by reference to Exhibit 4.03 to the Registrant's Registration Statement on Form S-8 (File No. 33-81894) filed on July 25, 1994.***
10.02	Registrant's 1995 Stock Option Plan, as amended to date (incorporated herein by reference to Exhibit 10.07 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997).***
10.03	Registrant's 2001 Stock Option Plan (incorporated herein by reference to Exhibit 10.07 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001 (the "2001 Form 10-K")).***
10.04	Registrant's Amended and Renewed 1994 Annual and Long-Term Incentive Based Compensation Plan (incorporated herein by reference to Exhibit 10.04 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).***
10.05	Registrant's 2001 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.08 of the 2001 Form 10-K).***
10.06	Form of Registrant's Indemnity Agreement entered into by Registrant with certain officers and directors (incorporated herein by reference to Exhibit 10.04 to the Form S-1).***
10.07	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).

Exhibit No.	Exhibit Title
10.08	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")).
10.09	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")).*
10.10	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).*
10.11	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 the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K").*
10.12	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).*
10.13	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).*
10.14	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 the 2001 Form 10-K).***
10.15	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).***
10.16	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).*
10.17	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 the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004).*
10.18	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 the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004).**
10.19	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 the Registrant's Form 10-Q for the quarter ended September 30, 1992).*
10.20	Second Amendment to Heads of Agreement (incorporated herein by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998).*
10.21	Offer letter entered into between the Registrant and Irene A. Chow, Ph.D., dated March 9, 2004.***
10.22	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.

Exhibit No.	Exhibit Title
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.

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

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENELABS TECHNOLOGIES, INC.

By: /s/ JAMES A.D. SMITH
James A.D. Smith
President and Chief Executive Officer

March 11, 2005

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints James A. D. Smith and Matthew M. Loar, and each of them, his or her true and lawful attorneys-in-fact and agents with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Principal Executive Officer:

/s/ JAMES A.D. SMITH James A.D. Smith	President and Chief Executive Officer and Director	March 11, 2005

Principal Financial and Accounting Officer:

/s/ MATTHEW M. LOAR Matthew M. Loar	Chief Financial Officer	March 11, 2005

Additional Directors:

/s/ IRENE A. CHOW Irene A. Chow	Chairman	March 11, 2005
/s/ ARTHUR GRAY, JR. Arthur Gray, Jr.		March 11, 2005
/s/ H. H. HAIGHT H. H. Haight		March 11, 2005
/s/ ALAN Y. KWAN Alan Y. Kwan		March 11, 2005

GENELABS TECHNOLOGIES, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Genelabs Technologies, Inc. at December 31, 2004 and 2003, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Genelabs Technologies Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2005 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California
March 8, 2005

GENELABS TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2004	December 31, 2003
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,358	$ 26,530
Restricted cash	150	—
Net assets of diagnostics subsidiary held for sale	—	582
Other current assets	824	874
Total current assets	27,332	27,986
Property and equipment, net	1,091	920
Long-term investment	960	960
	$ 29,383	$ 29,866
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 1,702	$ 1,534
Accrued compensation and related expenses	1,811	2,167
Accrued manufacturing costs	700	400
Unearned contract revenue	4,120	1,506
Total current liabilities	8,333	5,607
Accrued compensation	745	691
Unearned contract revenue	7,358	753
Total liabilities	16,436	7,051
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value, 4,990 shares authorized, none issued or outstanding at December 31, 2004 or 2003	—	—
Common stock, no par value, 125,000 shares authorized, 88,501 and 86,936 shares issued and outstanding at December 31, 2004 and 2003, respectively	230,815	227,172
Accumulated deficit	(217,868)	(204,357)
Total shareholders' equity	12,947	22,815
	$ 29,383	$ 29,866

See accompanying notes.

GENELABS TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,		
	2004	2003	2002
	(In thousands, except per share amounts)		
Revenue:			
Contract	$ 4,874	$ 2,384	$ 3,250
Royalty	682	532	395
Total revenue	5,556	2,916	3,645
Operating expenses:			
Research and development	15,113	16,838	13,987
General and administrative	6,505	6,484	6,079
Total operating expenses	21,618	23,322	20,066
Operating loss	(16,062)	(20,406)	(16,421)
Interest income	284	99	344
Interest expense	(15)	(15)	(3)
Loss from continuing operations	(15,793)	(20,322)	(16,080)
Discontinued operations:			
Income from diagnostics business	262	515	130
Gain on sale of diagnostics business	2,020	—	—
Net loss	$(13,511)	$(19,807)	$(15,950)
Loss per common share from continuing operations	$ (0.18)	$ (0.32)	$ (0.31)
Net loss per common share — basic and diluted	$ (0.15)	$ (0.31)	$ (0.31)
Weighted average shares outstanding to calculate basic and diluted net loss per common share	88,092	63,888	51,443

See accompanying notes.

