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**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

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

For the fiscal year ended December 31, 1993

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

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

Commission file number 0-19222

**GENELABS TECHNOLOGIES, INC.**

(Exact name of Registrant as specified in its charter)

California  
(State or other jurisdiction of  
incorporation or organization)

94-3050093  
(I.R.S. employer  
identification number)

505 Penobscot Drive  
Redwood City, California 94063  
(Address of principal executive offices, including zip code)

(415) 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.

As of January 31, 1994

Aggregate market value of the voting stock held by non-affiliates of the Registrant:	\$75,741,340
Number of shares of Common Stock outstanding:	21,625,668

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of Registrant's definitive Proxy Statement for its 1994 Annual Meeting of Shareholders are incorporated by reference into Part III (Items 10, 11, 12 and 13) hereof.

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*Priority Product Programs*

Genelabs has focused its product development efforts in three priority areas: developing a therapeutic to treat lupus, developing a vaccine for hepatitis E and identifying, and developing diagnostic and vaccine products for, the virus that is believed to cause a form of post-transfusion hepatitis known as hepatitis X.

PROGRAM	INDICATION	STATUS	MARKETING PARTNERS(1)		
			U.S.	EUROPE	ASIA
GL701 therapeutic	Lupus	Phase II/III			
HEV vaccine	Hepatitis E	Preclinical	SKB(2)	SKB(2)	SKB(2)
HXV discovery	Hepatitis X diagnostics	Research	ABT/BM(3)	ABT/BM(3)	ABT/BM(3)
	Hepatitis X vaccine	Research			

- (1) "ABT" means Abbott; "BM" means Boehringer Mannheim America Ltd.; and "SKB" means SmithKline Beecham p.l.c.
- (2) Genelabs has granted SKB exclusive marketing rights in the United States and Europe. Genelabs has co-marketing rights to HEV vaccine in certain Asian countries.
- (3) Genelabs has granted ABT and BM limited co-exclusive marketing rights worldwide. Genelabs retains the rights to market and to license a third party to market HXV screening diagnostic tests worldwide, and Genelabs retains the exclusive rights to market HXV confirmatory diagnostic tests and vaccines worldwide.

*GL701: Systemic Lupus Erythematosus*

Systemic lupus erythematosus ("lupus") is a severe, chronic and frequently debilitating autoimmune disease that can affect the skin, joints, kidneys and nervous system. It has an estimated 14 percent mortality rate within ten years of diagnosis. Current therapy for mild to moderate lupus is limited to non-steroidal anti-inflammatory drugs, anti-malarial agents such as hydroxychloroquine and glucocorticoids (steroids). Treatment is often inadequate, due either to limited benefits or to severe adverse side effects. With an estimated prevalence of 40 to 50 cases per 100,000 people, lupus affects approximately 135,000 patients in the United States, and Genelabs estimates that there are at least three times that number of patients worldwide. It is ten times more common in women than men and is most common and severe in Asian and black populations.

Studies by Genelabs' scientific collaborators at Stanford University have indicated that oral use of dehydroepiandrosterone ("DHEA"), a naturally occurring hormone that is produced by the adrenal glands, may be effective and safe for the treatment of lupus. Lupus patients generally have abnormally low levels of DHEA, and studies have shown that hormonal influences play a role in the development and progression of lupus. Under a physician IND, Stanford clinical investigators conducted a three-month Phase II study of 28 women with lupus during 1993. The patients received either DHEA or a placebo daily over the study period. Results of this study, reported at the American College of Rheumatology meeting in November 1993, indicated that DHEA-treated patients showed improvement on the basis of the patients' own assessments, the physicians' clinical assessments and a commonly accepted disease activity index, while placebo-treated patients did not. In addition, patients treated with DHEA were able to reduce their doses of prednisone, a glucocorticoid drug that is commonly used to treat lupus but has many serious side effects.

While DHEA is a compound that is in the public domain, Stanford has applied for a United States patent on its use to treat lupus and has granted Genelabs exclusive worldwide rights under that patent application and Stanford's clinical trial results. The Company filed an IND with the FDA in December 1993, and based on preliminary discussions with the FDA, the Company is planning to commence a pivotal Phase II/III human clinical trial of the drug as a therapy for lupus in the first half of 1994. Due to the public domain nature of the DHEA compound, the Company may not be able to obtain patent protection for its use against lupus. See "Patents and Licenses." However, the Company intends to seek an orphan drug designation for the treatment of lupus with DHEA, which, if granted

by the FDA, would provide the Company with up to seven years of exclusive marketing rights in the United States, subject to certain limitations, if it is the first company to obtain approval to market DHEA for this indication.

#### *Hepatitis E Vaccine*

Genelabs has focused significant efforts on the development of products for viral hepatitis, which is a serious worldwide health concern and is endemic in Asia. The five known forms of viral hepatitis are designated hepatitis A, B, C, D and E. The different hepatitis viruses vary in their basic biology as well as method of transmission and pathology. There are FDA-approved vaccines for hepatitis B virus ("HBV"), and an application for a vaccine for hepatitis A virus ("HAV") has been filed with the FDA, but not for any of the other hepatitis viruses. Like HAV, hepatitis E virus ("HEV") is a water-borne virus that causes a debilitating acute form of hepatitis that is prevalent worldwide and is endemic in much of Asia. Next to hepatitis A, hepatitis E is believed to be the leading cause of epidemic hepatitis. It is more severe than hepatitis A and has greater morbidity and mortality rates. HEV infection is reported to result in death in up to 20% of the pregnant women who contract it. Although hepatitis E's clinical and epidemiological significance is currently under investigation, serological screening studies in the United States find that 1% to 5% of all blood donors, depending on the population studied, have antibodies against HEV, suggesting that they have previously been exposed to the virus.

Genelabs scientists, together with scientific collaborators from the United States Centers for Disease Control and Prevention ("CDC"), were the first to isolate and identify HEV. Genelabs is continuing to work in collaboration with the CDC and SKB on the development of a vaccine for HEV. Preliminary studies of a prototype HEV vaccine in monkeys have shown indications of efficacy in preventing infection. Genelabs is now in the process of confirming these results with a group of larger animals. Genelabs believes that its hepatocyte culture system, which allows it to maintain cultures of immortalized liver cell lines and study the ability of these cells to be infected with hepatitis viruses, will significantly contribute to the Company's hepatitis E vaccine research and development. Genelabs has filed patent applications in the United States and internationally with claims covering the HEV genome, certain proteins and peptides derived therefrom, antibodies against such proteins and peptides, and multiple diagnostic and vaccine uses of HEV.

