EXHIBIT H-7

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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MAY 2 1986
COMMISSIONER'S OFFICE

MAY 2 - 1986

In re application of
Fu-Kuen Lin
Serial No.: 06/675,298
Filed: November 30, 1984
For: PRODUCTION OF ERYTHROPOIETIN

DECISION ON PETITION
TO MAKE SPECIAL
(Infringement)

The petition to make this case special has been considered.

If the examiner can make this case special without prejudice to any possible interfering applications, and he should make a rigid search for such, he is authorized to do so for the next action. Should the application be rejected, the case will not be considered special for the subsequent action unless the applicant promptly makes a bona fide effort to place the case in condition for allowance, even if it is necessary to have an interview with the examiner to accomplish this purpose.

If the examiner finds any interfering application for the same subject matter, he should consider such application simultaneously with this case and should state in the official letter of such application that he is taking it out of its turn because of a possible interference.

Should an appeal be taken in this case or should this case become involved in interference, consideration of the appeal and the interference will be expedited by all Patent and Trademark Office officials concerned, contingent likewise upon diligent prosecution by the applicant.

The petition is granted to the extent indicated.

Rene D. Tegtmeyer
Assistant Commissioner for Patents

Merriam, Marshall & Bicknell
Two First National Plaza, Ste. 2100
20 South Clark Street
Chicago, IL 60603

178 +55

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RECEIVED
JAN 10 1986
J. W. SCHULER

ELANEX CORPORATION
"FOR THE GOOD OF ALL"

1348 179TH AVENUE NORTHEAST BELLEVUE, WASHINGTON 98008
(206) 747-7832

January 2, 1986

RECEIVED
JAN 13 1986
G.B.R.

Mr. R.A. Schoellhorn
Chief Executive Officer
Abbott Laboratories
Abbott Park
North Chicago, Illinois 60064

cc GB HH NS
RW DV
1-13-86
from J. Schuler/Abb

Subj: Erythropoietin (EPO)

Dear sir:

Sales of Erythropoietin in the United States market are estimated at 100 million dollars per year for dialysis patients alone. Other anticipated uses, related to anemia, push the estimates higher. Additionally, the diagnostic applications and opportunities might easily be 60 million per year in sales. Worldwide sales of EPO and its related products probably would exceed 200 million per year.

I have written to you directly on this opportunity due to my lack of knowledge of the appropriate person in your company to address this pharmaceutical opportunity, as well as the size of the product market.

Our startup biotech firm has cloned and expressed EPO at levels of 25mg per liter. This makes us one of two firms, worldwide, that have the ability to produce EPO at commercial levels. We have no venture partners. We have no commitments to any other firm.

Our purpose is to inquire of your interest in pursuing the approvals, commercialization, and development of this product with us. This relationship would include the exclusive distribution rights for the United States. Information is enclosed for your review.

Very truly yours,

Lawrence H. Thompson

LHT/nt

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186

[redacted]nex Corp. Encl. of Jan. 2, 1986

January 2, 1986

Facts on Elanex Corporation Erythropoietin (EPO):

1. We are one of two companies in the world that have successfully cloned, expressed, and produced EPO at commercial levels (25mg/liter in lab/shake flasks). As you probably know, EPO is a hormone, made in the kidney, and it stimulates red blood cell production when low oxygen levels are sensed. Thus, its prime use is in patients with anemia and damaged or missing kidneys.

2. Other corporations have spent millions of dollars in research and joint venture money just hoping to reach this point.

3. EPO's use is in over 60,000 regular dialysis users in the United States who have dialysis three times a week. There are 300,000 renally deficient patients in the world, with 100,000 of those in the United States. We have been advised by a senior medical consultant for a NYSE company, specializing in this area, that it is his medical opinion that EPO is a valuable product and will be of great benefit to anemic patients, especially those on dialysis. It will restore their normal blood levels, raise their hematocrit levels to near normal, reduce the feeling of nausea, and make them productive people that feel well. Recent articles support his opinion. Our M.D./Sr. Scientist holds the same opinions.

4. We estimate that each chronic dialysis patient will require 6,000 to 10,0000 units of EPO per week to achieve therapeutic results. This is a rough estimate only. Clinical trials will show the correct amount. That is then for 52 weeks and at least 60,000 US patients.

5. EPO is now selling in the reagent market for 70 cents per unit as a recombinant product. Additionally our competitor sells a more pure product for about $4.50 per unit. We expect the price to drop drastically as therapeutic production comes on line and economies of scale, competition, and market supply/demand curves are analyzed. As mentioned later in this memo, our estimates for ultimate price would be $10• for a shot of about 2500 units.

6. It is public information in published data that Johnson & Johnson has paid our competitor 6 million dollars for the right to the non-dialysis market on EPO and for two other products. More money is due to flow in future years in the JJ venture.