GENELABS TECHNOLOGIES, INC.
CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY

	Shares of Common Stock	Common Stock	Accumulated Deficit	Total Shareholders' Equity
		(In thousands)		
Balance, December 31, 2001	**49,843**	**$180,500**	**$(168,600)**	**$11,900**
Net loss and comprehensive loss			(15,950)	(15,950)
Shares issued in financing agreement	3,100	6,001		6,001
Shares issued under the employee stock purchase plan	403	617		617
Shares issued under stock options	47	122		122
Non-employee equity awards		24		24
Balance, December 31, 2002	**53,393**	**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	9,767	9,654		9,654
Shares issued upon exercise of warrants	360	529		529
Shares issued in public offering, net of issuance costs of $2,345	23,000	29,165		29,165
Shares issued under the employee stock purchase plan	373	483		483
Shares issued under stock options	43	58		58
Non-employee equity awards		19		19
Balance, December 31, 2003	**86,936**	**227,172**	**(204,357)**	**22,815**
Net loss and comprehensive loss			(13,511)	(13,511)
Shares issued upon exercise of warrants	172	254		254
Shares issued to Tanabe Seiyaku Co. Ltd., net of issuance costs of $12	819	2,588		2,588
Shares issued under the employee stock purchase plan	455	550		550
Shares issued under stock options	119	215		215
Non-employee equity awards		36		36
Balance, December 31, 2004	**88,501**	**$230,815**	**$(217,868)**	**$12,947**

See accompanying notes.

GENELABS TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2004	2003	2002
	(In thousands)		
Cash flows from operating activities:			
Net loss	$(13,511)	$(19,807)	$(15,950)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	408	493	1,014
Income of discontinued diagnostics business	(262)	(515)	(130)
Gain on sale of discontinued diagnostics business	(2,020)	—	—
Non-employee equity awards	36	19	24
Changes in assets and liabilities:			
Other current assets	11	(362)	90
Accounts payable, accrued liabilities, and accrued compensation	161	1,841	(624)
Unearned contract revenue	9,219	(1,841)	(2,525)
Net cash used in operating activities	(5,958)	(20,172)	(18,101)
Cash flows from investing activities:			
Restricted cash	(150)	—	—
Net cash received from sale of discontinued diagnostics business	2,908	—	—
Remittances from discontinued diagnostics business	—	350	—
Proceeds from sales and maturities of short-term investments	—	3,535	13,545
Purchases of short-term investments	—	—	(6,706)
Purchases of property and equipment	(579)	(107)	(1,069)
Net cash provided by investing activities	2,179	3,778	5,770
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net	3,607	39,889	6,740
Net (decrease)/increase in cash and cash equivalents	(172)	23,495	(5,591)
Cash and cash equivalents, beginning of the period	26,530	3,035	8,626
Cash and cash equivalents, end of the period	$ 26,358	$ 26,530	$ 3,035

See accompanying notes.

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 and clinical development capabilities that can support various research and development projects. The Company is currently concentrating its capabilities on developing a late-stage product for lupus, 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.

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 preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. It is possible that actual amounts will differ from those estimates.

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 through development, a collaboration, or an obligation to supply product 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.

(tabular amounts in thousands, except per share data)

In 2004, there were four significant sources of revenue accounting for 26%, 25%, 17% and 13% of total revenue. In each of 2003 and 2002, there were two significant sources of revenue, accounting for 63% and 16% of total revenue in 2003, and 73% and 11% of total revenue in 2002.

Earnings per Share

Net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share has not been presented, as, due to the Company's net loss position, it is antidilutive. Had the Company been in a net income position, diluted earnings per share for 2004, 2003 and 2002 would have included an additional 1,937,000, 454,000 and 201,000 shares, respectively, related to the Company's outstanding stock options and warrants.