In 1992, Genelabs entered into an agreement with SKB to develop and commercialize a vaccine for HEV. Genelabs has retained co-marketing rights to HEV vaccine in Asia and has the co-marketing rights to combine SKB's existing HAV vaccine with HEV vaccine in Asia. See "Corporate Partner Arrangements." Hepatitis A vaccine is administered to travelers to areas where the disease is prevalent. Genelabs believes that because hepatitis E affects essentially the same populations as hepatitis A, and is in many cases more severe with higher fatality rates, the market will be essentially the same as for hepatitis A. Furthermore, because these infections are transmitted through the same mechanism, Genelabs believes that a vaccine for hepatitis E, sold in combination with a hepatitis A vaccine, would provide much more comprehensive protection for patients and provide the Company with an attractive market opportunity.

#### *Hepatitis X Discovery*

Although diagnostic products for hepatitis A and B viruses have existed since the 1970s, certain cases of post-transfusion hepatitis ("non-A non-B hepatitis") were long suspected to be caused by one or more unknown viruses. One virus, designated hepatitis C virus ("HCV"), was identified in the late 1980's, and the first diagnostic product for hepatitis C was introduced in 1990 by Ortho Diagnostic Systems through a joint venture with Chiron Corporation. Genelabs believes that there are one or more additional types of blood-borne viral hepatitis, called hepatitis X, for which the causative agent has not yet been identified. Based on this belief, Genelabs has focused its viral discovery efforts on identifying the virus referred to as hepatitis X virus ("HXV") that is believed to be the causative agent.

Genelabs believes that it is a leader in the discovery of hepatitis viruses and the development of diagnostic tests for hepatitis. Genelabs was one of the first to identify a portion of the hepatitis C virus

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

- Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 1994
- 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 No. 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)

(I.R.S. employer identification number)

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

94063  
(Zip code)

Registrant's telephone number, including area code: (415) 369-9500

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 x No \_\_\_\_\_.

There were 21,668,836 shares of the Registrant's Common Stock issued and outstanding on April 29, 1994.

This report on Form 10-Q consists of 18 sequentially numbered pages. The exhibit index is located at sequentially numbered page 15.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

collaborator resulting from the first commercial sale of Hepatitis E Virus screening tests in Europe, and laboratory services rendered by DBL. Contract and other revenues recognized in the future will be dependent upon the Company's ability to achieve milestones under current agreements, enter into new research and development and licensing agreements with corporate collaborators and obtain additional government grants and contracts. There can be no assurance that the Company will be successful in this regard.

*Cost of Product Sales*

Corresponding with the increase in product sales, the cost of product sales increased to \$1.5 million for the quarter ended March 31, 1994, compared to \$0.9 million for the same period in 1993. Cost of sales as a percentage of sales marginally decreased to 58% from 59% for the same periods. There can be no assurance that cost of product sales will continue to decrease as a percentage of sales in the future. Costs related to contract revenues for both the three months ended March 31, 1994 and 1993 were \$0.8 million. In the future, the Company expects that its research and development expenses on its collaborative programs may exceed the contract revenues associated with these programs.

*Research and Development Expenses*

For the three months ended March 31, 1993, the Company recorded a non-recurring, non-cash charge of \$3.2 million for purchased in-process research and development associated with the acquisition of DBL. The Company's research and development expenses were \$3.6 million for the three months ended March 31, 1994, compared to \$3.0 million for the three months ended March 31, 1993. This increase reflects the launching of projects GL701 for lupus and QC-PCR, as well as the inclusion of DBL for a full quarter in 1994 compared to one month in 1993.

*Selling, General and Administrative Expenses*

Selling, general and administrative ("SG&A") expenses increased to \$2.6 million for the three months ended March 31, 1994, compared to \$2.1 million for the same period of 1993, due primarily to the inclusion of DBL for the full quarter in 1994. The Company expects its SG&A expenses to increase in the future as diagnostic product sales increase, but expects these expenses to decline as a percentage of sales.

*Interest Income, Net*

The Company recognized net interest income of \$0.1 million in the three months ended March 31, 1994, compared to \$0.2 million for the same period in 1993. The decrease resulted from lower cash balances available for investment and lower interest rates during the period.

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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## FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 1994

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the transition period from.....to.....

Commission file number 0-19222

### GENELABS TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

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

**94-3010150**  
(I.R.S. employer  
identification number)

**505 Penobscot Drive**  
**Redwood City, California 94063**  
(Address of principal executive offices, including zip code)  
**(415) 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.

Aggregate market value of the voting stock held by  
non-affiliates of the Registrant:  
Number of shares of Common Stock outstanding:

As of February 28, 1995

**\$32,981,379**  
**24,315,344**

#### DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's definitive Proxy Statement for its 1995 Annual Meeting of Shareholders are incorporated by reference into Part III (Items 10, 11, 12 and 13) hereof.

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## PART I

### Section 1. Business.

#### Background

Genelabs is an international biopharmaceutical and diagnostics company focused on viral and immunological disorders. The Company is developing therapeutic and vaccine products for viral diseases, autoimmune disorders and other life threatening or debilitating conditions through its U.S.-based Biopharmaceutical business, and is developing and marketing a portfolio of viral diagnostic products through its Singapore-based Diagnostics business.

Genelabs is pursuing a two-tiered product development approach. Using Genelabs' core technologies and expertise in viral discovery, the Biopharmaceutical business is engaged in the development of potential new therapeutics and vaccines, both internally and through collaborations with academic institutions and corporations. At the same time, the Company's diagnostics business is generating current revenue and expects to generate future revenue from viral diagnostic products that have been and are expected to be developed from the Company's viral discovery program, and from products and technologies acquired from others.

Genelabs has initially focused its diagnostics business on the Asian and European markets. The Company believes that its growing Asia presence is of strategic importance because the continued expansion of the Asian economies is expected to increase the demand for high-quality and cost-effective health care products, and because there is no dominant provider of health care products in that region.

The Company was incorporated in California in 1985 and is the successor to Gene Labs Inc., a California corporation incorporated in 1983. Genelabs' principal executive offices are located at 505 Penobscot Drive, Redwood City, California 94063. Its telephone number is (415) 369-9500. Unless the context otherwise requires, "Genelabs" and the "Company" are used to refer to Genelabs Technologies, Inc. and its subsidiaries. "GLD" is used to refer to the Company's Singapore subsidiary, Genelabs Diagnostics (Pte.) Ltd., which is the successor to Diagnostic Biotechnology (Pte.) Ltd. ("DBL"), a Singapore company that was acquired by the Company in March 1993.

