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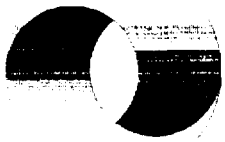

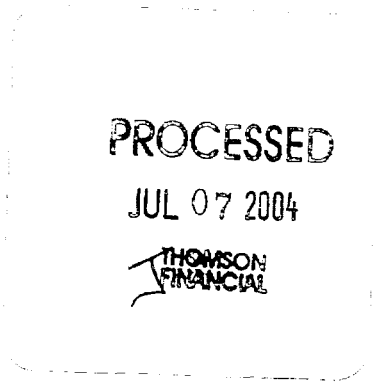

2003
Annual Report

Annual Meeting

The Annual Meeting of Shareholders will take place at 10:00 a.m. P.D.T. on Thursday, June 10, 2004 at corporate headquarters.

Stock Information

As of April 15, 2004 there were approximately 704 shareholders of record of the company's common stock with 88,014,488 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 set forth for the periods indicated the high and low closing sale prices of the company's common stock as reported by the Nasdaq National Market.

2003	High	Low
1st Quarter	1.88	1.12
2nd Quarter	2.10	1.26
3rd Quarter	1.86	1.38
4th Quarter	2.85	1.37

2002	High	Low
1st Quarter	2.69	1.75
2nd Quarter	2.50	0.63
3rd Quarter	3.55	1.07
4th Quarter	2.24	1.07

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

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

For the fiscal year ended December 31, 2003

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, 2003: $83,148,000, based on the last reported sales price on the Nasdaq Stock Market.

Number of shares of Registrant's Common Stock outstanding on March 1, 2004: 87,999,655

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its 2004 Annual Meeting of Shareholders to be held on June 10, 2004 are incorporated by reference into Part III (Items 10, 11, 12 and 13) hereof.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains or incorporates by reference 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 identified by the words "may," "will," "anticipates," "intends," "believes," "expects," "plans," "potential" and similar expressions. These forward-looking statements include, among others, statements regarding:

- estimates relating to the timing and completion of our pending clinical trials;
- the results of our confirmatory clinical trial of Prestara™;
- potential FDA actions with respect to our NDA for Prestara, including whether or not the Prestara NDA ultimately will receive marketing approval;
- if the NDA for Prestara is ultimately approved, our plans and ability to successfully commercialize Prestara for systemic lupus erythematosus;
- our ability to secure a European partner for Prestara;
- our strategy for pursuing approval of Prestara in Europe, our ability to obtain approval of Prestara in Europe, and the timing of any such approval;
- estimates relating to our cash resources and our ability to obtain additional funding for our business plans;
- our ability to complete the divestment of our diagnostics business on a timely basis, if at all;
- our ability to secure and defend intellectual property rights important to our business; and
- the potential success of our research efforts, including our ability to identify compounds for preclinical development and the success of any such preclinical development efforts.

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, and actual results could differ materially from those expressed or implied in these statements. All forward-looking statements included in this Annual Report on Form 10-K are made as of the date hereof. We assume no obligation to update any such forward-looking statement for subsequent events or any reason why actual results might differ except as required by the Exchange Act. 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.

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 filings are electronically filed with 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 to our website, is not part of this report.

PART I

Item 1. *Business.*

General

Genelabs Technologies, Inc., referred to as Genelabs or the Company, is a biopharmaceutical company pioneering the discovery and development of novel pharmaceutical products to improve human health. Genelabs is pursuing regulatory approval of Prestara™, its investigational drug for women with systemic lupus erythematosus, a disease for which no new drug has been approved in the past 40 years and for which current therapies are not adequate. We are also pursuing the discovery of novel antiviral compounds for treatment of hepatitis C virus infections are initiating preclinical development work in this area. In addition, the Company has established a portfolio of patents and patent applications based on inventions arising from its 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 may seek to grant additional licenses under these or other patents we own. We believe that these high-risk, potentially high reward programs focus our research and development expertise in areas where we have the opportunity to be scientific pioneers and, if successful, we believe that these programs will yield products that will address diseases for which current therapies are inadequate. At the same time, our established capabilities can be utilized as we diversify our research and development programs.

We have built drug discovery and clinical development capabilities that can support various research and development projects. We are concentrating our capabilities on:

- developing our late-stage product for lupus, Prestara™;
- discovering novel lead compounds that selectively inhibit replication of the hepatitis C virus, or HCV; and
- advancing our HCV research program into preclinical development.

Prestara. Our clinical development efforts are concentrated on Prestara™, 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 from the 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. Patient enrollment into this clinical study was completed in February 2004. As the treatment duration in the study is six months with either 200 mg per day of Prestara or placebo, the last patients enrolled are scheduled to complete their treatment in August 2004. Afterwards, we will unblind and analyze the data following a standard review for completeness and accuracy. We currently expect to be able to report the results in the fourth quarter of 2004.

Hepatitis C Virus. Our drug discovery research is focused on discovering orally active compounds for the treatment of infections caused by the hepatitis C virus, or HCV. The World Health Organization has estimated that 170 million people worldwide are chronically infected with HCV, including 4 million in the United States, where HCV is the most common chronic blood-borne virus. Patients with chronic HCV infection can be virtually symptom-free for decades but can eventually develop serious liver diseases. HCV infection is the leading cause of liver transplants in the United States. Currently available treatments are effective in only approximately 50% of the patients infected with HCV genotype 1, the genotype most prevalent in the United States.

Development of Prestara for Systemic Lupus Erythematosus

In August 2002, we received an approvable letter for Prestara from the FDA. FDA approval of Prestara 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 the bone mineral density of women with lupus

on glucocorticoids that was observed in a nested study within Genelabs' Study GL95-02. Separately, the FDA advised us that it considers Study GL95-02 to be a positive, adequate and well-controlled study with respect to its overall primary endpoint, which was a responder index comprised of measures of SLE disease activity, damage, and health-related quality of life.

Following receipt of the approvable letter, we worked with the FDA and clinical experts to design the required confirmatory clinical trial, submitted a study protocol to the FDA for their review in November 2002 and initiated the study, designated GL02-01, in December 2002. The primary endpoint of this study is bone mineral density at the lumbar spine, and the treatment duration will be six months with either 200 mg per day Prestara or placebo. Patient enrollment in Study GL02-01 was completed in February 2004. As the treatment duration in the study is six months, the last patients entered into the study should complete their treatment in August 2004. Afterwards, we will unblind and analyze the data following a standard review for completeness and accuracy. We currently expect to announce the results in the fourth quarter of 2004. Study GL02-01 was designed to generate data that, if positive, would satisfy the FDA's requirement for confirmation of the Study GL95-02 bone mineral density results. If approved by the FDA, Prestara will be the first new drug approved in the United States for this debilitating disease in more than 40 years.

Background of Prestara's Development. Genelabs licensed the rights to Prestara 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 acquired and developed this late-stage investigational drug to provide opportunities to fund and support our core business: the discovery and development of novel drug candidates.

After licensing Prestara from Stanford, Genelabs designed and completed two large, well-controlled Phase III clinical trials of Prestara in women with SLE. A small Phase III clinical trial in men with SLE, referred to as Study 97-01, was begun in 1997 and was principally designed to assess the safety of Prestara in this population. Genelabs closed Study 97-01 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. Upon completion of the second Phase III trial in 1999, which is referred to as Study GL95-02, Genelabs prepared an 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, and 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. Because we believed that Prestara had demonstrated usefulness in the management of lupus, Genelabs worked within the FDA's regulatory framework, actively continuing the NDA review process and seeking resolution of the issues raised in the letter. Our goal was to reach agreement with the FDA on the steps necessary for approval. As part of this process, in December 2001 we had a meeting with the agency which included presentations of the clinical data from our Phase III clinical trials. As a follow-up to the meeting, 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 this information to the FDA in February 2002. On August 28, 2002, we received the above-noted approvable letter from the FDA and have subsequently initiated a clinical trial which is designed to generate data that, if positive, would serve to confirm the positive results on bone mineral density observed in Study GL95-02.

Clinical Trial Results. Genelabs has successfully completed two Phase III double-blind randomized placebo controlled clinical trials of Prestara in women with lupus. The first of these Phase III 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. Among all patients enrolled in the study (intent-to-treat analysis), a strong trend in favor of Prestara was shown for the 200 mg dose over placebo (p=0.11). The effect was most evident in the 137 lupus patients with active disease, defined as those patients with a Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) score greater than 2 at study entry. Among these patients, 51% of those who received daily doses of 200 mg of Prestara achieved the primary endpoint compared to 29% of those who received placebo (p=0.03). The results of this study were published in the July 2002 issue of *Arthritis and Rheumatism.*

The second Phase III study, designated 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. In this trial, treatment with Prestara demonstrated a consistent pattern of efficacy across a number of primary and secondary variables. Prestara-treated patients with active disease, defined as a baseline SLEDAI score greater than 2, who met the protocol requirements showed a 35% greater rate of response than the placebo group: 66% of Prestara patients responded to treatment compared to 49% of placebo patients. All placebo and Prestara patients were allowed to continue taking their existing medications for the full course of this trial. This increased rate of response, defined as improvement or stabilization in all four scoring instruments measured, with no clinical deterioration, was statistically significant (p=0.005 for the defined per-protocol population). The scoring instruments were SLEDAI, Systemic Lupus Activity Measure (SLAM), Krupp Fatigue Severity Score (KFSS), and Patient Global Assessment. Because of the inherent variability in these scoring instruments, the classification of a patient as a responder allowed for a slight deterioration in any of the four scores from baseline. In an intent-to-treat analysis of these data, presented at the April 19, 2001 FDA Arthritis Advisory Committee meeting, 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 this clinical trial to be a positive, adequate and well-controlled study.

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 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 one of the primary therapies for the disease, glucocorticoids, is decreased bone density.