Stock-Based Compensation

The Company grants employee stock options at an exercise price equal to the fair market value of the shares at the date of grant. The Company accounts for employee stock-based compensation using the intrinsic value method and, accordingly, recognizes no compensation expense for stock options granted to employees. Option valuation models have been developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. These models require 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. Using the Black-Scholes pricing model, the following table presents information showing what the effects to the reported net loss and net loss per share would be if the Company had accounted for employee stock-based compensation using the fair-value method:

	2004	2003	2002
Net loss as reported	$(13,511)	$(19,807)	$(15,950)
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	(1,878)	(1,895)	(2,813)
Pro forma net loss	$(15,389)	$(21,702)	$(18,763)
Net loss per common share as reported, basic and diluted	$ (0.15)	$ (0.31)	$ (0.31)
Stock-based employee compensation cost:			
Included in net loss per share as reported	—	—	—
Amount that would have been included in net loss per common share if the Company had accounted for all stock- based employee compensation at its theoretical fair value	(0.02)	(0.03)	(0.05)
Pro forma net loss per common share, basic and diluted	$ (0.17)	$ (0.34)	$ (0.36)

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.

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 collaterizes a standby letter of credit in the same amount, and is renewable annually. At December 31, 2004 and 2003, all investments are in money market mutual funds and are 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 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. The Company holds less than 10% of the voting shares of this entity and management periodically monitors the liquidity and financing activities of this entity to determine if an impairment write-down is required.

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, 2004, there has been no such impairment.

Research and Development Expenses

Our 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.

(tabular amounts in thousands, except per share data)

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.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current year presentation. Reclassifications in the statement of operations decreased research and development expenses and increased general and administrative expenses by $589,000 in 2003 and $550,000 in 2002. Reclassifications in the balance sheet decreased accounts payable and other accrued liabilities and increased accrued compensation and related expenses by $594,000 as of December 31, 2003.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards 123 (revised 2004), "Share-Based Payment" (SFAS 123R), which currently is scheduled to become effective for public companies in periods beginning after June 15, 2005. SFAS 123R, which Genelabs is required to implement in the third quarter of 2005, addresses the accounting for stock options issued to employees, and eliminates the ability to account for employee stock options using the intrinsic value method currently used by the Company. 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. Genelabs is currently evaluating option valuation methodologies and assumptions in light of the newly issued SFAS 123R. Current estimates of option values using the Black-Scholes method (as shown above) may not be indicative of results from valuation methodologies permitted under SFAS 123R. Genelabs is presently evaluating its method of adopting SFAS 123R. Regardless of the method of adoption chosen, the Company expects SFAS 123R to increase its operating expenses, which will have a material impact on the statement of operations.

2. Property and Equipment

The components of property and equipment are as follows:

	2004	2003
Laboratory equipment	$ 5,529	$ 5,063
Leasehold improvements	4,655	4,639
Office and other equipment	2,693	2,600
	12,877	12,302
Less accumulated depreciation and amortization	(11,786)	(11,382)
	$ 1,091	$ 920

An asset purchased under capital lease is included in property and equipment at a cost of $309,000, with accumulated amortization of $144,000 and $82,000 at December 31, 2004 and 2003, respectively.

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, 2004, future minimum lease payments under all operating leases with original terms greater than one year are $1,308,000 and $1,231,000 for 2005 and 2006, respectively, for a total of $2,539,000, excluding sublease rentals. Future minimum rental payments to be received by Genelabs under one noncancelable sublease agreement are $139,000 and $130,000 for 2005 and 2006, respectively. Total lease expense, net of sublease income, was $1,470,000, $1,465,000, and $879,000 for 2004, 2003 and 2002, respectively.

The Company leases equipment under a non-cancelable capital lease that has a term expiring in August 2005. At December 31, 2004, future minimum lease payments total $70,000, all of which is due in 2005. The capital lease obligation is included in accounts payable and other accrued liabilities on the balance sheet.

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 certificiate 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, 2004.

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.

(tabular amounts in thousands, except per share data)

4. Shareholders' Equity

Common Stock

On January 28, 2004, Genelabs completed the sale of approximately 0.8 million shares of its common stock to Tanabe Seiyaku Co. Ltd. at a price of $3.175 per share for gross and net proceeds of $2.6 million.

On October 22, 2003, Genelabs completed the sale of 23 million shares of its common stock in a public offering at a price of $1.37 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 460,000 shares of our common stock at an exercise price of $1.42 per share.

On August 1, 2003, Genelabs completed the sale of approximately 1.7 million shares of its common stock at a price of $1.595 per share for gross proceeds of approximately $2.7 million. In connection with the sale, Genelabs also issued warrants to purchase approximately 1.7 million shares of Genelabs common stock at an exercise price of $1.50 per share. Net proceeds from the placement were approximately $2.4 million.