#### Recent Events and Current Condition

In March 1995, the Company and Chiron Corporation ("Chiron") entered into a heads of agreement to grant Chiron a worldwide, limited co-exclusive license to develop and commercialize diagnostic and screening products for the hepatitis G virus ("HGV"), a human virus newly discovered by the Company during 1994. The companies will also cross-license certain products and marketing rights for hepatitis and retrovirus technologies, including Chiron's hepatitis C virus ("HCV") technology. While the two companies negotiate the definitive agreement, Chiron advanced \$5.0 million to the Company in March 1995 in order to meet immediate cash needs for operations. Consummation of the agreement could dramatically alter the Company's future business plans. Among other things, the agreement provides for Genelabs to contribute virtually all of its diagnostic assets (including applicable intellectual property rights) to a newly organized company, which Chiron will have the option to purchase at fair market value after five years. See Note 14 to Notes to Consolidated Financial Statements and "Business - Corporate Collaborator Arrangements - Chiron Corporation - Worldwide Diagnostics Alliance" for further details on this agreement which calls for further funding upon the signing of a definitive agreement.

If the Chiron definitive agreement is not consummated, management intends to seek to license its HGV technology to other potential collaborative partners to raise additional funds. In addition, management is currently pursuing external funding for other key projects in the Company's biopharmaceutical portfolio, including GL701 therapeutic for lupus, a proprietary drug discovery assay to screen for novel sequence-specific DNA binding molecules, and cytokine discovery technology to isolate novel human genes.

There can be no assurances that any of the above efforts to secure additional funding will prove successful or that any transactions can be consummated to provide the Company with operating capital, as all such events are dependent on, among other things, the cooperation of outside parties over which the Company has no control. Should these efforts be unsuccessful, the Company plans to further reduce the number of employees, curtail operations, and, if necessary, postpone certain research and development activities. The Company anticipates that it can reduce its expenditure level to that necessary for the Company to be able to continue operations through August 1995. If the Company is unable to obtain the necessary cash, other more substantial restructuring options may become necessary, including ceasing certain or possibly all operations.

It should be noted that this business section describes the Company's operations only for fiscal year 1994, and given the need to obtain additional cash funding, this business description may not apply in future years.

### **Biopharmaceutical Business**

Genelabs' Biopharmaceutical business focuses on the development of products for the treatment of life threatening and severely debilitating diseases where no satisfactory treatment alternatives are currently available. Genelabs' biopharmaceutical strategy is to optimize the value of its product development efforts by developing products derived from the application of its core technologies and by selectively acquiring from third parties products in late stage of development to which the Company believes it can add substantial value.

Genelabs has focused its internal biopharmaceutical product programs on the development of its new virus that is believed to cause a form of post-transfusion hepatitis, the development of its therapeutic for lupus, and on the identification of novel drug candidates through its discovery research efforts. In addition, the Company is engaged in the research and development of a vaccine candidate for hepatitis E, and potential therapeutic agents for cancer.

Genelabs' strategy for all its biopharmaceutical products is to leverage its internal resources and accelerate their commercialization by seeking corporate collaborations with market leaders in the relevant fields of application to complete development, fund clinical trials and conduct marketing.

Genelabs' Biopharmaceutical business is managed by an experienced management team, headed by its President, Dr. Irene Chow, an experienced pharmaceutical industry executive. Dr. Chow joined the Company in August 1993, and was formerly a Senior Vice President for Drug Development for the CIBA-GEIGY Pharmaceutical Division where she directed all scientific, medical, technical and regulatory activities related to the development of new drugs. During her last eight years as Vice President and Senior Vice President, she was responsible for the approvals of 10 New Drug Applications ("NDAs") and the submission of 26 Investigational New Drug applications ("INDs") to the FDA.

### *Hepatitis X Discovery*

Although diagnostic products for hepatitis A and B viruses have existed since the 1970s, certain cases of post-transfusion hepatitis ("non-A non-B hepatitis") were long suspected to be caused by one or more unknown viruses. One virus, designated hepatitis C virus ("HCV"), was identified in the late 1980's, and the first diagnostic product for hepatitis C was introduced in 1990 by Ortho Diagnostic Systems through a joint venture with Chiron Corporation. Genelabs believed that there were one or more additional types of blood-borne viral hepatitis, called hepatitis X, for which the causative agent had not yet been identified. Based on this belief, Genelabs initiated a collaboration with investigators at the Centers for Disease Control and Prevention ("CDC") and the National Institutes of Health ("NIH") to identify residual cases of viral hepatitis that remained unaccounted for following the implementation of testing for hepatitis A, B and C viruses.

In January 1995, Genelabs announced the discovery of a new human virus called hepatitis G virus ("HGV") under its hepatitis research program. Preliminary findings indicate that the new virus is associated with hepatitis and can be

transmitted through transfusion of contaminated blood. Presence of the new virus has been detected in blood samples obtained from patients in the United States, Europe, Japan and elsewhere. Genelabs scientists and their collaborators are conducting extensive studies to determine the epidemiology and full clinical significance of the new virus. A broad based diagnostic test is being developed by Genelabs and its collaborators.

Genelabs has entered into a limited co-exclusive royalty-bearing licensing agreement with Boehringer Mannheim to develop and commercialize screening diagnostic products for HXV, including the Company's discovery of HGV. In addition, in March 1995, the Company signed a preliminary agreement with Chiron Corporation, which, among other things, will provide Chiron and its joint partner, Ortho Diagnostics Systems, Inc. ("Ortho"), a worldwide, limited co-exclusive royalty-bearing license to develop and commercialize screening diagnostic products for HGV. See "Business - Corporate Collaborator Arrangements - Chiron Corporation - Worldwide Diagnostics Alliance."

#### *GL701: Systemic Lupus Erythematosus*

Systemic lupus erythematosus ("lupus") is a severe, chronic and frequently debilitating autoimmune disease that can affect the skin, joints, kidneys and nervous system. It has an estimated 14 percent mortality rate within ten years of diagnosis. Current therapy for mild to moderate lupus is limited to non-steroidal anti-inflammatory drugs, anti-malarial agents such as hydroxychloroquine and glucocorticoids (steroids). Treatment is often inadequate, due either to limited benefits or to severe adverse side effects. With an estimated prevalence of 40 to 50 cases per 100,000 people, lupus affects approximately 135,000 patients in the United States, and Genelabs estimates that there are at least three times that number of patients worldwide. It is ten times more common in women than men and is most common and severe in Asian and black populations.

GL701, Genelabs' therapeutic candidate for lupus, is a pharmaceutical formulation designed for oral administration that contains dehydroepiandrosterone ("DHEA") as the active ingredient.

Studies by Genelabs' scientific collaborators at Stanford University have indicated that oral use of DHEA, a naturally occurring hormone that is produced by the adrenal glands, may be effective and safe for the treatment of lupus. Lupus patients generally have abnormally low levels of DHEA, and studies have shown that hormonal influences play a role in the development and progression of lupus. A Phase II clinical study conducted at Stanford University in 1993 involved 28 women with lupus who received either DHEA or a placebo over the study period. Results of this study, reported at the American College of Rheumatology meeting in November 1993, indicated that DHEA-treated patients showed improvement on the basis of the patients' own assessments, the physicians' clinical assessments and a commonly accepted disease activity index, while placebo-treated patients did not. In addition, patients treated with DHEA were able to reduce their doses of prednisone, a glucocorticoid drug that is commonly used to treat lupus but has many serious side effects.