7. Our product has in vitro activity, and invivo activity.

8. We assess our product is as good as or better than our competitor; and our product is believed to be potentially less allergenic.

9. Our product is made from a different cell line then that of our competitor. Different vectors have been used. We

Attachment to Elanex Ltr on EPO// Page 1

154 180

187

furnished our own clone. Thus, our product is differentiated for patent purposes.

10. Our competitor is now moving toward Clinical trials.

11. Our competitor and their venture partners can be caught and passed by us in a few months if the correct levels of effort are expended.

12. We are seeking a relationship with a pharmaceutical company that would likely be as follows:

a. Exclusive U.S. Distribution rights to our EPO.

b. Drug company:Clinical trials, regulatory approvals, and patents etc.

c. Elanex or licensee do production with drug company backing.

d. Elanex pursues research on a lab on the monoclonal and product purification on an R&D basis (incl. diagnostic).

13. Our cell lines have reached levels of production satisfactory for commercial production.

14. Our highest level of production in shake flask technology has been 100mg per liter. A consistent level is 25mg.

15. A simple one pass purification of the supernatant is expected to yield about 50,000 units per mg purity. 78,000 is estimated as 100% pure; and we are working on achieving that purity for the product.

16. The protein is glycocelated.

17. Production in units in the lab have averaged about 70 to 80 thousand units per liter.

18. We believe that roller bottle or batch process technology would easily be scaled up for commercial production. Cell optimization/characterization would take a few months longer. Traditional technology would produce sufficient quantities for clinical trials.

19. We are currently taking proposals from nationally known producers of product in cell line technology; and we are visiting their facilities. We have isolated the technology that we expect to use for commercial production.

20. We have not yet filed our IND or patent application; nor have we filed in any foreign country. We are in the process of starting preparation of the IND and patent application.

21. We believe our specific response curve is equal to that of our competitor's product and the national standard for EPO.

22. We would be pleased to send a sample of our product to you for testing or your review. We would of course have more information if you have interest.

23. The time issue and your help is important for us. We seek to catch and pass our competitor. We believe it should not be overly difficult to follow their administrative progress with FDA and related actions to make up time.

159 181

24. Other consultants have estimated the US market at 100 million dollars annually. We have done our own estimates and concur. There are at least 60,000 patients that will require EPO shots/IV three times a week. Dialysis is about $130 per treatment. We estimate that EPO would be appropriately priced around $10 to $25 per treatment. At $10 per treatment, that would be 156 treatments per year; and would equal $1,500 per patient. At 60,000+ patients, it comes to about 100 million dollars per year. Our preliminary price estimates for production indicate that the product can be very profitable in those price frontiers.

25. Further, there is the diagnostic market. Patients will have to be tested for EPO levels to determine the need for EPO. Then there will have to be frequent testing of those taking EPO to monitor EPO levels. We are in a unique position to pursue the monoclonal antibody and the diagnostic kit since it takes vast quantities of EPO to produce the antibody. Our competitor is the only other firm that has this pure EPO. They are offering it for sale at 4 to 5 dollars per unit. Less pure EPO is available from them for 70 cents per unit. Thus it would cost a company huge sums of money if they were to buy EPO to go after the monoclonal. We can produce our own EPO without much effort and have it at very low cost to pursue the monoclonal. We are seeking additional funds to R&D the monoclonal. Thus, the monoclonal/diagnostic will be part of the package that is available to the company that pursues the US market with us. That diagnostic market could be 60 million dollars or more per year.

In conclusion, it is our intent to enter a relationship with a strong drug company which meets our modest and reasonable needs. We are a small start up biotech firm. We are still negotiating for lab space to do the monoclonal and development work to further the product. We would look forward to a relationship on this product with a strong drug company. The markets for Japan, Europe and the rest of the world are also available for a distributor at this time. We would be pleased to answer any questions you may have. We have literature on EPO that has been published, as well as information from our senior scientist.