In addition to showing effects on disease activity and bone mineral density, the advantage of Prestara over placebo was consistent among secondary efficacy variables in Study GL95-02. Lupus flares occurred among 24% fewer patients who received Prestara than those who received placebo. Certain specific symptoms associated with SLE occurred less frequently among Prestara recipients, including muscle pain, nasal and mouth ulcers and hair loss. As expected, adverse events related to taking this hormone were generally androgenic in nature, and included reports of acne and facial hair growth. Other changes identified in the clinical trial included hormonal changes and reductions in HDL cholesterol and triglycerides. There were no major safety concerns raised by the clinical trials.

The FDA's approvable letter issued in August 2002 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 has designed and initiated a multicenter, randomized, placebo-controlled, double-blind clinical trial that is being conducted at leading U.S. medical centers, designated Study GL02-01. The primary endpoint in this study is bone mineral density at the lumbar spine and the protocol provides for approximately 150 women with SLE receiving glucocorticoids to be enrolled and treated for six months with either 200 mg per day Prestara or placebo. Patient enrollment in Study GL02-01 was completed in February 2004. Because the treatment duration in this study is six months, the last patients entered into the study should complete their treatment in August 2004. Afterwards, we will unblind and analyze the data following a standard review for completeness and accuracy. We currently expect to be able to announce the results in the fourth quarter of 2004. 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. If the results of Study GL02-01 are positive and no significant and new safety issues emerge, we plan to submit the results and our response to all other issues cited by the FDA as a complete response to the approvable letter issued by the agency for our NDA.

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.

Early studies at Stanford indicated that oral use of DHEA could be effective and safe for the treatment of SLE. A Phase II clinical study, conducted at Stanford in 1993 and published in *Arthritis and Rheumatism* in December 1995, indicated that DHEA-treated patients showed improvement on the basis of the patients' own assessments, the physicians' clinical assessments and the SLEDAI score, a measure of SLE disease activity, while placebo treated patients did not. In addition, mean prednisone dose was decreased in patients treated with DHEA. Prednisone, a commonly used glucocorticoid drug treatment for lupus, has many serious side effects including osteoporosis, atherosclerosis, diabetes and infection, and is a leading cause of long-term morbidity and mortality in lupus patients.

Market Position. Genelabs has exclusive rights under U.S. patents granted to Stanford for the use of DHEA to treat SLE. In addition, two U.S. patents issued to Genelabs during 2003, one of which relates to the use of DHEA to treat SLE and the other to the use of DHEA for treating subnormal bone mineral density. The FDA granted orphan drug status to Prestara for women with SLE, which, if Prestara is approved for marketing, provides for up to seven years of U.S. marketing exclusivity. We are pursuing additional patent applications relating to DHEA and its use in treating SLE.

Currently products containing DHEA are available as dietary supplements in the United States. Genelabs has consistently maintained that a governmental entity should regulate DHEA as a drug and submitted a petition and supporting documentation to the FDA seeking DHEA's removal from the market as a dietary supplement. In addition, we believe that DHEA has the potential to be classified as anabolic steroid by the U.S. Drug Enforcement Administration, or DEA, and submitted a petition and supporting documentation to the DEA supporting this classification. Neither the FDA nor the DEA has taken any action to date to limit or regulate the manufacture or sale of DHEA as a dietary supplement.

International Regulatory Applications. Independent of the United States regulatory process, Genelabs is pursuing approval of Prestara for the treatment of SLE in Europe. However, our primary business focus in 2003 and 2004 with respect to Prestara has been, and continues to be, meeting the requirements established in the approvable letter from the FDA, and we currently devote most of our drug development resources to completion of the confirmatory clinical trial with the ultimate goal of approval of Prestara in the United States. In Europe, we applied for and received Part B status, which enabled us to file a Marketing Authorization Application, or MAA, 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, and the centralized procedure allows companies to file one MAA for simultaneous consideration in 17 European countries, with a single review and decision regarding the application. We submitted our MAA for Prestara (under the trademark Anastar™) and it was validated in January 2003. Though the application is currently pending and the EMEA's review has not been completed, it may be necessary for Genelabs to, among other things, clarify the Company's analysis of data submitted and submit additional supportive data. In working with the EMEA toward the ultimate goal of approval of the MAA, we may continue to pursue approval of the pending application by submitting additional responses and attending an oral hearing in May 2004, or we may choose to withdraw the application and file again at a later date. We are currently in active discussions with companies that are interested in licensing the European marketing rights. As part of our process for evaluating potential European partners, we are evaluating their ability to participate in the regulatory process in Europe because we lack internal European regulatory expertise and resources. In Japan, our licensee Tanabe is responsible for pursuing approval of Prestara and for conducting and funding any associated studies that may be required.

Drug Discovery Research

Genelabs' drug discovery research organization is focused on the discovery of antiviral agents that inhibit replication of the hepatitis C virus (HCV). Our core capabilities include medicinal chemistry, combinatorial chemistry, computational modeling, molecular biology, assay development and high-throughput screening, drug metabolism and pharmacokinetics. These capabilities were initially built while we were pursuing DNA as our primary target for drug intervention. More recently we have expanded our emphasis to HCV, which is now the primary focus of our drug discovery efforts. In the future we may seek to expand our drug discovery efforts to encompass additional targets in order to build a more balanced product pipeline.

Background. Our drug discovery efforts were initially founded to explore DNA as a target for drug discovery. We began our efforts to discover new antimicrobial agents by targeting small molecules to bind reversibly to DNA. Our research team then was able to prove the concept that compounds synthesized in our DNA-binding program can selectively target infectious organisms. We conducted many experiments to expand upon our specialized knowledge regarding such compounds. These efforts resulted in the identification of a number of small molecule lead compounds showing potent activity against pathogenic fungi and bacteria and the decision to promote one lead compound with potent activity against *Aspergillus fumigatus* to preclinical status.

Drug Discovery Process. Genelabs' goal for our drug discovery research is to move compounds quickly from synthesis and discovery to preclinical development. We have established all of the capabilities necessary to achieve this goal and we continue to explore and utilize technologies to enhance and streamline this process. The establishment of these systems, combined with our clinical development capabilities, enables our employees to discover and develop potential pharmaceutical products. Our business objective for each of our research programs is to advance one or more of our lead compounds to pre-clinical development status, and we have achieved this objective in our HCV and antifungal programs. We also intend to collaborate with established pharmaceutical companies for further development of our compounds and our drug discovery programs.

Genelabs' drug discovery process includes:

- design and synthesis of novel compounds;
- screening for biological activity, including screens against viruses, replicating fragments of viruses and key viral enzymes;
- toxicity testing of compounds in cell culture and in animals;
- analysis of pharmacokinetics and metabolism;
- analysis of structure-activity relationship and optimization of lead structures based on efficacy, safety and pharmacokinetic profiles;
- determination of efficacy in animal models of disease; and
- selection of compounds for preclinical development, the successful completion of which enables the filing of Investigational New Drug applications (INDs) with the FDA prior to human clinical trials.

Genelabs creates a database of information gathered during the drug discovery process and uses this information to select lead compounds for further optimization. Compounds are selected as leads if they demonstrate certain drug-like properties desirable in early-stage pharmaceutical research. The desired outcome of this process is to select the compounds having the best pharmaceutical product profiles, taking into consideration activity against disease, potency, toxicity, and pharmacokinetics. Information obtained from optimization is used to determine how changes in compound structures affect their activity, known as the structure-activity relationship, or SAR, allowing for further refinement of the lead compounds. Our strategy is to pursue the optimization and development of promising compounds that demonstrate strong biological activity with acceptable toxicity and pharmacokinetic profiles. We focus our research in areas that address clinically unmet medical needs that are also commercially attractive. Lead compounds can qualify for advancement to preclinical candidate status if they meet or exceed a predetermined set of advancement criteria we establish for each therapeutic area. Once we identify a preclinical candidate, IND-enabling work can be initiated, including process chemistry, formulation, GLP animal studies, and pharmacokinetic studies.

Currently our drug discovery research efforts are focused on the discovery and advancement of novel compounds that selectively inhibit replication of the hepatitis C virus. Our core research strength is our expertise in designing, synthesizing, screening and testing of novel small molecules. In our HCV program we are actively synthesizing two distinct classes of compounds, nucleoside analogues, which are structurally similar to the building blocks of RNA, and non-nucleosides. During 2003, our program advanced 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 novel HCV compounds to serve as potential follow-up candidates for preclinical development. As we advance our existing research and additional resources become available, we intend to explore potential new targets that complement our current drug discovery capabilities to build a more balanced pipeline of pharmaceutical candidates. The ultimate objective of our drug discovery research is to discover novel chemical compounds that can be developed into drugs to treat human disease.

Antimicrobial Drug Discovery. Through our previous drug discovery efforts we have synthesized numerous DNA-binding antibacterial and antifungal lead compounds. During 2002, we made a decision to advance one of the antifungal lead compounds synthesized by our scientists to preclinical development status, having met our predefined criteria for such advancement, although we currently do not plan to conduct the preclinical development studies ourselves and are seeking a suitable research partner for this work. This compound is active against a variety of fungi in cell culture and has successfully protected mice against lethal infection with Aspergillus. This compound, GL48656, reproducibly showed significant improvement in survival of mice infected with *Aspergillus fumigatus* compared to untreated controls. The level of protection achieved with GL48656 is comparable to that achieved with Amphotericin B, the current standard of care for patients with invasive Aspergillus infections. The same compound also showed a significant reduction in Aspergillus colony forming units recoverable from the brains and kidneys of animals treated with effective doses of the compound. The acute toxicity of this compound observed in mice was less than that of

amphotericin B, and was comparable to that observed with caspofungin, a novel antifungal recently introduced to the market for treatment of invasive aspergillus infections. On the basis of these and other experiments, we determined that this lead compound met our pre-established criteria for advancement to preclinical development.

The antibacterial activity of certain Genelabs DNA-binding compounds has also been explored. A number of the compounds tested demonstrated activity against a panel of gram positive and gram negative bacterial species. Representative compounds were tested in vivo and found to be dose-dependently effective against both methicillin resistant and methicillin sensitive strains of *Staphylococcus aureus.* These compounds were bacteriocidal, meaning they kill the bacteria, rather than simply inhibiting their growth. In a widely used mouse model of infection, Genelabs compounds showed potency greater than that of vancomycin (a current antibiotic of last resort) at equivalent doses, in reducing bacterial colony formation. While the compounds were efficacious, they did not achieve an acceptable margin of safety.