On May 2, 2003, Genelabs completed the sale of 8.1 million shares of its common stock at a price of $1.00 per share for gross proceeds of $8.1 million. In connection with the sale, Genelabs also issued warrants to purchase an additional 2.43 million shares of Genelabs common stock at an exercise price of $1.50 per share. Net proceeds from the placement were approximately $7.2 million. The exercise price of the warrants issued in this offering adjusted to $1.47 per share after the public offering in October 2003.

The following table shows the warrants to purchase common stock that are outstanding at December 31, 2004:

Expiration Date	Number of Shares	Exercise Price
November 2005	500	$6.85
January 2006	75	5.25
May 2008	1,897	1.47
October 2008	460	1.42
August 2010	1,667	1.50
Total and weighted average exercise price	4,599	$2.12

At December 31, 2004, the Company had a total of 14,172,000 shares reserved for future stock issuances, which is comprised of the above warrants and shares authorized under employee stock purchase and option plans. At December 31, 2004, there were 22,327,000 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

(tabular amounts in thousands, except per share data)

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, 2004 and 2003, a cumulative total of 2,692,000 and 2,237,000 shares, respectively, had been issued under the Stock Purchase Plan and a similar predecessor plan, with 623,000 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, 2004, 2,004,000 shares were available for future grants.

Stock option transactions from 2002 through 2004 are summarized as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2001	4,187	$3.91
Granted	1,808	1.81
Exercised	(47)	2.62
Canceled	(518)	3.62
Outstanding at December 31, 2002	5,430	3.25
Granted	1,427	1.54
Exercised	(43)	1.33
Canceled	(632)	3.38
Outstanding at December 31, 2003	6,182	2.87
Granted	1,515	2.26
Exercised	(119)	1.80
Canceled	(633)	2.85
Outstanding at December 31, 2004	6,945	$2.76

(tabular amounts in thousands, except per share data)

The exercise price ranges and average remaining terms of options outstanding and exercisable at December 31, 2004 were:

Range of Exercise Prices	Number of Options Outstanding at 12/31/04	Weighted Average Remaining Term	Weighted Average Exercise Price	Number of Options Exercisable at 12/31/04	Weighted Average Exercise Price
$0.60-$1.00	723	8.2 years	$0.86	314	$0.91
$1.01-$2.00	1,960	7.4 years	$1.59	1,473	$1.61
$2.01-$3.00	2,641	6.4 years	$2.40	1,722	$2.36
$3.01-$5.00	567	3.4 years	$3.96	567	$3.96
$5.01-$10.91	1,054	4.7 years	$6.48	1,048	$6.48
$0.60-$10.91	6,945	6.4 years	$2.76	5,124	$3.07

There were options for 4,446,000 and 3,420,000 shares exercisable at December 31, 2003 and 2002, 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 2004, 2003 and 2002, respectively: dividend yields of zero; risk-free interest rates of 3.5%, 3.0% and 3.0%; volatility factors of 1.0; and a one, one and five year expected life of the options after vesting. Based on these assumptions, the weighted-average fair value of options granted during 2004, 2003 and 2002 was $1.18, $0.87 and $1.41 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 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

(tabular amounts in thousands, except per share data)

grant. The following table shows the weighted average exercise prices and fair values of stock options granted in 2004:

Stock options granted with an exercise price	Number of Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Options
Below market value of common stock	—	—	—
At market value of common stock	1,160	$2.19	$1.33
Above market value of common stock	355	2.50	0.68
Stock option grants in 2004	1,515	$2.26	$1.18

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 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. Under the agreement the Company recognized contract revenue of $1,400,000 for 2004, comprised of $500,000 for the pro-rata share of the up-front license fee and $900,000 received from Gilead to support the Company's research in 2004. At December 31, 2004, unearned contract revenue from Gilead included $7,500,000 from the up-front payment and an additional $900,000 received from Gilead to support the Company's research in the first quarter of 2005.

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.

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. The non-refundable payment 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 2004 the

(tabular amounts in thousands, except per share data)

Company lengthened the amortization period for the unearned contract revenue from Watson after Genelabs' U.S. clinical trial did not meet its primary endpoint, resulting in a longer period of time before the Company can potentially receive approval of Prestara. In 2003 the Company lengthened the amortization period based on the enrollment rate into the clinical trial. The lengthening of the amortization period in each year decreased the amount of revenue the Company recognized into the statement of operations.