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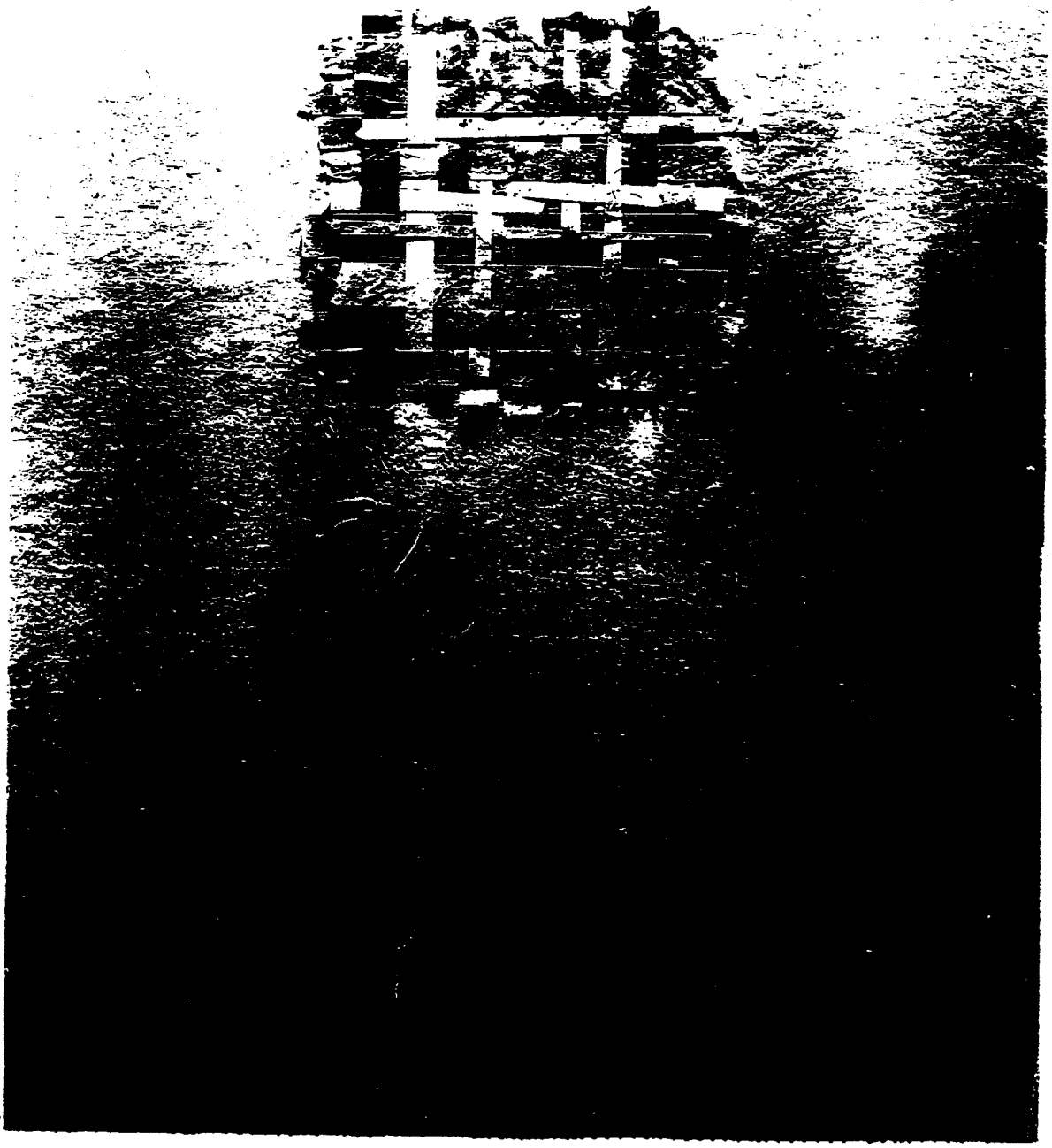

diseases and immunodeficiency. We have supplied bulk protein to Sandoz, Ltd., our collaborative partner on GM-CSF, and expect to initiate human clinical trials for several indications during 1986.

• Erythropoietin, or EPO, is the protein hormone which regulates the red blood cell level in the body. We have produced recombinant EPO which is fully functional in animal model systems. We have supplied bulk protein to Boehringer Mannheim GmbH and Chugai Pharmaceutical Co. Ltd., our collaborative partners on EPO, and expect to see EPO enter human clinical trials for treatment of the anemia due to chronic renal failure in 1986.

• Factor VIII, the clotting factor deficient in hemophilia A patients, has been successfully produced from mass cultures of genetically engineered host cells. The recombinant protein was shown to be efficacious in the treatment of canine hemophilia during collaborative studies with Baxter Travenol Laboratories, Inc., our partner in the commercial development of Factor VIII. We are optimistic that the results of human clinical trials, which should be available during 1987, will demonstrate that recombinant Factor VIII offers a safe and economical alternative to the current plasma-derived therapy for hemophilia.

• Our program in DNA-based diagnostics with Henley Group (formerly part of Allied-Signal, Inc.) is evolving from the base technology development phase to the product development phase. Initial commercial product targets for this program are rapid, highly sensitive, diagnostic kits for human infectious diseases.

• Our process to produce human tissue plasminogen activator in mammalian cells was transferred to Wellcome Biotechnology, Ltd. during 1984. Our partner has successfully scaled the process up to the high level required for commercially feasible production of this clot dissolving agent. We anticipate that human clinical trials will be initiated early in 1986.

Agriculture

• We are applying sophisticated DNA probe techniques in our corn genotypic analysis program to develop molecular finger-printing of the entire corn genome. The technology and the data base ultimately developed in conjunction with this program will allow plant breeders at

184102

United AgriSeeds, Inc., our affiliate, to shorten the time period required to produce new, improved hybrid seed corn varieties.