We are currently focusing the resources that were previously devoted to DNA-binding research towards our HCV drug discovery efforts.

HCV Drug Discovery. Treatment for HCV infection is characterized by a dual objective: preventing the progression of liver disease by reducing the amount of virus in the body to low levels, and modifying the process of liver inflammation. Currently approved treatments for chronic HCV infections are interferon alpha and the combination of interferon alpha with the nucleoside analogue ribavirin. Unfortunately, these interferon alpha-based treatments are only effective in achieving sustained reduction in viral titers in approximately 50% of patients infected with HCV genotype 1, the genotype most prevalent in the United States. These treatments are also associated with significant toxicities. HCV infection remains an important public health problem throughout the world and there is a significant need for improved treatments.

In 2002, we expanded on our drug discovery research by initiating a program to discover orally active compounds for the treatment of HCV infections by targeting a viral-specific enzyme which is called the NS5b RNA-dependent RNA polymerase. Since establishing this program, 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 virus;
- synthesized a large number of nucleoside and non-nucleoside compounds and tested them for activity;
- acquired a library of non-nucleoside compounds and initiated testing in our assay systems;
- identified nucleoside and non-nucleoside lead compounds;
- written and submitted multiple patent applications claiming novel compounds with activity against HCV; and,
- initiated preclinical studies in the HCV research program.

Research Program Next Steps. Genelabs' strategy for realizing value from our research programs is to aggressively pursue optimization of our current lead compounds, with the goal of identifying additional potential drug candidates and ultimately filing INDs, either on our own or with a partner, allowing the initiation of clinical development. We are concentrating our activities in HCV, where we believe there is the greatest opportunity for success of our program, due to the research capabilities we have established and the clear market need for improved therapeutic options.

During 2004, we intend to pursue further optimization and generation of HCV lead compounds and to initiate preclinical studies in our HCV research program. To maximize the utilization of our expertise and resources, and our opportunities for success, we will continue to evaluate additional targets and explore the feasibility of initiating drug discovery efforts against these targets as resource availability and other factors permit. Our objectives for research are to generate preclinical candidates and to continue to build a pipeline of lead compounds and potential lead compounds. Our business strategy is to establish collaborations with

pharmaceutical or larger biotechnology companies to further advance the HCV program and the antifungal preclinical development candidate.

Investments

Minority Investment in Taiwan-based Biopharmaceutical Company. Genelabs holds approximately 8% of the equity in a Taiwan-based company, Genovate Biotechnology Co., Ltd., referred to as Genovate, 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. Genovate has conducted a 119-patient Phase III clinical trial of Prestara 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. Since the founding of Genovate, we have periodically 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. Another one of our directors, Ms. Nina K. Wang, is a principal of several investment entities, one of which owns approximately 6% of Genelabs outstanding common stock, another of which owns approximately 13% of Genovate common stock. Mrs. Wang also owns approximately 35% of a publicly traded company that has a subsidiary which owns approximately 14% of Genovate.

Genelabs Diagnostics Pte. Ltd. (GLD). Through a series of subsidiaries Genelabs owns 100% of GLD which is located in Singapore. GLD develops, manufactures and markets diagnostic products primarily in Europe and Asia. Based on our plan to divest our interest in GLD, we account for our diagnostics business as a discontinued operation in the consolidated financial statements. In March 2004, Genelabs entered into an agreement with a third party to sell GLD and its immediate parent, Genelabs Asia Pte. Ltd., subject to certain closing conditions.

Patents and Licenses

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 many 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.

United States patents were issued to Genelabs in 2000 covering fundamental nucleic acid amplification techniques first developed at the Company. One of these technologies 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, researchers add linkers of known sequences 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. Another of these technologies is commonly known as RACE (Rapid Amplification of cDNA Ends). In the RACE technique, a mixture of different sequence DNA fragments is first treated with terminal deoxynucleotide transferase to form a homopolymer tail on the DNA fragments. Complementary homopolymer primers are then used to amplify the DNA fragments. In 2002, we entered into our initial non-exclusive license agreement for Genelabs' LADA technology with a leading genetic analysis tool company. In addition to the license fees we have received, this agreement provides us with annual fees and royalties. We are pursuing additional, similar license agreements with others practicing these technologies.

Licensing of Prestara™. Genelabs currently intends to commercialize Prestara (which may be known by different tradenames in different territories) through licensing agreements with established pharmaceutical companies and to receive revenue in the form of license fees, milestone payments upon achievement of certain

development and regulatory goals, and royalties on net sales generated by its licensees. Exclusive rights to Prestara for North America have been licensed to Watson Pharmaceuticals, Inc. The collaboration and license agreement with Watson provides Genelabs with milestone payments of up to $45 million and significant royalties on product sales if the FDA approves the Prestara NDA for SLE. Through the collaboration, Genelabs and Watson have agreed to make certain decisions about the product, including decisions regarding the future development of Prestara for the pursuit of new formulations and new indications and the conduct of marketing studies.

In January 2004 Genelabs licensed exclusive rights to Prestara for Japan to Tanabe Seiyaku Co., Ltd. Under the terms of the collaboration and license agreement, Tanabe paid an up-front license fee of $2 million to Genelabs and purchased 818,897 shares of Genelabs common stock for $2.6 million. Genelabs has the right to receive up to $10 million in additional milestone payments upon the achievement of certain pre-determined development and regulatory goals. In addition, Genelabs is entitled to receive royalties on net sales of Prestara in Japan. Tanabe is responsible for obtaining regulatory approval of Prestara in Japan, including conducting and funding any development work that may be required.

Genelabs previously licensed marketing rights for Asia (excluding Japan), Australia and New Zealand to 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.

Genelabs is actively seeking a collaborator or collaborators to license European rights to Prestara.

Licensing of Novel Viruses Discovered by Genelabs.

Hepatitis G Virus. On February 13, 2003, at the 10th Conference on Retroviruses and Opportunistic Infections, data were presented confirming two earlier *New England Journal of Medicine* articles showing that patients infected with both the human immunodeficiency virus, HIV, and GB virus C, also known as hepatitis G virus, or HGV, had 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. During 2002, we granted non-exclusive research licenses to academic institutions to facilitate their continuing research on the interaction between HGV and HIV. We have previously granted Boehringer Mannheim (now Roche Diagnostics), Chiron Corporation and Ortho Diagnostic Systems royalty-bearing license agreements for diagnostic applications of HGV and Genelabs retains all other commercial rights to its discovery of HGV, such as vaccine or therapeutic applications of the virus. 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.

Hepatitis E Virus. In connection with its discovery of the hepatitis E virus, or HEV, 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 successfully completed two Phase I clinical trials, showing the vaccine to be safe and immunogenic. In 2001, the Walter Reed Army Institute of Research initiated a Phase II clinical trial of this vaccine candidate in collaboration with the Medical Department of the Royal Nepal Army, the U.S. National Institutes of Health and GlaxoSmithKline. The trial has enrolled approximately 2,000 adult volunteers in Nepal who have received three doses of either HEV vaccine or placebo over a six month period. The follow-up period was 18 months after the last dose. The clinical phase of the trial has been completed but results are not yet available. In addition to GlaxoSmithKline's vaccine license, Genelabs has granted Abbott Laboratories a royalty-bearing, non-exclusive worldwide license to develop and commercialize diagnostic products for HEV. To date, royalties received under these HEV agreements have not been significant, and we do not foresee receiving significant royalties in the near future.

Hepatitis C Virus. After its discovery of certain polypeptide regions of the hepatitis C virus, or 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.

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 our 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.

Employees

As of December 31, 2003, Genelabs had 74 full-time employees, of whom 60 were involved in research and development and 14 were in administration. Our employees are not represented by any collective bargaining agreements, and we have never experienced a work stoppage.

Available Information

The Company is subject to the informational requirements of the Securities Exchange Act of 1934. The Company therefore files periodic reports, proxy statements and other information with the Securities and Exchange Commission. Such reports may be obtained by visiting the Public Reference Room of the Commission at 450 Fifth Street, NW, Washington, D.C. 20549, or by calling the SEC at 1-800-732-0330. In addition, the SEC maintains an Internet site (http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically.

The Company's Internet address is www.genelabs.com. The Company makes available, free of charge, through its Internet website copies of its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the Commission.

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

If the results of our confirmatory clinical trial of Prestara™, Genelabs' drug candidate for systemic lupus erythematosus, are not positive, the FDA will not approve Prestara and our business prospects will suffer because the U.S. royalties for Prestara are the most significant near-term source of potential revenue.

Genelabs has focused its development efforts to date on conducting clinical trials for an investigational new drug, Prestara, 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.

Before our North American partner, Watson, can market Prestara in the United States, the FDA must approve the Prestara New Drug Application, or NDA, submitted by Genelabs. In 2000, we submitted the NDA for Prestara to the FDA. In 2001 we received a letter from the FDA stating that the Prestara NDA was not approvable, listing deficiencies that must be addressed before the NDA could be approved. Throughout 2001 we worked with the FDA to respond to these issues. In 2002 we received an approvable letter which, among other things, requires us to conduct an additional clinical trial to confirm the positive effect of Prestara we previously noted on the bone mineral density of women with lupus who are receiving treatment with glucocorticoids. Even if the results of our clinical trial are positive, the FDA still has the authority to decline to approve Prestara. Genelabs' business plans depend on FDA approval of Prestara in the United States, and if the clinical trial currently underway does not confirm our previous findings or if significant and new safety issues emerge, the FDA will not approve our new drug application in a timely manner, if at all, and our business would suffer because 1) we would not be entitled to a milestone payment from Watson and 2) royalties we are entitled to receive from Prestara sales in the United States are our most significant near-term source of potential revenue.

If we are unable to find a European marketing partner for Prestara™our business prospects will suffer because we do not have capabilities to market Prestara in Europe ourselves and we would lose a significant near-term source of 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. If we are unable to find a European marketing partner, 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 revenue from Prestara in Europe.