Stanford has applied for a United States patent on the use of DHEA to treat lupus and has granted Genelabs exclusive worldwide rights under that patent application and Stanford's clinical trial results. The Company filed an IND with the FDA in December 1993. In May 1994, the Company started a randomized, double-blind, placebo controlled, multi-center, Phase II/III human clinical trial for the treatment of mild to moderate systemic lupus erythematosus in women who require prednisone or other steroids for their treatment. The Company believes this trial is the largest controlled clinical trial conducted in patients with lupus.

Due to the public domain nature of the DHEA compound, the Company may not be able to obtain patent protection for its use against lupus. See "Patents and Licenses."

#### *Pharmaceutical Discovery Research*

Genelabs undertakes research directed toward discovery of novel pharmaceuticals in two fields: (1) Low molecular weight DNA-binding compounds for modification of gene expression; and (2) identification of novel cytokines.

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## FORM 10-K

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For the transition period from.....to.....

Commission file number 0-19222

### GENELABS TECHNOLOGIES, INC.

(Exact name of Registrant as specified in its charter)

California  
(State or other jurisdiction of  
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identification number)

505 Penobscot Drive  
Redwood City, California 94063

(Address of principal executive offices, including zip code)

(415) 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.

Aggregate market value of the voting stock held by  
non-affiliates of the Registrant:  
Number of shares of Common Stock outstanding:

As of February 29, 1996

\$191,675,000  
33,164,381

#### DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's definitive Proxy Statement for its 1996 Annual Meeting of Shareholders are incorporated by reference into Part III (Items 10, 11, 12 and 13) hereof.

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Using a positional cloning method called direct selection, the Cytokine Discovery Group has selected cDNAs from genes encoded within the immunomodulatory gene cluster on chromosome 5. The cDNAs are prioritized by several methods in order to select the genes of potential commercial interest for further investigation. During the prioritization process, the cDNAs were subjected to simple tests to determine which of the cDNAs are encoded by novel genes from chromosome 5 and which are expressed selectively in immunomodulatory cell types, such as bone marrow, activated T cells or B cells. Using this approach, the Cytokine Discovery Group has identified hundreds of cDNAs encoded by human chromosome 5 that are expressed in immunomodulatory cells. A patent application has been filed in the United States to claim these novel sequences. The Company is actively pursuing funding through potential external collaborators to investigate the biological function and commercial potential of these genes.

#### *GL701: Systemic Lupus Erythematosus*

Systemic lupus erythematosus ("lupus") is a severe, chronic and frequently debilitating autoimmune disease that can affect the skin, joints, kidneys and nervous system. It has an estimated 10 percent mortality rate within ten years of diagnosis. Current treatment is often inadequate, due either to limited benefits or to severe adverse side effects. With an estimated prevalence of 40 to 50 cases per 100,000 people, lupus affects approximately 150,000 patients in the United States, and Genelabs estimates that there are at least three times that number of patients worldwide. It is ten times more common in women than men and is more severe in Asian and African-American populations.

GL701, Genelabs' therapeutic candidate for lupus, is a pharmaceutical formulation designed for oral administration that contains dehydroepiandrosterone ("DHEA") as the active ingredient. DHEA is a naturally occurring hormone that is produced by the adrenal glands.

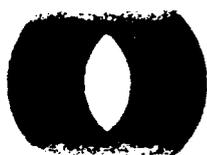
Studies by Genelabs' scientific collaborators at Stanford University have indicated that oral use of DHEA may be effective and safe for the treatment of lupus. Lupus patients generally have abnormally low levels of DHEA, and studies have shown that hormonal influences play a role in the development and progression of lupus. A Phase II clinical study conducted at Stanford University in 1993 involved 28 women with lupus who received either DHEA or a placebo over the three month study period. Results of this study, 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 a commonly accepted disease activity index, while placebo-treated patients did not. In addition, mean prednisone dose was decreased in patients treated with DHEA. Prednisone, a glucocorticoid drug that is commonly used to treat lupus, has many serious side effects and is a leading cause of disability and death in lupus patients.

Stanford has applied for a United States patent on the use of GL701 to treat lupus and has granted Genelabs exclusive worldwide rights under that patent application and Stanford's clinical trial results. The Company filed a Investigational New Drug Application ("IND") with the U.S. Food and Drug Administration ("FDA") in December 1993. In May 1994, the Company started a randomized, double-blind, placebo controlled, multi-center, Phase II/III human clinical trial for the treatment of mild to moderate lupus in women who require prednisone or other steroids for their treatment. Enrollment in the study was completed in November 1995, with 193 patients participating. The Company believes this trial is the largest controlled clinical trial conducted in patients with lupus.

The FDA has recognized the severely debilitating nature of lupus and the lack of adequate treatment by granting Subpart E designation to GL701. This designation permits accelerated regulatory review of applications for a new drug approval. FDA also granted GL701 Orphan Drug Status for the treatment of lupus, a designation that provides seven years of U.S. marketing exclusivity and tax benefits to the first company to sponsor an approved new drug application.

Due to the public domain nature of the DHEA compound, the Company may not be able to obtain patent protection for its use in the treatment of lupus. See "Patents and Licenses." Genelabs has licensed certain Asian development and marketing rights to GL701 to GBL.

1,350,000 Shares



**Genelabs Technologies, Inc.  
Common Stock**

All of the 1,350,000 shares of Common Stock offered hereby are being sold by Genelabs Technologies, Inc. ("Genelabs" or the "Company"). The Common Stock is quoted on the Nasdaq National Market under the symbol "GNLB." On June 14, 1994, the last reported sale price of the Common Stock was \$2.50 per share. See "Price Range of Common Stock." The Company is simultaneously selling to certain European investors an additional 1,000,000 shares of Common Stock pursuant to Regulation S of the Securities and Exchange Commission.

The shares of Common Stock offered hereby involve a high degree of risk. See "Risk Factors."

**THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION NOR HAS THE SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

	Price to Public	Underwriting Discounts and Commissions(1)	Proceeds to Company(2)
Per Share.....	\$2.25	\$0.16	\$2.09
Total (3) .....	\$3,037,500	\$216,000	\$2,821,500

- (1) The Company has agreed to indemnify the Underwriter against certain liabilities, including liabilities under the Securities Act of 1933. See "Underwriting."
- (2) Before deducting expenses of the offering estimated at \$400,000.
- (3) The Company has granted the Underwriter a 30-day option to purchase up to 202,500 additional shares of Common Stock on the same terms and conditions to cover over-allotments, if any. If such option is exercised in full, the total Price to Public, Underwriting Discounts and Commissions and Proceeds to Company will be \$3,493,125, \$248,400 and \$3,244,725, respectively. See "Underwriting."