- Our biological controls program is aimed initially at developing a novel insecticide for Heliothis, a major world agricultural pest. During 1986 we hope to have the basic process for an agricultural product which offers considerable advantages over existing chemical pesticide alternatives and which may be extended to markets beyond Heliothis.

Industrial Biocatalysis

- Efforts in the industrial biocatalysis area have been largely proprietary to date. Such efforts are focused on the development and production of enzymes and cells which may be useful in more efficiently producing products in the chemicals and other related businesses. We presently have one confidential biocatalysis program with Gist-Brocades N.V., a world leader in enzyme and yeast technology; this program is expected to generate a product for commercial use by as early as 1987.

New Commercial Arrangements

As previously stated, we consummated new licensing and development agreements in each of our three business areas of human healthcare, agriculture and industrial biocatalysis during fiscal 1985.

In human healthcare, European and South American rights to erythropoietin were licensed to Boehringer Mannheim. Under this agreement Genetics Institute will be responsible for developing a commercial process for EPO and also has the right to manufacture a substantial portion of Boehringer Mannheim's clinical trial and eventual commercial product requirements. Boehringer Mannheim will be responsible for the conduct of human clinical trials and eventual product marketing and distribution. Licensing fees for product development and contractual fees for the supply of bulk material for EPO clinical trials are substantial and are being realized over the period 1985 to 1987.

In agriculture, we signed an agreement with Uniroyal, Inc. in early 1985 that involves the development of a biological insecticide. Uniroyal agreed to fund research and development

L63 185

To Our Stockholders and Employees,

We are pleased to report continued progress and accomplishment throughout 1985 at Genetics Institute. The following events and achievements highlighted the Company's continued development over the past year:

- We accomplished process and product development milestones during 1985 which have laid the groundwork for commencement of human clinical trials of several potentially significant protein therapeutics in 1986.
- We produced protein material in our pilot plant under Good Manufacturing Practices ("GMP") conditions mandated by the Food and Drug Administration for materials contemplated for use in human clinical trials.
- We signed licensing and development agreements in each of our three business areas of human healthcare, agriculture and industrial biocatalysis.
- We moved in to 125,000 square feet of new facilities encompassing state-of-the-art research and development laboratories and a GMP pilot production plant.
- We continued to reasonably balance revenues and expenses while increasing our total 1985 operating expenditure base to over $22 million, approximately one third of these expenditures related to self-funded research projects and programs for which Genetics Institute owns all rights.

Research and Development Progress

Research and development productivity remains high at Genetics Institute. We believe that all of our major projects and programs are focused on the development of products with significant commercial market potential. In addition, we are confident that we have established strong competitive positions in each of these programs in terms of both technical accomplishment and proprietary considerations.

Human Healthcare

- GM-CSF (granulocyte-monocyte colony stimulating factor), a protein hormone naturally produced by the immune system to regulate the white blood cells which protect the body from infection, has been manufactured in large quantity using proprietary technology developed at Genetics Institute. Results of primate studies have provided dramatic evidence for the therapeutic potential of GM-CSF in the treatment of conditions involving deficiency in the quantity or quality of blood cells. These include the side effects of cancer therapy, infectious

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PRELIMINARY PROSPECTUS
Issued April 11, 1986

1,750,000 Shares

Genetics Institute, Inc.

COMMON STOCK

All of the Shares of Common Stock offered hereby are being sold by the Company. Prior to this offering, there has been no public market for the Common Stock of the Company. It is currently estimated that the initial public offering price per share will be between $25 and $28. See "Underwriters" for a discussion of the factors considered in determining the initial public offering price.

THIS OFFERING INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS".

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

PRICE $ A SHARE

	Price to Public	Underwriting Discounts and Commissions (1)	Proceeds to Company (2)
Per Share	$	$	$
Total (3)	$	$	$

(1) See "Underwriters" for information on indemnification provided by the Company.
(2) Before deducting expenses, estimated at $, payable by the Company.
(3) The Company has granted to the Underwriters an option, exercisable within 30 days of the date hereof, to purchase up to an aggregate of 262,500 additional Shares at the price to public less underwriting discounts and commissions for the purpose of covering over-allotments, if any. If the Underwriters exercise such option in full, the total price to public, underwriting discounts and commissions and proceeds to Company will be $, $ and $, respectively. See "Underwriters".

The Shares are offered, subject to prior sale, when, as and if accepted by the Underwriters named herein and subject to approval of certain legal matters by Davis Polk & Wardwell, counsel for the Underwriters. It is expected that delivery of certificates for the Shares will be made on or about May , 1986 at the office of Morgan Stanley & Co. Incorporated, 55 Water Street, New York, New York, against payment therefor in New York funds.