If the FDA and the EMEA do not approve Prestara™ for marketing, our business prospects will suffer because Prestara is our only near-term source of potential revenue.

Before our North American partner, Watson, and any potential European partner can market Prestara in their respective territories, appropriate regulatory agencies must review and approve applications seeking to market the investigational drug which have been submitted by Genelabs. Our business plans depend on approval of Prestara in both the United States and in Europe. If the regulatory agencies do not approve one or both of our applications in a timely manner, our business would suffer because we have no other near-term source of potential revenue.

If the regulatory agencies determine that Prestara can only be approved with significant additional requirements and we determine that it is not feasible for us to satisfy one or more of the requirements requested, we could be forced to abandon the development of Prestara. We cannot predict whether the regulatory agencies will require the submission of additional data in order to approve our applications, what these requirements may be, whether we will be successful in responding to requests from these agencies for additional requirements or whether there will be additional substantial obstacles to, or delays in, our development of Prestara for lupus.

Similar regulatory requirements exist in Japan and elsewhere in the world. Genelabs has not conducted any clinical trials for Prestara for lupus in other countries. We plan to enter into collaborations or licensing agreements for commercializing Prestara in other areas with pharmaceutical companies that have resources greater than Genelabs. If we do not enter into these agreements, we may not be able to sell, or might face delays related to commercial introduction of, Prestara in these other territories, because we lack the necessary resources.

If Prestara™ is approved in the United States or Europe but does not gain sufficient market acceptance, our business will suffer because we would not receive anticipated royalties to fund future operations.

A number of factors may affect the market acceptance of Prestara for lupus, even if it is approved, including:

- availability and level of reimbursement by insurance companies or government programs such as Medicaid;
- the price of Prestara relative to other drugs for lupus treatment;
- the perception by patients, physicians and other members of the health care community of the effectiveness and safety of Prestara for the treatment of lupus;
- the effectiveness of sales and marketing efforts by our licensees;
- side effects;
- competition from other prescription and over-the-counter products; and
- unfavorable publicity concerning Prestara or other drugs on the market.

In addition, if regulatory authorities fail to restrict the sale of dietary supplement DHEA products, which do not require a prescription, the market may not accept Prestara. A number of dietary supplement manufacturers market products containing DHEA as dietary supplements in the United States. Prestara contains highly purified prasterone, the synthetic equivalent of DHEA, as the active ingredient. The body produces DHEA, an androgenic hormone or steroid hormone that develops and maintains masculine characteristics, which is not a component of the diet. While we have consistently maintained that a governmental entity should regulate DHEA as a drug and as a controlled substance, neither the FDA nor the Drug Enforcement Agency, or DEA, has taken any specific action to date to limit or regulate the sale of dietary supplement DHEA. The FDA and DEA may not wish to, or may be unable to, regulate DHEA in the future. We have submitted documentation to the FDA requesting clarification of DHEA's status as a drug and removal from the market as a dietary supplement. We have also submitted documentation to the DEA requesting clarification of DHEA's status as an anabolic steroid, a steroid that promotes the storage of protein and growth of tissue. Anabolic steroids are scheduled as controlled substances. If the FDA restricts the marketing of DHEA as a dietary supplement or the DEA agrees that DHEA is an anabolic steroid, DHEA may no longer be publicly available as a dietary supplement. In the event that Prestara receives FDA approval, the concurrent sale of these dietary supplement products could significantly adversely affect or significantly limit the market for or the selling price of Prestara.

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.

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 August 27, 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 the amount of time and expense involved in transferring the process of manufacture, and receiving regulatory qualifications, could negatively impact the timing or probability of approval of our NDA, or if the product is approved by the FDA, the supply of the product to the market.

The FDA requires the existence of at least one qualified manufacturer before it will approve a drug for commercialization. If we fail to maintain a relationship with at least one qualified supplier of prasterone and at least one qualified manufacturer of the Prestara finished pharmaceutical product it would negatively impact our business because the NDA could not be approved by the FDA. If our NDA is approved and our supplier or manufacturer fails to meet and maintain compliance with FDA requirements or if they fail to manufacture Prestara active ingredient, capsules and packaging as required for our needs, we may not be able to ship product in a timely manner, if at all. This failure could negatively impact our relationships with customers and would harm sales of Prestara. The following could harm our ability to manufacture and market Prestara:

- the unavailability of adequate quantities of the active ingredient for commercial sale;
- 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;
- an interruption in supply of prasterone or finished product; 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 are dependent on Watson Pharmaceuticals to market Prestara™ in North America and if Prestara is approved by the FDA and they fail to meet expected levels of sales our business will suffer.

We must rely on Watson to market Prestara in North America. Because royalties from sales of Prestara would be our primary near-term source of revenue, successful marketing, promotion and distribution of this product in the United States are critical to our success. Though Genelabs has the right to co-promote the product in the United States beginning the third calendar year after the first commercial sale of the product by Watson, we currently have limited internal sales, marketing and distribution capabilities and are entirely dependent on Watson to promote Prestara. If Prestara is approved by the FDA and Watson fails to promote Prestara, our business will suffer because we will not receive anticipated revenue from product sales. Though the agreement with Watson requires them to use commercially reasonable efforts to promote the sale, marketing and distribution of the product in their territory, it does not prevent them from marketing competing products should they become available. Our agreement with Watson provides us with the right to terminate the agreement or make it non-exclusive in the event that Watson fails to meet specified minimum sales requirement or materially breaches the agreement; however, it may be difficult or impossible to find a marketing partner to replace Watson should they breach the agreement or fail to meet these minimum requirements.

Our ability to market Prestara in Europe will depend upon our ability to obtain a European partner. Similar to the United States, successful marketing, promotion and distribution of this product in Europe are important to our success. As we have limited capabilities and will rely on our potential future European partner for marketing, promotion and distribution, if they fail to promote Prestara our business will suffer because we will not receive anticipated revenue from product sales.

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

We have incurred losses each year since our inception and have accumulated approximately $204 million in net losses through December 31, 2003, including a net loss of $19.8 million in 2003. If the FDA approves Prestara, we anticipate realizing a net loss at least until Prestara is sufficiently accepted by the market, and we may never achieve profitability. If the FDA does not approve Prestara, we may never be profitable and our revenues may never be sufficient to fund operations.

On March 15, 2004, after giving effect to the 2004 payments we received from entering into the license agreement with Tanabe Seiyaku Co. Ltd., Genelabs had cash, cash equivalents and short-term investment balances totaling approximately $26.3 million. Genelabs estimates that our current cash resources are adequate to provide liquidity into 2005. 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 additional funds:

- our stock price and market capitalization are low, therefore there are limited funds we can raise through equity financings;
- our ability to successfully complete an additional equity financing will be negatively impacted should we become unable to meet Nasdaq's listing requirements;
- our ability to find a European marketing partner for Prestara would be negatively impacted if we receive indications that the EMEA's review of our MAA is unlikely to result in approval of our application; and
- our research programs are in an early stage, therefore there are fewer opportunities to enter into collaborations with other companies and up-front payments for early-stage pharmaceutical research collaborations are generally smaller for projects that are further from potential marketability.

The results of our clinical trial measuring the effect of Prestara on the bone mineral density of women with lupus and future FDA actions with respect to our NDA for Prestara will each have a material impact on our ability to successfully secure funding in the future. If Prestara™ is ultimately approved for marketing in

the U.S., Genelabs may receive a milestone payment of up to $45 million and significant royalties on Watson's net sales of Prestara. However, the clinical trial results may not be positive and/or the FDA may never approve Prestara and, even if they do, we may never receive a milestone payment or royalties on net sales.

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, 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.

If we are unable to obtain patents or protect our intellectual property rights, we would lose competitive advantage.

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. It is not 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 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 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.

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 research has been focused on a limited number of mechanisms which have not been proven as a viable mechanism of drug action, such as DNA-binding. Although we have identified an antifungal compound that has met our criteria for advancement to preclinical status, we have not devoted resources to preclinical development of this compound, but have initiated preclinical development in our HCV research program in early 2004. Genelabs' product candidates, other than Prestara, are in an early stage of research. The goal of our research programs is to discover novel chemical compounds and develop them into drugs. 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 have a competitive disadvantage.

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 the following 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. While we believe that the amount of general liability insurance we carry, $6 million, is sufficient for typical risks regarding our handling of these materials, it may not be sufficient to cover extraordinary or unanticipated events. We do not specifically insure against environmental liabilities. 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 industry and sufficient for risks we typically face, we may not be able to maintain this type of insurance for any of our clinical trials or 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, 2003 and December 31, 2003, the price of our common stock fluctuated between $1.12 and $2.85 per share. Between January 1, 2004 and March 1, 2004, the price of our common stock fluctuated between $2.01 and $3.25 per share. In addition to the factors discussed in this Risk Factors section, a variety of events can impact the stock price, including the low percentage of institutional ownership of our stock, which contributes to lack of stability for the stock price. The availability of a large block of stock for sale in relation to our normal trading volume could also result in a decline in the market price of our common stock.

In addition, numerous events occurring outside of our control may also impact the price of our common stock, including market conditions 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.

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

Genelabs may be unable to meet the requirements of the Nasdaq National Market System in the future. 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 bid price of at least $1.00 per share of common stock. If Genelabs is unable to meet these 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. The Nasdaq SmallCap Market, however, also has 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 would significantly limit the liquidity of our common stock and would adversely affect its trading price.

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 an annual base rent averaging approximately $1,250,000. 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
2002		
1st Quarter	2.69	1.75
2nd Quarter	2.50	0.63
3rd Quarter	3.55	1.07
4th Quarter	2.24	1.07

As of March 1, 2004, there were approximately 704 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, 2003.

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	6,182,000	$2.87	2,887,000
Equity compensation plans not approved by security holders	—	—	—
Total	6,182,000	$2.87	2,887,000

Genelabs' equity compensation plans do not contain evergreen provisions.