The shares of Common Stock are offered by the Underwriter when, as and if delivered to and accepted by the Underwriter, subject to prior sale and certain other conditions. It is expected that delivery of the shares of Common Stock will be made at the office of Kemper Clearing Corp., New York, New York or through the facilities of The Depository Trust Company on or about June 22, 1994.

**Kemper Securities, Inc.**

The date of this Prospectus is June 15, 1994

## AVAILABLE INFORMATION

The Company has filed with the Securities and Exchange Commission (the "Commission") a Registration Statement on Form S-3 under the Securities Act of 1933, as amended (the "Securities Act"), with respect to the Common Stock offered hereby. This Prospectus does not contain all of the information set forth in the Registration Statement and the exhibits thereto, certain parts of which have been omitted in accordance with the rules and regulations of the Commission. For further information with respect to the Company and the Common Stock offered hereby, reference is made to the Registration Statement and the exhibits thereto. Copies of the Registration Statement and the exhibits thereto may be inspected, without charge, at the offices of the Commission, or obtained at prescribed rates from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549.

The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and in accordance therewith files reports, proxy statements and other information with the Commission. Such reports, proxy statements and other information filed by the Company can be inspected and copied at the public reference facilities maintained by the Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, and at the Commission's regional offices located at 7 World Trade Center, 13th Floor, New York, New York 10048, and at 500 West Madison Street, Suite 1400, Chicago, Illinois 60661-2511. Copies of such material can be obtained at prescribed rates from the Public Reference Section of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The documents listed below have been filed by the Company with the Commission and are incorporated herein by reference: (i) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1992 and its Form 10-K/A filed with the Commission on June 14, 1993; (ii) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 1993 and its Form 10-K/A filed with the Commission on May 19, 1994; (iii) the Company's Form 10-Q filed with the Commission on May 12, 1994 and (iv) the description of the Company's Common Stock contained in the Company's registration statement on Form 8-A filed under the Exchange Act, and any amendment or report filed for the purpose of updating such description.

All documents filed with the Commission pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial filing of the Registration Statement of which this Prospectus forms a part and prior to the termination of this offering shall be deemed to be incorporated by reference into this Prospectus and to be a part hereof from the date of filing of such documents. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Prospectus to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as modified or superseded, to constitute a part of this Prospectus.

The Company undertakes to provide without charge to each person to whom this Prospectus is delivered, upon the written or oral request of such person, a copy of any and all of the documents referred to above that have been incorporated in this Prospectus by reference, other than exhibits to such documents. Requests for such copies should be directed to Andrea Boscoe, Manager, Public Relations, Genelabs Technologies, Inc., 505 Penobscot Drive, Redwood City, California 94063 (telephone number 415-369-9500).

**IN CONNECTION WITH THIS OFFERING, THE UNDERWRITER MAY OVER-ALLOT OR EFFECT TRANSACTIONS WHICH STABILIZE OR MAINTAIN THE MARKET PRICE OF THE COMMON STOCK OF THE COMPANY AT A LEVEL ABOVE THAT WHICH MIGHT OTHERWISE PREVAIL IN THE OPEN MARKET. SUCH STABILIZING, IF COMMENCED, MAY BE DISCONTINUED AT ANY TIME.**

## BIOPHARMACEUTICAL BUSINESS

### *Priority Product Programs*

PROGRAM	INDICATION	STATUS(1)	MARKETING LICENSEES(2)		
			U.S.	EUROPE	ASIA
GL701 therapeutic	Lupus	Phase II/III			
HEV vaccine	Hepatitis E	Preclinical	SKB(3)	SKB(3)	SKB(3)
HXV discovery	Hepatitis X diagnostics	Research	ABT/BM(4)	ABT/BM(4)	ABT/BM(4)
	Hepatitis X vaccine	Research			

### *Programs Targeted for Corporate Collaborations*

PROGRAM	INDICATION	STATUS(1)	APPLICATION
GLQ223* therapeutic	Anti-HIV and AIDS	Phase II	HIV infection (AIDS)
GL331 therapeutic	Anti-MDR cancer	Phase I	small cell lung and colorectal cancer
GL288 therapeutic	Anti-herpes	Research	herpes simplex virus treatment
GL241 prophylactic	Topical antiviral	Research	AIDS prophylaxis

### *Core Technologies*

TECHNOLOGY	APPLICATION
QC-PCR	Measurement of viral load to test efficacy of anti-virals in patients
SISPA	Amplification of genes from small samples for new virus discovery
Hepatocyte culture	Growth of liver cells <i>in vitro</i> to study hepatitis infection
DNA-binding assay	Discovery of new drugs that target specific genes
Human genome	Identification of new genes based on gene clusters

- (1) "Research" indicates that the Company is in the discovery phase of investigating the potential pharmacological activity of new compounds for therapeutic or prophylactic use; "Preclinical" indicates that the Company is studying candidate vaccines in animals; "Phase I" indicates that the product is in Phase I human clinical trials for safety; "Phase II" indicates that the product is in Phase II human clinical trials for safety and preliminary indications of efficacy; "Phase II/III" indicates that the product is in late Phase II or Phase III human clinical trials to study efficacy.
- (2) "ABT" means Abbott Laboratories; "BM" means Boehringer Mannheim America Ltd., a subsidiary of Corange International Limited; and "SKB" means SmithKline Beecham p.l.c.
- (3) Genelabs has granted SKB exclusive marketing rights in the United States and Europe. Genelabs has co-marketing rights to HEV vaccine in certain Asian countries.
- (4) Genelabs has granted ABT and BM limited co-exclusive marketing rights worldwide. Genelabs retains the rights to market and to license a third party to market HXV screening diagnostic tests worldwide, and Genelabs retains the exclusive rights to market HXV confirmatory diagnostic tests and vaccines worldwide.