MORGAN STANLEY & CO. *Incorporated* ***ROBERTSON, COLMAN & STEPHENS***

May , 1986

H65 187

PROSPECTUS SUMMARY

The following information is qualified in its entirety by the detailed information and financial statements appearing elsewhere in this Prospectus.

THE COMPANY

Genetics Institute, Inc. is engaged principally in the development of human pharmaceutical and diagnostic products using recombinant DNA and related technologies. It is also developing products for use in agriculture and industrial processing. The Company is currently conducting approximately 20 research and development programs. Four of the most advanced programs involve the following health care products which have been developed in collaboration with corporate sponsors:

Granulocyte-Monocyte Colony Stimulating Factor (GM-CSF): A protein that stimulates the production and activity of certain white blood cells and may be useful in mitigating certain side effects of cancer therapy and in the treatment of certain immunodeficiencies;

Erythropoietin (EPO): A protein that stimulates the production of red blood cells and may be useful in treating certain types of anemia;

Antihemophilic Factor (Factor VIII:C): A blood clotting protein that may be useful in treating the predominant form of hemophilia; and

Tissue Plasminogen Activator (tPA): An enzyme that naturally aids in dissolving blood clots and may be useful in the treatment of heart attack and pulmonary embolism.

GM-CSF, EPO and tPA are expected to enter human clinical trials in 1986, and Factor VIII:C is expected to enter such trials in 1987.

The Company has financed a large portion of its research and development activities through sponsored research and collaboration agreements with major corporate sponsors, including Allied-Signal, Inc., Baxter Travenol Laboratories, Inc., Boehringer Mannheim GmbH, Chugai Pharmaceutical Co., Ltd., Sandoz Ltd. and Wellcome Biotechnology, Limited. Four of these sponsors are investors in the Company.

In fiscal 1985, approximately 30%, or $7 million, of the Company's total operating expenses (consisting primarily of research and development costs) was attributable to self-funded research programs. Genetics Institute intends to continue to increase the amounts it dedicates to the development of self-funded proprietary products, and plans over the long term to become a fully integrated manufacturer and marketer of certain of its self-funded products.

The Company operates a pilot production plant and is currently producing certain therapeutic products in quantities sufficient for the commencement of human clinical trials. The Company is planning, either alone or with a joint venture partner, to construct and equip a facility for the manufacture of products in commercial quantities.

THE OFFERING

Common Stock offered	1,750,000 shares
Common Stock to be outstanding after the offering	10,475,806 shares
Use of proceeds	For increased funding of proprietary research and development, construction of a manufacturing facility and working capital.
Proposed NASDAQ symbol	GENI

~~46~~ 188

THE COMPANY

Genetics Institute, Inc. ("Genetics Institute" or the "Company") is engaged principally in the development of human pharmaceutical and diagnostic products using recombinant DNA and related technologies. It is also developing products for use in agriculture and industrial processing.

The Company is currently conducting approximately 20 research and development programs. Four of the most advanced programs involve the following health care products which have been developed in collaboration with corporate sponsors:

- Granulocyte-Monocyte Colony Stimulating Factor (GM-CSF) — a protein that stimulates the production and activity of certain white blood cells and may be useful in mitigating certain side effects of cancer therapy and in the treatment of certain immunodeficiencies
- Erythropoietin (EPO) — a protein that stimulates the production of red blood cells and may be useful in treating certain types of anemia
- Antihemophilic Factor (Factor VIII:C) — a blood clotting protein that may be useful in treating the predominant form of hemophilia
- Tissue Plasminogen Activator (tPA) — an enzyme that naturally aids in dissolving blood clots and may be useful in the treatment of heart attack and pulmonary embolism

GM-CSF, EPO and tPA are expected to enter human clinical trials in 1986, and Factor VIII:C is expected to enter such trials in 1987.

The Company was founded in December 1980 by Dr. Mark S. Ptashne, who was then Chairman of the Department of Biochemistry and Molecular Biology at Harvard University, and Dr. Thomas P. Maniatis, who is currently Chairman of that Department. Dr. Ptashne and Dr. Maniatis have, since the Company's inception, served as scientific advisers and have aided in attracting and retaining key scientific talent to the Company. Shortly after the founding of the Company, Gabriel Schmergel was recruited to serve as President and Chief Executive Officer of the Company. Mr. Schmergel is the former President of the International Division of Baxter Travenol Laboratories, Inc. The Company's research efforts are headed by Dr. Robert I. Kamen, Vice President — Research, who is a former head of the Transcription Laboratory at the Imperial Cancer Research Fund Laboratory, London, England.

The Company has financed a large portion of its research and development activities through sponsored research and collaboration agreements. These arrangements provided the Company with the funding and scientific projects necessary to assemble a broad-based group of scientific and technical personnel, to accelerate the development of its core technologies and to pursue a wide range of product opportunities. Under these arrangements, the Company is entitled to receive royalties based on product sales. The Company's corporate sponsors include Allied-Signal, Inc., Baxter Travenol Laboratories, Inc., Boehringer Mannheim GmbH, Chugai Pharmaceutical Co., Ltd., Sandoz Ltd. and Wellcome Biotechnology, Limited. Four of these sponsors are investors in the Company.