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)			
2003 Quarter Ended:				
Contract revenue	$ 715	$ 698	$ 776	$ 727
Research and development expenses	5,518	4,581	3,771	3,557
General and administrative expenses	1,924	1,091	1,489	1,391
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)

	December 31	September 30	June 30	March 31
	(In thousands, except per share amounts)			
2002 Quarter Ended:				
Contract revenue	$ 849	$ 774	$ 991	$1,031
Research and development expenses	3,450	3,749	3,958	3,380
General and administrative expenses	1,294	1,301	1,568	1,366
Loss from continuing operations	(3,862)	(4,160)	(4,415)	(3,643)
Net loss	(3,860)	(4,291)	(4,232)	(3,567)
Loss per share from continuing operations	(0.07)	(0.08)	(0.09)	(0.07)
Net loss per share	(0.07)	(0.08)	(0.08)	(0.07)

All of Genelabs employees participate in an incentive bonus plan in which a portion of their compensation is tied to meeting corporate objectives. For 2002, Genelabs board of directors determined that certain critical objectives were substantially achieved and designated that 2002 objectives had been achieved at 90% of the target level. However, because of financial constraints, the board also determined that bonuses would only be paid contingent upon Genelabs' ability in the future to secure a specified level of additional financing. This additional financing had not been secured at the time the Company filed its 2002 Annual Report on Form 10-K. Significant uncertainties existed as to whether this financing would be obtained and it was not probable that the bonus would be paid. Therefore, in the fourth quarter of 2002 Genelabs reversed its provision for accrued bonuses. In the fourth quarter of 2002, research and development expenses and general and administrative expenses decreased from the prior two quarters of 2002 because of this unusual circumstance. The reversal of accrued bonuses lowered research and development expenses by $642,000 and general and administrative expenses by $214,000 in the fourth quarter of 2002, for a reduction of operating expenses aggregating $856,000.

In the fourth quarter of 2003, Genelabs secured sufficient additional financing to satisfy conditions the board of directors had established for payment of the contingent bonuses, and bonus payments were made aggregating $853,000. These payments increased research and development expenses by $640,000 and general and administrative expenses by $213,000. The board also determined that an important objective for payment of employee bonuses for 2003 was the securing of additional financing and additional charges were also accrued in the fourth quarter of 2003. The accruals for 2003 bonuses aggregated $1,133,000 in the fourth quarter of 2003, of which $850,000 was included in research and development and $283,000 was included in general and administrative expenses. As a result of the contingency and the 2003 objective both being met during the fourth quarter of 2003, the total charges incurred for the incentive bonus plan during the 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. The 2003 bonuses were paid out in the first quarter of 2004. As a result of these circumstances, the costs recorded in the fourth quarter of 2003 aggregate more that what would

otherwise be recorded in a complete year, and are approximately 50% greater than what has been budgeted for 2004.

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

	Years Ended December 31,				
	2003	2002	2001	2000	1999
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Contract revenue	$ 2,916	$ 3,645	$ 4,769	$ 7,075	$ 8,017
Research and development expenses	17,427	14,537	13,238	14,671	13,953
General and administrative expenses	5,895	5,529	6,464	5,626	4,704
Loss from continuing operations	(20,322)	(16,080)	(13,287)	(12,282)	(10,139)
Net loss	(19,807)	(15,950)	(13,000)	(12,282)	(12,821)
Loss per share from continuing operations	(0.32)	(0.31)	(0.27)	(0.28)	(0.25)
Net loss per share	(0.31)	(0.31)	(0.26)	(0.28)	(0.32)

	December 31,				
	2003	2002	2001	2000	1999
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$26,530	$6,570	$19,000	$34,671	$ 8,099
Working capital	22,379	2,684	13,646	28,758	3,010
Total assets	29,866	9,765	22,100	37,594	11,689
Shareholders' equity	22,815	2,714	11,900	24,000	5,571

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. 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 on 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 pioneering the discovery and development of novel pharmaceutical products to improve human health. Genelabs is pursuing regulatory approval of Prestara, its investigational drug for women with systemic lupus erythematosus, a disease for which no new drug has been approved in the past 40 years and for which current therapies are not adequate. We are also pursuing the discovery of novel antiviral compounds for treatment of hepatitis C infections, and are initiating preclinical development work in this area. We believe that these high-risk, potentially high reward programs focus our research and development expertise in areas where we have the opportunity to be scientific pioneers and, if successful, we believe that these programs will yield products that will address diseases for which current therapies are inadequate. At the same time, our established capabilities can be utilized as we diversify our research and development programs.

Critical Accounting Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States 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 recognized ratably over the development period. Unearned contract revenue at December 31, 2003 and at December 31, 2002, is from a single source, an up-front payment received in 2000 from Watson Pharmaceuticals, Inc., referred to as Watson, for our license to them of the North American marketing rights to Prestara. Genelabs' management considers the amortization period for the up-front payment from Watson a critical accounting estimate. The amortization period we use is based on our current estimate of the period we have significant obligations to Watson. In August 2002, the FDA issued an approvable letter to Genelabs for Prestara, citing issues to be addressed prior to approval, including, among other things, the successful completion of an additional clinical trial to confirm the positive effect of Prestara on bone mineral density previously observed in women with mild to moderate lupus while on low-dose glucocorticoids. Genelabs' management believes that its significant obligations under the agreement with Watson extend to the submission of a complete response to the approvable letter to the FDA and the FDA reaching a final decision regarding approval of the NDA. The date upon which we may receive a final FDA decision on approval will vary based on, among other things, the time period necessary for analysis of the results of the clinical trial, what the results of the trial are, our preparation of a re-submission to the FDA, and the length of time the FDA will take to review the data submitted after the conclusion of the trial. Genelabs currently estimates that it will take until June 2005 for an FDA decision on the NDA. The estimated period for amortization has a noteworthy impact on the revenue recognized, and, in turn, the net loss reported in Genelabs' financial statements. For example, if a longer term were estimated Genelabs' revenue would be lower and the net loss would be higher. Conversely, if a shorter amortization term were estimated, Genelabs' revenue would be greater and the net loss lower. We periodically assess the remaining term over which the up-front payment from Watson is being recognized into the statement of operations and will make changes based on updated information. One of these changes occurred in 2002, when we lengthened the amortization period based on FDA's clarification of requirements for approval in the approvable letter, and subsequently, we made additional changes during 2003 based on new information about the time required to enroll patients in the clinical trial.

We have assessed the remaining term over which the up-front payment from Watson is being recognized into the statement of operations, and believe it is the most appropriate term 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, 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 the up-front revenue from Watson.

Discontinued Operations. We account for our diagnostics subsidiary, Genelabs Diagnostics Pte. Ltd., referred to as GLD, as a discontinued operation because we are selling this business. Accounting treatment for discontinued operations involves segregation of the net assets and operating results of the discontinued operation for separate disclosure in the financial statements, rather than including the results within the other line-items of the financial statements. We have accounted for GLD as a discontinued operation since 1998, the year we adopted a plan to divest GLD. We have determined that GLD meets held-for-sale criteria of current accounting requirements as of December 31, 2003, and that discontinued operation accounting continues to apply. Judgments and estimates were used in reaching this conclusion. A different interpretation of current accounting literature that concluded discontinued operation accounting did not apply would have a significant impact on the financial statements, increasing revenues, operating expenses, assets and liabilities, although shareholders' equity and the net loss would remain the same. In March 2004 we entered into an agreement to sell GLD and its immediate parent corporation, Genelabs Asia Pte. Ltd., subject to certain closing conditions.

Results of Operations

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, related to the confirmatory clinical trial we are conducting in women with lupus and also due to incentive bonus costs that were incurred as a result of the liquidity provided by financings

closed by Genelabs during the year. 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.

Contract Revenue. Contract revenues were $2.9 million in 2003, a decrease of $0.7 million from $3.6 million in contract revenues in 2002. The following table breaks down contract revenue by major source:

	2003	2002
Watson	$1,841	$2,525
Royalties and license fees	623	520
Data analysis services	452	600
Total contract 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 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 we submit a complete response to the approvable letter. The period of time to receive an answer from the FDA is the period over which we have significant obligation to Watson and are amortizing the deferred revenue. Genelabs currently estimates that it will take until June 2005 for an FDA decision on the NDA. Accordingly, during the third and fourth quarters of 2003, Genelabs extended the amortization period of the up-front payment received from Watson from a period ending December 31, 2004 to a period ending June 30, 2005. If this change were applied over a full year, this change would reduce annual revenue by approximately $0.5 million from the rate used at the end of 2002. This amount is less than the decrease in the contract revenue recognized from Watson for 2003 compared to 2002 because during 2002 a separate adjustment was made to the amortization period upon the FDA's issuance of the approvable letter, which clarified the obligations of Genelabs under its agreement with Watson.

Aside from the revenue recognized from Watson, other sources of revenue include data analysis services performed for larger pharmaceutical companies, royalties and license fees. 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.

	2003	2002	Change
Research and development	$17,427	$14,537	+20%
General and administrative	5,895	5,529	+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 confirmatory 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 — Background

Because we are in the business of drug discovery and development and have not developed any products that have been approved for sale, the majority of our costs are classified as research and development and are expensed 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, the majority of Genelabs' research and development has been directed toward two major projects — developing Prestara™ as an investigational new drug for lupus and discovery of entirely new drugs, both of which are on-going.

Research and Development Expenses by Project

In 2003, $17.4 million of operating expenses were in research and development, compared to $14.5 million in 2002, an increase of $2.9 million for 2003 as compared to 2002. The following table breaks down the research and development expenses by major project (in thousands):

	2003	2002	Change
Drug development (Prestara™)	$ 6,539	$ 4,847	+35%
Drug discovery (HCV and DNA-binding)	4,847	5,505	−12%
Support costs and other R&D	6,041	4,185	+44%
Total research and development	$17,427	$14,537	+20%

Drug Development (Prestara™)

Costs for Prestara increased to $6.5 million in 2003 compared to $4.8 million in 2002 primarily as a result of our confirmatory 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. 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 drug candidate, 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 through clinical trials to its current approvable status with the FDA have been approximately $42 million through December 31, 2003. If the clinical trial results, currently expected in the fourth quarter of 2004, are positive and the FDA approves Prestara for lupus, Genelabs expects to continue work on this project, seeking approval in other countries and investigating other indications and potential uses of the investigational drug. If the clinical trial results are not positive and the FDA does not approve Prestara for lupus, Genelabs plans to evaluate the results and the requirements for approval prior to making a decision on further development. As these results are not expected to be available until the fourth quarter of 2004, we do not expect the clinical trial results will significantly impact our costs for 2004, which are expected to increase approximately 5% to 10% in 2004. We expect to incur additional costs after 2004, but these will be dependent on the clinical trial results and future decisions from the FDA and regulatory authorities in Europe and other countries. Major collaborations for Prestara are with Watson Pharmaceuticals, Inc. in North America and with Tanabe Seiyaku Co., Ltd. in Japan.