## PROSPECTUS SUMMARY

*The following information is qualified in its entirety by the more detailed information and consolidated financial statements appearing elsewhere in this Prospectus. Unless otherwise indicated, the information in this Prospectus assumes no exercise of the Underwriter's over-allotment option and the simultaneous sale of 1,000,000 shares of Common Stock to certain European investors pursuant to Regulation S of the Commission. Prospective investors should carefully consider the factors set forth under "Risk Factors."*

### The Company

Genelabs is a global biopharmaceutical and diagnostics company. Through two operating units, a biopharmaceutical business based in the United States and a diagnostics business based in Singapore, the Company is developing therapeutic and vaccine products for viral diseases, autoimmune disorders and other life threatening and debilitating conditions, and is developing and marketing a portfolio of viral diagnostic products. The Company's three priority product programs are the development of a therapeutic to treat lupus, the development of a vaccine for hepatitis E and the identification of a virus that is believed to cause a form of post-transfusion hepatitis known as hepatitis X. The Company's principal collaborators are Stanford University for lupus, SmithKline Beecham p.l.c ("SKB" or "SmithKline Beecham") for hepatitis E vaccine, Abbott Laboratories ("ABT" or "Abbott") for hepatitis E and X diagnostic tests, and Boehringer Mannheim America Ltd., a subsidiary of Corange International Limited ("Boehringer Mannheim") for hepatitis X diagnostic tests.

Genelabs is pursuing a two-tiered product development approach. Using Genelabs' core technologies and expertise in viral discovery, the biopharmaceutical business is engaged in the development of potential new therapeutics and vaccines, both internally and through collaborations with academic institutions and corporations. At the same time, the Company's diagnostics business is generating current revenue and expects to generate future revenue from viral diagnostic products that have been and are expected to be developed from the Company's viral discovery program, and from products and technologies acquired from others.

Genelabs' biopharmaceutical strategy is to optimize the value of its product development efforts by developing products derived from the application of its core technologies and by selectively acquiring from third parties products in late stages of development to which the Company believes it can add substantial value. In accordance with that strategy, Genelabs has focused its internal biopharmaceutical product development programs on developing a therapeutic for lupus and a vaccine for hepatitis E and on identifying the virus that causes hepatitis X. In addition, the Company is engaged in the research and development of potential therapeutic agents for AIDS, cancer, herpes and other viral infections. Genelabs' strategy for these products is to leverage its internal resources and accelerate their commercialization by seeking corporate collaborations with market leaders in the relevant fields of application to complete development, fund clinical trials and conduct marketing.

Genelabs has used its technological leadership in molecular virology to build an international diagnostics business with a rapidly expanding global infrastructure. In 1993 and the first quarter of 1994, Genelabs generated \$9.6 million and \$2.6 million, respectively, in product sales from diagnostic products, and increased the number of different products sold from eight to 20. Genelabs' diagnostics business is conducted through its Singapore-based subsidiary Genelabs Diagnostics (Pte.) Ltd. ("GLD"), which is a fully-integrated diagnostics business with sales offices in Taipei, Shanghai, Bangkok, Geneva, Leuven (Belgium) and Redwood City (California) and a joint venture with the Korean Green Cross in Seoul, South Korea. GLD is currently manufacturing and marketing screening, confirmatory and rapid test diagnostic products and reagents for viral diseases such as hepatitis, AIDS and human T-cell leukemia. Genelabs maintains an active diagnostic product development pipeline and, in addition to its research program to identify the virus that causes hepatitis X, Genelabs is developing a portfolio of new confirmatory and rapid test diagnostic products.

Genelabs has initially focused its diagnostics business on the Asian and European markets and expects to expand its activities to the United States market in the future upon obtaining regulatory approvals. The Company believes that its growing Asia presence is of strategic importance because the continued expansion of the Asian economies is expected to increase the demand for high-quality and cost-effective health care products, and because there is no dominant provider of health care products in that region.

1993 and 1994 were \$0.8 million. In the future, the Company expects that its research and development expenses on its collaborative programs may exceed the contract revenues associated with these programs.

#### *Research and Development Expenses*

For the three months ended March 31, 1993, the Company recorded a non-recurring, non-cash charge of \$3.2 million for purchased in-process research and development associated with the acquisition of DBL. The Company's research and development expenses were \$3.0 million for the three months ended March 31, 1993 compared to \$3.6 million for the three months ended March 31, 1994. This increase reflects the launching of projects for GL701 for lupus and QC-PCR, as well as the inclusion of DBL for a full quarter in 1994 compared to one month in 1993.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative ("SG&A") expenses increased from \$2.1 million for the three months ended March 31, 1993 to \$2.6 million for the same period of 1994, due primarily to the inclusion of DBL for the full quarter in 1994. The Company expects its SG&A expenses to increase in the future as diagnostic product sales increase, but expects these expenses to decline as a percentage of sales.

#### *Interest Income, Net*

The Company recognized net interest income of \$0.2 million in the three months ended March 31, 1993, compared to \$0.1 million for the same period in 1994. The decrease resulted from lower cash balances available for investment and lower interest rates during the period.

#### *Net Loss*

The Company has operated at a loss since its inception and had an accumulated deficit of \$77.3 million as of March 31, 1994. The net loss for the three months ended March 31, 1993 was \$6.9 million, compared to a net loss of \$3.8 million for the same period in 1994. This decrease in net loss was due primarily to the non-recurring, non-cash charge of \$3.2 million recorded for the three months ended March 31, 1993 for purchased in-process research and development associated with the acquisition of DBL.

#### *Accounting Pronouncement*

Through December 31, 1993, the Company classified its debt securities as held-for-investment and carried them at amortized cost plus accrued interest. Effective January 1, 1994, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Under the new rules and based upon management's intent, effective January 1, 1994, the Company classified its debt securities as available-for-sale and carries them at fair value. Unrealized gains on these securities were approximately \$39,000 at March 31, 1994 and were included as a component of accumulated deficit.

#### *Three Years Ended December 31, 1991, 1992 and 1993*

##### *Revenues*

The Company generated total revenues of \$4.3 million in 1991, \$4.9 million in 1992 and \$12.9 million in 1993. The increase in 1993 was due primarily to increased diagnostic product sales, particularly confirmatory, rapid and screening tests, and reagents, sold by Genelabs. Diagnostic product sales increased to \$9.6 million in 1993 from \$1.5 million in 1992 and \$0.5 million in 1991. The results of operations, including revenues, of DBL have been included in the Company's consolidated financial results since March 1993.

Contract and other revenues were \$3.8 million in 1991, \$3.4 million in 1992 and \$3.4 million in 1993. Revenues from government grants and contracts were \$0.9 million in 1991, \$0.7 million in 1992 and \$0.8 million in 1993. During 1992, the Company's collaborative agreements with Abbott and SKB together provided a total of \$1.4 million in contract revenues. During 1993, the Company recognized an additional total of \$2.3 million in contract revenues from these two companies.

### *Cost of Product Sales*

Cost of product sales increased from \$0.3 million in 1991 and \$0.9 million in 1992 to \$5.4 million in 1993. The increases were due to increased diagnostic product sales, particularly confirmatory, rapid and screening tests, and reagents. Cost of sales as a percentage of sales decreased from 66% in 1991 to 63% and 56% in 1992 and 1993, respectively. This decrease was attributable primarily to economies of scale resulting from the increase in product sales over the three year period and to the introduction of new products with higher margins. Costs related to contract revenues for 1991, 1992 and 1993 were \$1.8 million, \$1.8 million and \$4.2 million, respectively, and are included in research and development expenses.