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

	At December 31,	
	2004	2003
Gilead Sciences, Inc.	$8,400	$ —
Tanabe Seiyaku Co., Ltd.	1,739	—
Watson Pharmaceuticals, Inc.	1,339	2,259
Total unearned contract revenue	11,478	2,259
Amount classified as current	4,120	1,506
Amount classified as long-term	$7,358	$ 753

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

	For the year ended December 31,		
	2004	2003	2002
Gilead Sciences, Inc.	$1,400	$ —	$ —
Tanabe Seiyaku Co., Ltd.	261	—	—
Watson Pharmaceuticals, Inc.	921	1,841	2,525

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

(tabular amounts in thousands, except per share data)

business as a discontinued operation. Summarized financial information for GLD prior to the date of sale in 2004 is as follows:

Statements of Operations

	January 1 through April 20, 2004	For the years ended December 31, 2003	2002
Product sales	$1,965	$6,168	$4,520
Cost of sales	961	3,323	2,544
Gross profit	1,004	2,845	1,976
Operating expenses	742	2,330	1,846
Income from discontinued operations	$ 262	$ 515	$ 130

Balance Sheets

	April 20, 2004	December 31, 2003
Cash, cash equivalents and short-term investments	$ 633	$ 655
Accounts receivable	788	1,037
Inventories	689	565
Total assets	$2,110	$2,257
Liabilities, principally current	$1,266	$1,675
Net equity of Genelabs Diagnostics Pte. Ltd.	844	582
Total liabilities and net equity	$2,110	$2,257

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

(tabular amounts in thousands, except per share data)

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:

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$66,900	$61,000
Deferred revenue	4,600	900
Research credits	3,700	3,500
Capitalized research expenditures	2,400	1,500
Capital loss carryforwards	900	—
Foreign net operating losses	—	1,900
Other individually immaterial items, net	1,000	1,600
Total deferred tax assets	79,500	70,400
Valuation allowance for deferred tax assets	(79,500)	(70,400)
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 2004, 2003 and 2002, the valuation allowance increased by $9.1 million, $6.1 million and $5.7 million, respectively. Deferred tax assets at December 31, 2004 include approximately $2.9 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to shareholder's equity.

At December 31, 2004, the Company had net operating loss carryforwards for federal income tax purposes of approximately $189 million which expire in the years 2005 through 2024 and federal research and development tax credits of approximately $2.2 million which expire in the years 2005 through 2024. The Company's federal capital loss carryfowards of $2.4 million expire in 2009. In addition, the Company had net operating loss carryforwards for state income tax purposes of approximately $43 million which expire in the years 2005 through 2014 and state research and development tax credits of approximately $2.2 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 $13,000 in 2004, or $16,000 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 not made any contributions to the plan on behalf of employees.

Exhibit No.	Exhibit Title
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 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 (incorporated herein by reference to Exhibit 4.01 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")).
10.01	Registrant's 1985 Employee Stock Option Plan and related documents, as amended to date (incorporated herein by reference to Exhibit 4.03 to the Registrant's Registration Statement on Form S-8 (File No. 33-81894) filed on July 25, 1994.***
10.02	Registrant's 1995 Stock Option Plan, as amended to date (incorporated herein by reference to Exhibit 10.07 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997).***
10.03	Registrant's 2001 Stock Option Plan (incorporated herein by reference to Exhibit 10.07 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001 (the "2001 Form 10-K")).***
10.04	Registrant's Amended and Renewed 1994 Annual and Long-Term Incentive Based Compensation Plan (incorporated herein by reference to Exhibit 10.04 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003).***
10.05	Registrant's 2001 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.08 of the 2001 Form 10-K).***
10.06	Form of Registrant's Indemnity Agreement entered into by Registrant with certain officers and directors (incorporated herein by reference to Exhibit 10.04 to the Form S-1).***
10.07	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).
10.08	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")).
10.09	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")).*
10.10	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).*
10.11	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 the Registrant's Annual Report on Form 10-K for the year ended December 31, 1995 (the "1995 Form 10-K").*
10.12	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).*

Exhibit No.	Exhibit Title
10.13	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).*
10.14	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 the 2001 Form 10-K).***
10.15	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).***
10.16	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).*
10.17	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 the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004).*
10.18	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 the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004).**
10.19	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 the Registrant's Form 10-Q for the quarter ended September 30, 1992).*
10.20	Second Amendment to Heads of Agreement (incorporated herein by reference to Exhibit 10.13 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998).*
10.21	Offer letter entered into between the Registrant and Irene A. Chow, Ph.D., dated March 9, 2004.***
10.22	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.