Drug Discovery

Costs for our drug discovery program decreased to $4.8 million in 2003 from $5.5 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. Genelabs' current drug discovery efforts have evolved from a program that initially focused on DNA as a target for drug intervention. Since initiating this drug discovery program, 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 for these efforts from the inception of our DNA-binding program in 1993 through December 31, 2003 of approximately $33 million. Our drug discovery efforts have generated lead compounds for fungal, bacterial and viral infections. In addition, these efforts have generated a preclinical candidate for Aspergillus, an often fatal systemic fungal infection, and we have initiated preclinical studies in our hepatitis C virus research program. Our drug discovery efforts are presently concentrated on identifying a new drug to combat infection with HCV, which includes the further testing of

our preclinical drug candidates and other lead compounds, as well as identification of additional potential lead compounds. The following table breaks down the percentage of direct drug discovery costs by major project:

	2003	2002
Hepatitis C virus	87%	67%
DNA-binding	13%	33%
Total direct drug discovery costs	100%	100%

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. However, we presently estimate that drug discovery costs for 2004 will be approximately 10% greater than 2003, although the outcome of our corporate partnering discussions and current scientific experiments may result in significant changes to this estimate. Management continually evaluates the status of our drug discovery research programs and expects to continue to devote resources toward our hepatitis C drug discovery program, while at the same time managing the level of expenditures to balance advancement of potential product candidates against Genelabs' limited cash resources and the 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 company bonus, all allocated based on the headcount ratio between research and development and general and administrative. Support costs and other R&D were $6.0 million in 2003 and $4.2 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
Employee bonus	33%	0%
Facility rent	18%	15%
Insurance and depreciation	14%	27%
Support staff	9%	16%
Utilities, maintenance and security	9%	14%
Other R&D and related intellectual property costs	17%	28%
Total support and other R&D costs	100%	100%

The $1.8 million increase in costs during 2003 was primarily due to approximately $2.0 million related to bonuses for all employees incurred in 2003 as compared to no bonus charge in 2002. No bonus charge was incurred in 2002 due to liquidity issues. In addition, we entered into a new facility lease at the end of 2002, increasing the support and other R&D costs by an additional $0.4 million, although this did not significantly increase the percentage of support and other R&D costs in 2003 compared to 2002 because the total was higher. 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. In 2004, we expect support costs and other R&D to decrease approximately 10%, primarily because we expect the bonus charges to be lower.

General and Administrative

In 2003, $5.9 million in operating expenses were general and administrative expenses, compared to $5.5 million in 2002, an increase of $0.4 million. Our general and administrative expenses consist primarily of personnel costs for executive management, finance, marketing, business development, human resources and legal departments, as well as professional expenses, such as legal and audit, and allocated facilities costs such as rent and insurance. During 2003, higher general and administrative costs were incurred due to accrual of bonuses in 2003 upon meeting board-determined goals for our level of funding compared to no expense in 2002. Meeting these goals 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. Future general and administrative expenses will vary depending upon our execution of our business plans, although management currently expects 2004 general and administrative expenses to be within approximately 5% of the 2003 general and administrative expenses.

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 and short-term investment 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.

Years Ended December 31, 2002 and 2001

Introduction. Genelabs' net loss was $16.0 million in 2002, an increase of $3.0 million from the $13.0 million net loss in 2001. This increase is primarily the result of lower contract revenue and interest income in 2002. A more detailed discussion of the changes in Genelabs' statement of operations follows.

Contract Revenue. Contract revenues were $3.6 million in 2002, a decrease of $1.2 million from $4.8 million in contract revenues in 2001. In 2002, approximately 69% of revenue, or $2.5 million, was the recognition of a previously received up-front license payment from Watson. In 2002, this source of revenue decreased by $0.5 million from the $3.0 million recorded as revenue from Watson in 2001 due to the FDA's clarification in the August 2002 approvable letter of the period over which we have significant obligation to Watson. Based on this clarification, beginning in the third quarter of 2002, Genelabs extended the amortization period of the up-front payment received from Watson to a period ending December 31, 2004. This change reduced 2002 revenue by $0.5 million, as it was implemented beginning in the third quarter. If this change were applied over a full year, it would have reduced annual revenue by approximately $1.0 million.

Aside from the revenue recognized from Watson, none of our other sources of revenue for 2002 exceeded $0.6 million. Other sources of revenue include data analysis services performed for larger pharmaceutical companies, royalties and grants. Collectively, these other sources declined by $0.7 million in 2002 compared to 2001. One component of this decrease was the scheduled expiration of Genelabs' Defense Advanced Research Projects Agency (DARPA) grant at the end of January 2001, resulting in a decrease in contract revenue of $0.4 million in 2002 compared to 2001. In addition, revenues from data analysis services performed for pharmaceutical companies also decreased by $0.4 million. Partially offsetting these decreases, in 2002 Genelabs recognized $0.1 million in revenue from the license of DNA amplification technologies to a leading genetic analysis tool company.

Operating Expenses. Operating expenses were $20.1 million in 2002, an increase of $0.4 million from the $19.7 million in operating expenses in 2001. All operating expenses are related to Genelabs' business of discovering and developing pharmaceutical products. In 2002, $14.5 million of operating expenses were in research and development, compared to $13.2 million in 2000, an increase of $1.3 million for 2002 as compared to 2001. Costs related to Prestara were approximately $0.5 million higher in 2002 due to our frequent meetings with the FDA and initiation of a confirmatory Phase III clinical trial for Prestara for lupus. Costs for Genelabs' drug discovery efforts increased by $0.8 million in 2002 compared to 2001, as we built

additional discovery research capabilities in chemistry and pharmacokinetics while initiating a new project directed towards discovery of a new treatment for infection with the hepatitis C virus.

In 2002, $5.5 million in operating expenses were general and administrative expenses, compared to $6.5 million in 2001, a decrease of $1.0 million. Lower general and administrative costs were incurred in 2002 compared to 2001 as a result of the resolution of a legal matter in 2001, the costs of which included legal fees and payments to the other party of approximately $0.4 million. The balance of the savings, $0.6 million, was due to overall cost savings measures implemented in the majority of administrative areas.

Nonoperating Expenses. Interest income was $0.3 million in 2002, a decrease of $1.3 million from 2001. The decrease in interest income was due to lower interest rates and lower average cash and short-term investment balances during 2002 than during 2001.

In 2002, we recorded $0.1 million in income from the discontinued operations of Genelabs Diagnostics Pte. Ltd., a decrease from $0.3 million in income for 2001 primarily due to lower sales of diagnostics products.

Liquidity and Capital Resources

Genelabs had cash, cash equivalents and short-term investment balances totaling $26.5 million at December 31, 2003. During 2003, our cash and short-term investments balance increased by $19.9 million, largely due to $39.9 million, net, raised from the sale of common stock, partially offset by $20.2 million cash used in operations. The cash used in operations funded our development of Prestara for lupus and the continued research on the discovery of a new treatment for hepatitis C virus infection. On March 15, 2004, after giving effect to $4.6 million received upon execution of the collaboration and license agreement with Tanabe Seiyaku, Genelabs had cash, cash equivalents and short-term investment balances totaling approximately $26.3 million. Genelabs estimates that our current cash resources are adequate to provide liquidity into 2005. However, we will require additional capital to carry out our business plans in 2005 and expect to continue to rely on outside sources of financing to meet our capital needs. The Company is pursuing the sale of its diagnostics operation and also negotiating licenses for the European rights to Prestara, which, if completed, we expect would provide additional cash resources to Genelabs. Genelabs is 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. In addition, the results of our clinical trial measuring the effect of Prestara on bone mineral density of women with lupus will have a material impact on our ability to secure funding and the amount and terms of funding that may be available.

Longer-term, Genelabs' liquidity and capital resources will be materially impacted by FDA actions with respect to our NDA for Prestara. If Prestara is approved for marketing in the U.S., Genelabs may receive a one-time milestone payment of up to $45 million from Watson. Receipt of a milestone payment from Watson would materially improve Genelabs' liquidity and capital resources. However, Genelabs believes that the most important impact of the Watson collaboration for Genelabs' long-term liquidity and capital resources is the significant royalties Genelabs is entitled to receive on net sales of Prestara. During the first three quarters after product launch, a separate royalty schedule applies to support the product launch.

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 any FDA actions, progress of our research and development programs and the status of corporate partnership agreements.

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, 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 as those costs are incurred over the term of the lease. Other than the facility operating leases, Genelabs does not have any off-balance sheet arrangements. There are no contractual financial obligations that extend beyond the next five years, although we have an option to extend our current operating lease for a four-year period beyond its current expiration in November 2006. Our contractual 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	$1,269	$2,539	—	$3,808
Equipment loans	104	70	—	174
Total	$1,373	$2,609	—	$3,982

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 each security in our portfolio of short-term investments matures in less than two years, to date we have not used derivative instruments, and we have placed our investments with high quality debt issuers. As of December 31, 2003, the overall average maturity of Genelabs' short-term investment portfolio was less than six months, as all of Genelabs short-term investments were in a money market fund, 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.

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

The Company's Consolidated Financial Statements are set forth in the "Genelabs Technologies, Inc. Consolidated Financial Statements and Annual Report on Form 10-K Index" 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 defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this report. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, 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.