Genetics Institute intends to continue to pursue collaborative arrangements in those areas where it believes corporate sponsors may enhance the Company's ability to exploit its technology. At the same time, the Company plans to continue to increase the resources it dedicates to the development of self-funded proprietary products. Through such self-funding, the Company believes it can retain greater flexibility in structuring and implementing its development programs and increase its participation in future product revenues — either by commercializing products itself or by carrying products to a more advanced stage of development before licensing them to others. The Company plans, over the long term, to become a fully integrated manufacturer and marketer of certain of its current and future self-funded products in the areas of human pharmaceuticals and plant agriculture. In fiscal 1985, approximately 30%, or $7 million, of the Company's total operating expenses (consisting primarily of research and development costs) was attributable to self-funded research programs.

167 189

The Company operates a pilot production plant and is currently producing certain therapeutic products in quantities sufficient for the commencement of human clinical trials. The Company is planning, either alone or with a joint venture partner, to construct and equip a facility for the manufacture of products in commercial quantities. See "Business — Manufacturing".

The principal executive offices of the Company are located at 87 CambridgePark Drive, Cambridge, Massachusetts 02140, and the Company's telephone number is (617) 876-1170. Unless otherwise indicated, all references in this Prospectus to the Company include the Company and its wholly-owned subsidiary, Genetics Institute, Inc. of Japan.

RISK FACTORS

The following risk factors should be carefully considered in evaluating the Company and its business prospects before purchasing the shares offered by this Prospectus:

Early Stage of Product Development. Genetics Institute has not yet generated revenues from the commercialization of products. Most of the products currently under development by the Company will require significant development, laboratory and clinical testing and investment prior to their commercialization. While some of the Company's products have been tested in preclinical laboratory and animal studies, none of these products has been tested in humans. Results obtained in these preclinical studies are not necessarily indicative of results that will be obtained in human clinical testing. Genetics Institute does not expect products under development to be available for commercial sale or use for several years. There can be no assurance that such products will be successfully developed, prove to be safe and efficacious in clinical trials, meet applicable regulatory standards, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed.

Absence of Operating Profits. The Company has incurred increasing losses from operations over the past three fiscal years. The Company's results of operations have fluctuated from period to period due to changes in amounts of funding under its sponsored development agreements and changes in the amount of expenditures committed to self-funded research and development programs. The Company expects to continue to increase the amounts it dedicates to self-funded research and development programs, which may contribute to continuing losses from operations. The Company's operating results may also be adversely affected if the Company does not enter into sponsored development agreements for new research projects to replace existing programs which are either completed or cancelled. The Company's development agreements can generally be cancelled on relatively short notice if certain objectives are not met or, in some cases, for reasons unrelated to the Company's research and development progress. The Company's results of operations may continue to fluctuate in the future and the Company expects to continue to incur operating losses over the next several years.

Dependence on Corporate Sponsors. The Company's existing development agreements generally provide the Company's corporate sponsors with exclusive rights to manufacture and market the developed products. Assuming the Company is able to successfully develop one or more of the products currently under development, the Company's revenues from product sales will depend, in large part, upon the efforts and abilities of its corporate sponsors to perform clinical testing, obtain regulatory approvals, market and, in most cases, manufacture the Company's products. The amount and timing of resources devoted to these activities will be controlled by the corporate sponsors. Such sponsors will have certain discretion in deciding whether or not to commercialize the products, and may develop or market products competitive with those of the Company. There can be no assurance that the corporate sponsors will actively market, or have the financial means or incentives to actively market, the products developed by the Company. If and when product sales commence, the Company's revenues with respect to products developed for its corporate sponsors will generally be limited to royalties based on product sales.

The Company has granted certain corporate sponsors exclusive rights to fund and exploit developed technology in the fields of immune mediators (including GM-CSF) and diagnostics. To the extent that such corporate sponsors are unwilling to fund new projects initiated by the Company in fields of use where exclusive rights have been granted, the Company may be unable to develop collaborative relationships and to obtain funding from other corporate sponsors to conduct such projects.

Patents. Genetics Institute has filed applications for a number of patents. There can be no assurance that these patents will be issued to the Company or that any issued patents will provide the Company with significant protection against competitors.