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

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

EXHIBIT 21.01

GENELABS TECHNOLOGIES, INC.

LIST OF REGISTRANT'S SIGNIFICANT SUBSIDIARIES

Name	State or Country of Organization	Percent Owned by Genelabs Technologies, Inc.
Accelerated Clinical Research Organization, Inc.	Delaware	100%
Genelabs Diagnostic, Inc.	Delaware	100%
Genelabs Europe B.V.	Netherlands	100%

EXHIBIT 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-108604, 333-64418, 333-64092, 333-5769, and 33-81894) pertaining to the 2001 Stock Option Plan, 2001 Employee Stock Purchase Plan, the 1995 Stock Option Plan, the 1985 Employee Stock Option Plan of Genelabs Technologies, Inc. and in the Registration Statements (Form S-3 Nos. 333-108608, 333-108035 and 333-105390) and in the related Prospectuses, respectively, of our reports dated March 8, 2005, with respect to the consolidated financial statements of Genelabs Technologies, Inc., Genelabs Technologies, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Genelabs Technologies, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ Ernst & Young LLP

Palo Alto, California
March 8, 2005

EXHIBIT 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

CERTIFICATION

I, James A.D. Smith, certify that:

1. I have reviewed this annual report on Form 10-K of Genelabs Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2005

/s/ JAMES A.D. SMITH

James A.D. Smith
President and Chief Executive Officer

EXHIBIT 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

CERTIFICATION

I, Matthew M. Loar, certify that:

1. I have reviewed this annual report on Form 10-K of Genelabs Technologies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2005

/s/ MATTHEW M. LOAR

Matthew M. Loar
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C § 1350, as adopted), James A.D. Smith, President and Chief Executive Officer of Genelabs Technologies, Inc. (the "Company"), and Matthew M. Loar, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2004, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Periodic Report and results of operations of the Company for the period covered by the Periodic Report.

Dated: March 11, 2005

/s/ JAMES A.D. SMITH	/s/ MATTHEW M. LOAR
James A.D. Smith	Matthew M. Loar
President and Chief Executive Officer	*Chief Financial Officer*

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DIRECTORS >

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

Arthur Gray, Jr. [1] [2] [3]
Senior Managing Director
Carret and Company

H. H. Haight [1] [2]
President and Chief Executive Officer
Argo Global Capital, Inc.

Alan Y. Kwan [1] [2] [3]
Attorney
Private Practice

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

[1] Member, Audit Committee
[2] Member, Nominating Committee
[3] 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 >

Mellon Investor Services
Shareholder Relations
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TDD For Hearing Impaired 800-231-5469
Foreign Shareholders 201-329-8660
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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.
Vice President, Research

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 Time on Tuesday, June 14, 2005 at the company's headquarters.

STOCK INFORMATION > As of April 22, 2005, there were approximately 678 shareholders of record of the company's common stock, with 88,503,779 shares outstanding. The common stock of the company is traded on the Nasdaq National 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 closing sales prices of the company's common stock as reported by the Nasdaq National Market.

R&D PIPELINE >

Products in Development	Indication	Research/Discovery	Lead Optimization	Pre-Clinical	Phase I	Phase II	Phase III	New Drug Application	Marketed	Corporate Partnerships	
Prestara™	Prevention of BMD loss in women with lupus									**Watson** **Tanabe** **Teva** **Genovate** **Not Partnered**	North America Japan Israel Asia/Australia/NZ Europe/ROW
HEV Vaccine	Prevention of disease caused by Hepatitis E virus									**GlaxoSmithKline**	Worldwide
HCV											
Nucleosides	Treatment of Hepatitis C virus infections									**Gilead Sciences**	
Non-Nucleosides										**Not Partnered**	
New Target										**Not Partnered**	
Bacteria	Broad spectrum antibiotic									**Not Partnered**	
Technologies											
DNA Amplification	Technology									**Affymetrix**	
HGV/HIV Interaction	HIV Research									**Academic Institutions & Government**	

STOCK INFORMATION >

2004	High	Low	2003	High	Low	2002	High	Low
Q1	3.25	2.01	Q1	1.88	1.12	Q1	2.69	1.75
Q2	3.20	2.00	Q2	2.10	1.26	Q2	2.50	0.63
Q3	2.92	1.76	Q3	1.86	1.38	Q3	3.55	1.07
Q4	2.68	0.48	Q4	2.85	1.37	Q4	2.24	1.07

GENELABS
TECHNOLOGIES, INC.

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