(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 fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

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

The information concerning the Company's directors required by Item 10 is incorporated herein by reference to the section entitled "Proposal No. 1 — Election of Directors" of the definitive Proxy Statement for the Company's 2004 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 Other Information" and "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 Accounting Fees and Services.***

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

PART IV

Item 15. ***Exhibits, Financial Statement Schedules, and Reports on Form 8-K.***

(a)(1), (a)(2) and (d) *Financial Statements and Schedules.* Reference is made to "Genelabs Technologies, Inc. Consolidated Financial Statements Annual Report on Form 10-K Index" 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 (the "July 1994 Form S-8").
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"))*.

Exhibit No.	Exhibit Title
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)*.
21.01	List of Subsidiaries.
23.01	Consent of Ernst & Young LLP, Independent Auditors.
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.

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

(b) *Reports on Form 8-K.*

During the quarter ended December 31, 2003, we filed the following Current Reports on Form 8-K:

On October 1, 2003, we filed a Current Report on Form 8-K announcing a best efforts public offering of up to 15,000,000 shares of our common stock under an exclusive Agency Agreement with Natexis Bleichroeder Inc., or Natexis, and attaching the Agency Agreement.

On October 22, 2003, we filed a Current Report on Form 8-K announcing an Underwriting Agreement with Natexis providing for the issuance and sale of up to 23,000,000 shares of our common stock and attaching the Underwriting Agreement. Pursuant to the terms of the Underwriting Agreement, the earlier Agency Agreement between the Company and Natexis dated September 30, 2003 was terminated.

On November 14, 2003, we filed a Current Report on Form 8-K attaching a press release for our third quarter 2003 operating results.

After the year ended December 31, 2003, we filed the following Current Report on Form 8-K:

On February 13, 2004, we filed a Current Report on Form 8-K announcing the retirement of Dr. Irene Chow from her responsibilities as Chief Executive Officer and the appointment of Mr. James A.D. Smith as Chief Executive Officer.

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 15, 2004

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	March 15, 2004

Principal Financial and Accounting Officer:

/s/ MATTHEW M. LOAR Matthew M. Loar	Chief Financial Officer	March 15, 2004

Additional Directors:

/s/ IRENE A. CHOW Irene A. Chow	Chairman	March 15, 2004
/s/ J. RICHARD CROUT J. Richard Crout		March 15, 2004
/s/ ARTHUR GRAY, JR. Arthur Gray, Jr.		March 15, 2004

/s/ H. H. HAIGHT	March 15, 2004
H. H. Haight	
/s/ ALAN Y. KWAN	March 15, 2004
Alan Y. Kwan	
/s/ NINA K. WANG	March 15, 2004
Nina K. Wang	

GENELABS TECHNOLOGIES, INC.

CONSOLIDATED FINANCIAL STATEMENTS AND
ANNUAL REPORT ON FORM 10-K

INDEX

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 ERNST & YOUNG LLP, INDEPENDENT AUDITORS

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, 2003 and 2002, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2003. 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 auditing standards generally accepted in the 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, 2003 and 2002, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
February 6, 2004

GENELABS TECHNOLOGIES, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2003	December 31, 2002
	(In thousands)	
ASSETS		
Current assets:		
Cash, cash equivalents and short-term investments:		
Cash and cash equivalents	$ 26,530	$ 3,035
Short-term investments	—	3,535
Total cash, cash equivalents and short-term investments	26,530	6,570
Net assets of diagnostics subsidiary held for sale	582	417
Other current assets	874	512
Total current assets	27,986	7,499
Property and equipment, net	920	1,306
Long-term investments	960	960
	$ 29,866	$ 9,765
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	$ 2,528	$ 1,853
Accrued compensation and related expenses	1,573	912
Unearned contract revenue	1,506	2,050
Total current liabilities	5,607	4,815
Accrued compensation	691	186
Unearned contract revenue	753	2,050
Total liabilities	7,051	7,051
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value, 4,990 shares authorized, none issued or outstanding at December 31, 2003 or 2002	—	—
Common stock, no par value, 125,000 and 75,000 shares authorized, and 86,936 and 53,393 shares issued and outstanding, at December 31, 2003 and 2002, respectively	227,172	187,264
Accumulated deficit	(204,357)	(184,550)
Total shareholders' equity	22,815	2,714
	$ 29,866	$ 9,765

See accompanying notes.

GENELABS TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	2003	2002	2001
	(In thousands, except per share amounts)		
Contract revenue	$ 2,916	$ 3,645	$ 4,769
Operating expenses:			
Research and development	17,427	14,537	13,238
General and administrative	5,895	5,529	6,464
Total operating expenses	23,322	20,066	19,702
Operating loss	(20,406)	(16,421)	(14,933)
Interest income, net	84	341	1,646
Loss from continuing operations	(20,322)	(16,080)	(13,287)
Income from discontinued operations of diagnostics subsidiary	515	130	287
Net loss	$(19,807)	$(15,950)	$(13,000)
Loss per share from continuing operations	$ (0.32)	$ (0.31)	$ (0.27)
Net loss per share — basic and diluted	$ (0.31)	$ (0.31)	$ (0.26)
Weighted average shares outstanding — basic and diluted	63,888	51,443	49,584

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, 2000	49,398	$179,600	$(155,600)	$ 24,000
Comprehensive loss:				
Net loss			(13,000)	(13,000)
Shares issued under employee stock purchase plans	336	504		504
Shares issued under stock options	109	278		278
Non-employee equity awards		118		118
Balance, December 31, 2001	49,843	180,500	(168,600)	11,900
Comprehensive loss:				
Net 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
Comprehensive loss:				
Net 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

See accompanying notes.

GENELABS TECHNOLOGIES, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Increase (Decrease) in Cash and Cash Equivalents)

	2003	2002	2001
		(In thousands)	
Cash flows from operating activities:			
Net loss	$(19,807)	$(15,950)	$(13,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	493	1,014	692
Income of discontinued diagnostics subsidiary	(515)	(130)	(287)
Non-employee equity awards	19	24	118
Changes in assets and liabilities:			
Other current assets	(362)	90	(124)
Accounts payable, accrued liabilities, and accrued compensation	1,841	(624)	23
Unearned contract revenue	(1,841)	(2,525)	(3,417)
Net cash used in operating activities	(20,172)	(18,101)	(15,995)
Cash flows from investing activities:			
Proceeds from sales and maturities of short-term investments	3,535	13,545	48,866
Purchases of short-term investments	—	(6,706)	(36,215)
Capital expenditures	(107)	(1,069)	(484)
Remittances from diagnostics subsidiary	350	—	—
Proceeds from sale of long-term investments	—	—	26
Net cash provided by investing activities	3,778	5,770	12,193
Cash flows from financing activities:			
Proceeds from issuance of common stock and warrants, net	39,889	6,740	782
Net increase/(decrease) in cash and cash equivalents	23,495	(5,591)	(3,020)
Cash and cash equivalents, beginning of the period	3,035	8,626	11,646
Cash and cash equivalents, end of the period	$ 26,530	$ 3,035	$ 8,626

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 novel 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 lead compounds that selectively inhibit replication of the hepatitis C virus, or HCV, and advancing our HCV research program into preclinical development.

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. See Note 4 for discussion of the Company's diagnostics subsidiary.

Certain reclassifications of prior year amounts have been made to conform to the current year presentation.

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, or R&D, is recorded as earned based on the performance requirements of 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 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 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 development period when, at the execution of the agreement, the development period involves significant risk due to the incomplete stage of the product's development.

Revenue associated with development milestones, if any, is recognized based upon the achievement of the milestones, as defined in the respective agreements. Revenue associated with royalty payments based on third party sales, if any, is recognized as earned in accordance with contract terms, when third-party results are reliably measured and collectibility is reasonably assured.

Revenue under R&D cost reimbursement contracts is recognized as the related costs are incurred.

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

In November 2000, Genelabs entered into an agreement with Watson Pharmaceuticals, Inc. providing Watson with an exclusive license to Prestara™ (formerly Aslera™) in North America. Under the agreement, Genelabs received a $10 million non-refundable up-front license fee in 2000. The non-refundable license fee has been deferred and is being recognized on a straight-line basis over the term that Genelabs management

believes it has significant ongoing obligations to Watson, currently estimated to be the completion of a confirmatory clinical trial, submission of a complete response to the U.S. Food and Drug Administration's (FDA) approvable letter for Prestara and the FDA reaching a final decision on approval of Prestara. Of the $10 million non-refundable up-front license fee, $1,841,000, $2,525,000 and $3,000,000 was recognized as revenue in 2003, 2002 and 2001, respectively. Unearned contract revenue at December 31, 2003 of $2,259,000 consists entirely of the remaining portion of the up-front fee received from Watson in 2000. During 2003 Genelabs extended the amortization period of the upfront payment received from Watson from a period ending December 31, 2004 to a period ending June 30, 2005. During 2002 Genelabs extended the amortization period of the upfront payment received from Watson from a period ending March 31, 2004 to a period ending December 31, 2004. The estimated period for amortization has a noteworthy impact on the revenue recognized and the net loss reported in Genelabs' financial statements. The 2003 change in accounting estimate had the effect of decreasing revenue in the second half of the year by $209,000 although this did not increase the loss per share. The 2002 change in accounting estimate had the effect of decreasing revenue earned in the second half of 2002 by an aggregate amount of $425,000 with a resulting increase of $0.01 in loss per share. The collaboration and license agreement with Watson also provides Genelabs with significant royalties on product sales and a milestone payment of up to $45 million if the FDA approves the marketing of Prestara for the treatment of systemic lupus erythematosus.

Revenue recognized from certain of Company's grants and collaborations represents 10% or more of total contract revenue. In 2003, there were two significant sources of revenue accounting for 63%, and 16% of total contract revenue. In 2002, there were two significant sources of revenue accounting for 73% and 11% of total contract revenue. In 2001, there was one significant source of revenue accounting for 63% of total contract revenue.

Earnings per Share

Net loss per share has been computed using the weighted average number of shares of common stock outstanding during the period. 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 2003, 2002 and 2001 would have included an additional 310,000, 201,000 and 529,000 shares, respectively, related to the Company's outstanding stock options.