### *Research and Development Expenses*

The Company's research and development expenses during the past three years were \$13.2 million in 1991, \$15.1 million in 1992 and \$15.0 million in 1993. A significant portion of the Company's research and development expenses during the past three years was devoted to clinical trials of GLQ223, which the Company plans to license to a corporate collaborator for further development. The Company's principal ongoing research and development expenses are directed toward its priority projects, GL701 for lupus, HEV vaccine and HXV discovery.

In 1991 and 1993, the Company recorded non-recurring, non-cash charges for purchased in-process research and development of \$9.3 million and \$3.6 million, respectively, associated with the acquisitions of BTR and DBL, respectively. These acquisitions were accounted for under the purchase method. As required by generally accepted accounting principles, the portion of the purchase price that was allocated to in-process research and development was expensed at the time of the acquisition. In connection with the acquisition of DBL, the Company may be obligated to issue up to an additional 506,175 shares of its Common Stock in February 1995 to those DBL shareholders who, as of that date, have retained their shares of the Company's Common Stock issued to them as part of the acquisition. The number of shares of Common Stock to be issued, if any, will depend on the trading price of the Company's Common Stock in February 1995. The Company will not be obligated to issue any additional shares if its stock price at that time exceeds \$9.81 per share. If the Company issues such shares, the fair market value of these shares at the time of their issuance would result in additional purchase price of up to approximately \$3.5 million, which will be charged to operations during the first quarter of fiscal 1995.

### *Selling, General and Administrative Expenses*

SG&A expenses increased during the three-year period from \$5.8 million in 1991 and \$7.1 million in 1992 to \$11.7 million in 1993. The increases in SG&A expenses in 1992 and 1993 resulted primarily from the expansion of the Company's diagnostics marketing and distribution capabilities, which was due in part to the acquisition of BTR in 1991 and primarily to the acquisition of DBL in 1993. The Company expects its SG&A expenses to increase in the future as diagnostic product sales increase, but expects these expenses to decline as a percentage of sales.

### *Interest Income, Net*

The Company recognized net interest income of \$1.4 million in 1991, \$1.0 million in 1992 and \$0.7 million in 1993. The decreases resulted from lower cash balances available for investment and lower interest rates during the three year period.

### *Net Loss*

The net loss for 1991 was \$22.9 million, compared to a net loss of \$17.3 million in 1992 and \$22.0 million in 1993. The 1991 and 1993 losses include the non-recurring, non-cash charges of \$9.3 million and \$3.6 million, respectively, for purchased in-process research and development, resulting from the acquisitions of DBL and BTR, respectively.

### *Income Taxes*

At December 31, 1993, the Company had net operating loss carryforwards for federal and California income tax purposes of approximately \$49.0 million and \$9.0 million, respectively. In addition, the

## BUSINESS

Genelabs is a biopharmaceutical and diagnostics company. Through two operating units, a biopharmaceutical business based in the United States and a diagnostics business based in Singapore, the Company is developing therapeutic and vaccine products for viral diseases, autoimmune disorders and other life threatening and debilitating conditions, and is developing and marketing a portfolio of viral diagnostic products. The Company's three priority product programs are the development of a therapeutic to treat lupus, the development of a vaccine for hepatitis E and the identification of a virus that is believed to cause a form of post-transfusion hepatitis known as hepatitis X. The Company's principal collaborators are Stanford University for lupus, SmithKline Beecham for hepatitis E vaccine, Abbott for hepatitis E and X diagnostic tests, and Boehringer Mannheim for hepatitis X diagnostic tests.

Genelabs is pursuing a two-tiered product development approach. Using Genelabs' core technologies and expertise in viral discovery, the biopharmaceutical business is engaged in the development of potential new therapeutics and vaccines, both internally and through collaborations with academic institutions and corporations. At the same time, the Company's diagnostics business is generating current revenue and expects to generate future revenue from viral diagnostic products that have been and are expected to be developed from the Company's viral discovery program, and from products and technologies acquired from others.

Genelabs has initially focused its diagnostics business on the Asian and European markets and expects to expand its activities to the United States market in the future upon obtaining regulatory approvals. The Company believes that its growing Asia presence is of strategic importance because the continued expansion of the Asian economies is expected to increase the demand for high-quality and cost-effective health care products, and because there is no dominant provider of health care products in that region.

### Biopharmaceutical Business

Genelabs' biopharmaceutical business focuses on the development of products for the treatment of life threatening and severely debilitating diseases where no satisfactory treatment alternatives are currently available. Genelabs' biopharmaceutical strategy is to optimize the value of its product development efforts by developing products derived from the application of its core technologies and by selectively acquiring from third parties products in late stage of development to which the Company believes it can add substantial value. In accordance with that strategy, Genelabs has focused its internal biopharmaceutical product development programs on developing its therapeutic for lupus and its vaccine for hepatitis E and on identifying the virus that causes hepatitis X. In addition, the Company is engaged in the research and development of potential therapeutic agents for AIDS, cancer, herpes and other viral infections. Genelabs' strategy for these products is to leverage its internal resources and accelerate their commercialization by seeking corporate collaborations with market leaders in the relevant fields of application to complete development, fund clinical trials and conduct marketing.

Genelabs' biopharmaceutical business is managed by an experienced management team, headed by its President, Dr. Irene Chow, an experienced pharmaceutical industry executive. Dr. Chow joined the Company in August 1993, and was formerly a Senior Vice President for Drug Development for the CIBA-GEIGY Pharmaceutical Division where she directed all scientific, medical, technical and regulatory activities related to the development of new drugs. During her last eight years as Vice President and Senior Vice President, she was responsible for the approvals of 10 New Drug Applications ("NDAs") and the submission of 26 Investigational New Drug applications ("INDs") to the FDA.

*Priority Product Programs*

Genelabs has focused its product development efforts in three priority areas: developing a therapeutic to treat lupus, developing a vaccine for hepatitis E and identifying, and developing diagnostic and vaccine products for, the virus that is believed to cause a form of post-transfusion hepatitis known as hepatitis X.