The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions. A number of products and processes important to the Company's business, such as GM-CSF, EPO, Factor VIII:C and tPA, are subject to this uncertainty. Competitors have filed applications for, or have been issued, patents and may obtain additional patents and other proprietary rights relating to products or processes competitive with those of the Company. The scope and validity of such patents, the extent to which the Company or its corporate sponsors may be required to obtain licenses under any such patents or other proprietary rights and the cost and availability of such licenses are presently unknown. No assurance can be given that any licenses required under any such patents or proprietary rights will be made available, or if available, on acceptable terms. If the Company's corporate sponsors are required to pay royalties or make similar payments to a third party in order to obtain any such licenses which are required to market and sell the products developed for such sponsors, such sponsors are generally entitled to deduct a portion of such payments from royalties otherwise payable to the Company. See "Business — Patents and Proprietary Rights".

Technological Change and Competition. The Company's industry is subject to rapid and significant technological change. Competitors engaged in all areas of biotechnology in the United States and abroad are numerous and include, among others, major pharmaceutical, agricultural, energy, food and chemical companies, specialized biotechnology firms, universities and other research institutions.

The Company believes that it is likely to encounter significant competition with respect to the principal pharmaceutical products under development by the Company. Companies which are able to complete human clinical trials, obtain required regulatory approvals, and commence commercial sales of their products before their competitors are able to do so may achieve a significant competitive advantage. Certain of the Company's competitors have commenced human clinical trials for products similar to those under development by the Company, including EPO and tPA. See "Business — Competition".

Many of the large firms involved in or expected to become involved in biotechnology have substantially greater resources than the Company. There can be no assurance that developments by others will not render the Company's products or technologies obsolete or non-competitive.

Capital Needs. The Company may require substantial additional funding to successfully develop its products. The Company currently has no commercial manufacturing facility, no internal capability to conduct human clinical trials and no sales organization. The Company is planning to develop, either alone or through a joint venture partner, commercial manufacturing capabilities. It may also decide to conduct human clinical trials and market certain of its products. The establishment or expansion of such commercial manufacturing and clinical testing capabilities and the establishment of marketing and distribution channels will require substantial additional funds. There can be no assurance that such funds will be available or, if available, on terms satisfactory to the Company.

Retention of Key Personnel. Because of the specialized nature of the Company's business, the Company's success will depend, in large part, on its continued ability to attract and retain highly qualified scientific and business personnel and on its ability to develop and maintain relationships with leading research institutions. Competition for such personnel and relationships is intense.

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BUSINESS

Overview

Genetics Institute is engaged principally in the development of human pharmaceutical and diagnostic products using recombinant DNA and related technologies. It is also developing products for use in agriculture and industrial processing.

Genetics Institute has financed a large portion of its research and development activities through sponsored research and collaboration agreements. The Company intends to continue to pursue collaborative arrangements in those areas where it believes corporate sponsors may enhance the Company's ability to exploit its technology. At the same time, the Company plans to continue to increase the resources it dedicates to the development of self-funded proprietary programs. Through such self-funding, the Company believes that it can retain greater flexibility in structuring and implementing its development programs and increase its participation in future product revenues — either by commercializing products itself or by carrying products to a more advanced stage of development before licensing them to others. The Company plans, over the long term, to become a fully integrated manufacturer and marketer of certain of its current and future self-funded products in the areas of human pharmaceuticals and plant agriculture. In fiscal 1985, approximately 30%, or $7 million, of the Company's total operating expenses (consisting primarily of research and development costs) was attributable to self-funded research programs.

The Company operates a pilot production plant and is currently producing certain therapeutic products in quantities sufficient for commencement of human clinical trials. The Company is planning, either alone or with a joint venture partner, to construct and equip a facility for the manufacture of products in commercial quantities. See "Business — Manufacturing".

Products Under Development

Human Pharmaceutical Products

GM-CSF and Other Immune Mediators. Granulocyte-monocyte colony stimulating factor is a lymphokine (immune regulatory protein) which is produced by cells of the immune system as part of the natural defense against infections. GM-CSF stimulates the production and activity of a variety of different types of white blood cells. It may also be important in stimulating the production of red blood cells.

Genetics Institute and its corporate sponsor, Sandoz Ltd. ("Sandoz"), have separately demonstrated in preclinical studies that recombinant GM-CSF can significantly elevate white blood cell levels in normal monkeys. The Company has also used GM-CSF to increase circulating white blood cell levels in a small number of monkeys with a virally induced white blood cell deficiency. These studies suggest that GM-CSF may have therapeutic potential for treating the symptoms of certain blood cell deficiencies in humans. Sandoz is planning human clinical trials to test the use of GM-CSF in the treatment of blood cell deficiencies such as those caused by cancer chemotherapy, bone marrow transplantation and acquired immune deficiency syndrome (AIDS). These clinical trials are expected to commence in 1986.

Genetics Institute believes that it was the first company to characterize the human GM-CSF protein and to isolate and express human GM-CSF DNA. The Company has produced GM-CSF from a mammalian cell system in its pilot production plant in quantities sufficient for Sandoz to commence human clinical trials.