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. Because 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, the Company's management believes that these models do not provide a representative measure of the fair value of options actually granted to employees under the Company's stock-based compensation plans. Using one of these models, 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:

	2003	2002	2001
Net loss as reported	$(19,807)	$(15,950)	$(13,000)
Stock-based employee compensation cost:			
Included in net loss as reported	—	—	—
Amount that would have been included in net loss if we had accounted for all stock-based employee compensation at its theoretical (Black-Scholes) fair value	(1,895)	(2,813)	(3,695)
Pro forma net loss as if the fair value method had been applied to all awards	$(21,702)	$(18,763)	$(16,695)
Net loss per share as reported	$ (0.31)	$ (0.31)	$ (0.26)
Stock-based employee compensation cost:			
Included in net loss per share as reported	—	—	—
Amount that would have been included in net loss per share if we had accounted for all stock-based employee compensation at its theoretical (Black-Scholes) fair value	(0.03)	(0.05)	(0.08)
Pro forma net loss per share as if the fair value method had been applied to all awards	$ (0.34)	$ (0.36)	$ (0.34)

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 Short-Term Investments

Cash, cash equivalents and short-term investments 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.

The Company invests funds that are not required for immediate operating needs either in money market mutual funds or in 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. As of December 31, 2003 and 2002, all marketable securities are classified as available-for-sale as the Company does not intend to hold them to maturity. These securities are stated at estimated fair value based upon market quotes. Unrealized gains and losses, when material, are included in accumulated other comprehensive income. Amortization of premiums and discounts and realized gains and losses are included in interest income. The cost of securities sold is based on the specific identification method. The Company has not experienced any significant losses on its investments.

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.

Long-Term Investments

The Company uses the cost method of accounting for its equity investment in a private company. The Company holds less than 20% 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.

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 corporate costs.

Recent Accounting Pronouncements

In January 2003, the FASB issued FIN 46, *Consolidation of Variable Interest Entities*, which requires consolidation of a variable interest entity by the primary beneficiary of the entity if the entity's equity investors do not have sufficient equity at risk or if the entity cannot finance its activities without additional financial support. As Genelabs does not have any variable interest entities, our adoption of this interpretation did not have a material effect on our financial position or results of operations.

In November 2002, the FASB's Emerging Issues Task Force reached a consensus on Issue 00-21, *Multiple-Deliverable Revenue Arrangements*, which addresses accounting for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The consensus applies to agreements entered into after June 15, 2003, and our adoption did not have a material impact on our financial position or results of operations.

2. Available-for-Sale Securities

The following table summarizes estimated fair value and cost of available-for-sale securities at December 31:

	2003	2002
Description:		
Money-market mutual funds	$25,821	$2,035
U.S. Treasury securities and obligations of U.S. government agencies	—	2,678
Corporate debt securities	—	244
Asset-backed securities	—	613
	$25,821	$5,570
Balance Sheet Classification:		
Included in cash and cash equivalents	$25,821	$2,035
Included in short-term investments	—	3,535
	$25,821	$5,570
Maturity:		
Due within one year	$25,821	$4,021
Due after one year through two years	—	1,549
	$25,821	$5,570

3. Property and Equipment

The components of property and equipment are as follows:

	2003	2002
Laboratory equipment	$ 5,063	$ 4,990
Leasehold improvements	4,639	4,639
Office and other equipment	2,600	2,566
	12,302	12,195
Less accumulated depreciation and amortization	(11,382)	(10,889)
	$ 920	$ 1,306

4. Discontinued Operation — Diagnostics Subsidiary

At December 31, 2003, the Company owned 100% of the common stock of Genelabs Diagnostics Pte. Ltd. ("GLD") through a series of separate domestic and foreign corporations. Genelabs plans to divest GLD and accordingly accounts for it as a discontinued operation. Summarized financial information for GLD for the years ended and as of December 31, is as follows:

Statements of Operations

	2003	2002	2001
Product sales	$6,168	$4,520	$6,676
Cost of sales	3,323	2,544	3,467
Gross profit	2,845	1,976	3,209
Operating expenses	2,330	1,846	2,792
Income prior to additional charge incurred in consolidation	515	130	417
Additional charge accrued in consolidation	—	—	130
Income from discontinued operations	$ 515	$ 130	$ 287

Balance Sheets

	2003	2002
Cash, cash equivalents and short-term investments	$ 655	$ 714
Accounts receivable	1,037	545
Inventories	565	432
Total assets	$2,257	$1,691
Liabilities, principally current	$1,675	$1,274
Net equity of Genelabs Diagnostics Pte. Ltd.	582	417
Total liabilities and net equity	$2,257	$1,691

5. Commitments and Contingencies

The Company leases its primary office and laboratory facilities under a non-cancelable operating lease that has a term expiring November 2006. The Company is required to pay certain maintenance expenses in addition to monthly rent. At December 31, 2003, future minimum lease payments under all operating leases

with original terms greater than one year are $1,269,000, $1,308,000 and $1,231,000 for 2004, 2005, and 2006, respectively, for a total of $3,808,000, excluding sublease rentals. Future minimum rental payments to be received by Genelabs under one noncancelable sublease agreement are $134,000, $139,000 and $130,000 for 2004, 2005 and 2006, respectively. Total lease expense, net of sublease income, was $1,465,000, $879,000 and $883,000 for 2003, 2002 and 2001, respectively.

The Company leases equipment under a non-cancelable capital lease that has a term expiring August 2005. At December 31, 2003, future minimum lease payments are $104,000 and $70,000 for 2004 and 2005, respectively, for a total of $174,000.

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.

6. Shareholders' Equity

Common Stock

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.

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 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.

At December 31, 2003, the Company had a total of 14,993,000 shares reserved for future stock issuances, which is comprised of warrants and shares authorized for issuance under employee stock purchase and option plans.

At December 31, 2003 there were warrants outstanding for the purchase of 4,847,000 shares of common stock exercisable in 2004 through 2010 at a weighted average exercise price of $2.14 per share.

At December 31, 2003, there were 23,071,000 shares available for future issuance.

7. Stock-Based Compensation

Employee Stock Purchase Plan ("Stock Purchase Plan"). Employees who meet certain minimum requirements are eligible to participate in the Company's Stock Purchase Plan. Eligible employees are entitled to purchase stock at 85% of the market value at the beginning or ending of six-month purchase periods, whichever is lower, and stock may be purchased at the same price for up to four periods. Purchases are limited to a maximum of $25,000 per year and employees can contribute up to 15% of total compensation. Through

December 31, 2003 and 2002, a cumulative total of 2,237,000 and 1,864,000 shares, respectively, had been issued under the Stock Purchase Plan and a similar predecessor plan, with 1,078,000 shares remaining for future purchases.

Stock Award Plan. During 2003, the Company terminated its stock award plan.

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 may not be granted at prices lower than fair market value on the date of grant and vest over periods ranging from two to four years, with expiration no later than ten years from the date of grant. At December 31, 2003, 2,887,000 shares were available for future grants.

Stock option transactions from 2001 through 2003 are summarized as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2000	3,428	$3.85
Granted	1,392	4.22
Exercised	(109)	2.50
Canceled	(524)	4.63
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

The exercise price ranges and average remaining terms of options outstanding and exercisable at December 31, 2003 were:

Range of Exercise Prices	Number of Options Outstanding at 12/31/03	Weighted Average Remaining Term	Weighted Average Exercise Price	Number of Options Exercisable at 12/31/03	Weighted Average Exercise Price
$0.71-$2.00	2,589	8.3 years	$1.45	1,347	$1.52
$2.01-$4.00	2,161	5.2 years	$2.50	1,798	$2.56
$4.01-$10.91	1,432	5.1 years	$5.99	1,301	$5.96
$0.71-$10.91	6,182	6.5 years	$2.87	4,446	$3.24

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. Because 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, the Company's management believes that this model does not provide a representative measure of the fair value of the options actually granted under the Company's stock-based compensation plans. To determine the pro forma disclosure, the Company used the following weighted average assumptions for 2003, 2002 and 2001, respectively: dividend yields of zero, risk-free interest rates of 3.0%, 3.0% and 4.0%, volatility factors of 1.0 and a one to five year expected life of the options after vesting. Based on these assumptions, the weighted-average fair value of options granted during 2003, 2002 and 2001 was $0.87, $1.41 and $3.53 per share, respectively. For purposes of pro forma disclosures, the estimated fair value of the options is expensed ratably over the options' vesting period.

8. Income Taxes

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

Deferred tax assets and liabilities reflect the net tax effects of net operating loss and tax credit carryovers and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31 are as follows:

	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 61,000	$ 53,900
Foreign net operating loss carryforwards	1,900	2,100
Research credits	3,500	3,300
Capitalized research expenditures	1,500	1,800
Deferred revenue	900	1,600
Other individually immaterial items, net	1,600	1,600
Total deferred tax assets	70,400	64,300
Valuation allowance for deferred tax assets	(70,400)	(64,300)
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 2003, 2002 and 2001, the valuation allowance increased by $6.1 million, $5.7 million and $4.8 million, respectively. Deferred tax assets at December 31, 2003 include approximately $2.8 million associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to shareholder's equity.

At December 31, 2003, the Company had net operating loss carryforwards for federal income tax purposes of approximately $175 million which expire in the years 2004 through 2023 and federal research and development tax credits of approximately $2.2 million which expire in the years 2004 through 2023. In addition the Company had net operating loss carryforwards for state income tax purposes of approximately $23 million which expire in the years 2004 through 2013 and state research and development tax credits of

approximately $1.8 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. Subsequent Event

On January 28, 2004, Genelabs granted Tanabe Seiyaku Co. Ltd. (Tanabe) an exclusive license to Prestara in Japan and received a $2 million non-refundable initial license fee. Under the terms of the agreement, Genelabs is entitled to additional milestone payments based on pre-determined development goals and is also entitled to royalties on sales of Prestara in Japan. In connection with the agreement, Genelabs also sold 818,897 shares of its common stock to Tanabe for $2.6 million.

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