PROGRAM	INDICATION	STATUS	MARKETING LICENSEES(1)		
			U.S.	EUROPE	ASIA
GL701 therapeutic	Lupus	Phase II/III			
HEV vaccine	Hepatitis E	Preclinical	SKB(2)	SKB(2)	SKB(2)
HXV discovery	Hepatitis X diagnostics	Research	ABT/BM(3)	ABT/BM(3)	ABT/BM(3)
	Hepatitis X vaccine	Research			

- (1) "ABT" means Abbott; "BM" means Boehringer Mannheim; and "SKB" means SmithKline Beecham p.l.c.
- (2) Genelabs has granted SKB exclusive marketing rights in the United States and Europe. Genelabs has co-marketing rights to HEV vaccine in certain Asian countries.
- (3) Genelabs has granted ABT and BM limited co-exclusive marketing rights worldwide. Genelabs retains the rights to market and to license a third party to market HXV screening diagnostic tests worldwide, and Genelabs retains the exclusive rights to market HXV confirmatory diagnostic tests and vaccines worldwide.

*GL701: Systemic Lupus Erythematosus*

Systemic lupus erythematosus ("lupus") is a severe, chronic and frequently debilitating autoimmune disease that can affect the skin, joints, kidneys and nervous system. It has an estimated 14 percent mortality rate within ten years of diagnosis. Current therapy for mild to moderate lupus is limited to non-steroidal anti-inflammatory drugs, anti-malarial agents such as hydroxychloroquine and glucocorticoids (steroids). Treatment is often inadequate, due either to limited benefits or to severe adverse side effects. With an estimated prevalence of 40 to 50 cases per 100,000 people, lupus affects approximately 135,000 patients in the United States, and Genelabs estimates that there are at least three times that number of patients worldwide. It is ten times more common in women than men and is most common and severe in Asian and black populations.

Studies by Genelabs' scientific collaborators at Stanford University have indicated that oral use of dehydroepiandrosterone ("DHEA"), a naturally occurring hormone that is produced by the adrenal glands, may be effective and safe for the treatment of lupus. Lupus patients generally have abnormally low levels of DHEA, and studies have shown that hormonal influences play a role in the development and progression of lupus. Under a physician IND, Stanford clinical investigators conducted a three-month Phase II study of 28 women with lupus during 1993. The patients received either DHEA or a placebo daily over the study period. Results of this study, reported at the American College of Rheumatology meeting in November 1993, indicated that DHEA-treated patients showed improvement on the basis of the patients' own assessments, the physicians' clinical assessments and a commonly accepted disease activity index, while placebo-treated patients did not. In addition, patients treated with DHEA were able to reduce their doses of prednisone, a glucocorticoid drug that is commonly used to treat lupus but has many serious side effects.

While DHEA is a compound that is in the public domain, Stanford has applied for a United States patent on its use to treat lupus and has granted Genelabs exclusive worldwide rights under that patent application and Stanford's clinical trial results. The Company filed an IND with the FDA in December 1993 and commenced a randomized, double-blind, placebo controlled, multicenter Phase II/III human clinical trial of the drug as a therapy for lupus in May 1994. Due to the public domain nature of the DHEA compound, the Company may not be able to obtain patent protection for its use against lupus. See "Patents and Licenses." However, the Company intends to seek an orphan drug

designation for the treatment of lupus with DHEA, which, if granted by the FDA, would provide the Company with up to seven years of exclusive marketing rights in the United States, subject to certain limitations, if it is the first company to obtain approval to market DHEA for this indication.

#### *Hepatitis E Vaccine*

Genelabs has focused significant efforts on the development of products for viral hepatitis, which is a serious worldwide health concern and is endemic in Asia. The five known forms of viral hepatitis are designated hepatitis A, B, C, D and E. The different hepatitis viruses vary in their basic biology as well as method of transmission and pathology. There are FDA-approved vaccines for hepatitis B virus ("HBV"), and an application for a vaccine for hepatitis A virus ("HAV") has been filed with the FDA, but not for any of the other hepatitis viruses. Like HAV, hepatitis E virus ("HEV") is a water-borne virus that causes a debilitating acute form of hepatitis that is prevalent worldwide and is endemic in much of Asia. Next to hepatitis A, hepatitis E is believed to be the leading cause of epidemic hepatitis. It is more severe than hepatitis A and has greater morbidity and mortality rates. HEV infection is reported to result in death in up to 20% of the pregnant women who contract it. Although hepatitis E's clinical and epidemiological significance is currently under investigation, serological screening studies in the United States find that 1% to 3% of all blood donors, depending on the population studied, have antibodies against HEV, suggesting that they have previously been exposed to the virus.

Genelabs scientists, together with scientific collaborators from the United States Centers for Disease Control and Prevention ("CDC"), were the first to isolate and identify HEV. Genelabs is continuing to work in collaboration with the CDC and SKB on the development of a vaccine for HEV. Preliminary studies of a prototype HEV vaccine in monkeys have shown indications of efficacy in preventing infection. Genelabs is now in the process of confirming these results with a group of larger animals. Genelabs believes that its hepatocyte culture system, which allows it to maintain cultures of immortalized liver cell lines and study the ability of these cells to be infected with hepatitis viruses, will significantly contribute to the Company's hepatitis E vaccine research and development. Genelabs has filed patent applications in the United States and internationally with claims covering the HEV genome, certain proteins and peptides derived therefrom, antibodies against such proteins and peptides, and multiple diagnostic and vaccine uses of HEV.

In 1992, Genelabs entered into an agreement with SKB to develop and commercialize a vaccine for HEV. Genelabs has retained co-marketing rights to HEV vaccine in Asia and has the co-marketing rights to combine SKB's existing HAV vaccine with HEV vaccine in Asia. See "Corporate Collaborator Arrangements." Hepatitis A vaccine is administered to travelers to areas where the disease is prevalent. Genelabs believes that because hepatitis E affects essentially the same populations as hepatitis A, and is in many cases more severe with higher fatality rates, the market will be essentially the same as for hepatitis A. Furthermore, because these infections are transmitted through the same mechanism, Genelabs believes that a vaccine for hepatitis E, sold in combination with a hepatitis A vaccine, would provide much more comprehensive protection for patients and provide the Company with an attractive market opportunity.

#### *Hepatitis X Discovery*

Although diagnostic products for hepatitis A and B viruses have existed since the 1970s, certain cases of post-transfusion hepatitis ("non-A non-B hepatitis") were long suspected to be caused by one or more unknown viruses. One virus, designated hepatitis C virus ("HCV"), was identified in the late 1980's, and the first diagnostic product for hepatitis C was introduced in 1990 by Ortho Diagnostic Systems through a joint venture with Chiron Corporation. Genelabs believes that there are one or more additional types of blood-borne viral hepatitis, called hepatitis X, for which the causative agent has not yet been identified. Based on this belief, Genelabs has focused its viral discovery efforts on identifying the virus referred to as hepatitis X virus ("HXV") that is believed to be the causative agent.

Genelabs believes that it is a leader in the discovery of hepatitis viruses and the development of diagnostic tests for hepatitis. Genelabs was one of the first to identify a portion of the hepatitis C virus