Under its development agreement with the Company, Sandoz has the exclusive right to manufacture and market GM-CSF on a worldwide basis and is responsible for conducting the clinical trials for GM-CSF. The Company has granted Sandoz exclusive rights and rights of first refusal until 1992 to fund research and development in the fields of lymphokines, monokines and other immune mediators, and the Company is entitled to receive royalties from Sandoz based on sales of GM-CSF and other

~~190~~ 192

products developed under this agreement. In the course of its research program for Sandoz, the Company has explored the feasibility of developing other immune mediators and is currently working to identify and characterize several additional products which it believes may have therapeutic value in regulating the human immune system. Sandoz provided approximately 19%, 23% and 17% of the Company's revenues in fiscal 1983, 1984 and 1985, respectively, and is an investor in the Company.

Erythropoietin. EPO is a protein which is normally synthesized by the kidney and which stimulates the production of red blood cells by the bone marrow. Deficient production of EPO results in decreased red blood cell production and therefore anemia. The Company believes that many patients with chronic kidney disease, including many of those undergoing hemodialysis, suffer from anemia caused primarily by deficient EPO production. It is estimated that there are approximately 75,000 patients in the United States undergoing hemodialysis, of which approximately 90% also suffer from anemia. The only current treatment for this form of anemia is repeated blood or red cell transfusions, which may expose the patient to various side effects and the risk of contracting infectious diseases including hepatitis or AIDS. EPO may provide anemic dialysis patients with an alternative to blood transfusions and may have additional applications in the treatment of certain other anemias.

Genetics Institute has cloned DNA encoding EPO, commenced pilot scale production of EPO using a mammalian cell expression system and demonstrated that its EPO stimulates red blood cell production in laboratory animals. The development of EPO products is being pursued by the Company in collaboration with Chugai Pharmaceutical Co., Ltd. ("Chugai") and Boehringer Mannheim GmbH ("Boehringer Mannheim"). Chugai has an exclusive royalty-bearing license to manufacture and market EPO in the Far East (except for China) and North America. Boehringer Mannheim has an exclusive royalty-bearing license to manufacture and market EPO in Europe, South America, Africa and the Middle East. The Company has retained the right to supply Boehringer Mannheim with all of its requirements of EPO for three years after the market introduction of EPO and a portion of its requirements thereafter. It is currently expected that Chugai and Boehringer Mannheim will commence human clinical trials of EPO in 1986 for the treatment of anemia due to chronic kidney failure. Chugai provided approximately 27% of the Company's revenues in fiscal 1985 and is an investor in the Company.

Factor VIII:C. Factor VIII:C is the blood clotting protein which is deficient in persons who suffer from hemophilia A, an inherited disease. Hemophiliacs have impaired blood clotting capability and therefore can suffer from severe hemorrhage after injury and from chronic internal bleeding.

Current hemophilia therapy uses concentrates of Factor VIII:C that are processed from donor-derived blood. This therapy entails the risk of exposure to infectious diseases and is also often too costly for prophylactic treatment.

Genetics Institute has isolated the DNA encoding human Factor VIII:C and has expressed the protein in mammalian cells. In certain preclinical tests undertaken by the Company in collaboration with its corporate sponsor, Baxter Travenol Laboratories, Inc. ("Baxter Travenol"), the efficacy of the Company's Factor VIII:C protein has been demonstrated in dogs with hemophilia A. The Company is currently focusing on scale-up needed for the production of Factor VIII:C for preclinical and clinical trials and on the development of a cost-effective commercial scale process for this product. It is currently expected that Baxter Travenol will commence human clinical trials for this product in 1987.

Under its development agreement with the Company, Baxter Travenol has been granted an exclusive worldwide royalty-bearing license to manufacture and market the Company's recombinant Factor VIII:C. Subject to certain conditions, the Company has a nonassignable right to manufacture a portion of Baxter Travenol's requirements for this product. The Company has granted Baxter Travenol certain rights of first refusal until 1987 with respect to certain products in the blood protein field, and until 1992 with respect to a genetically engineered second generation Factor VIII:C product. Since the commencement of their collaborative relationship in 1982, the Company has worked on the development of certain other blood protein products and the initial development of tPA in collaboration with Baxter Travenol. Baxter Travenol provided approximately 64%, 54% and 21% of the Company's revenues in fiscal 1983, 1984 and 1985, respectively, and is an investor in the Company.

AA 193

The Company has obtained preliminary design and engineering specifications for the construction of a manufacturing facility capable of producing recombinant DNA products in commercial quantities. The Company expects that in late 1986 it will begin to commit funds for the construction of this facility, which the Company plans to locate in New England. The Company expects that the cost of constructing and equipping this facility may approximate $20 million and that this facility will not become operational before late 1988. The Company may build its manufacturing facility either alone or with a joint venture partner. The Company is currently negotiating with a major international pharmaceutical company to form a joint venture for the construction and operation of such facility. However, there can be no assurance that this joint venture will be established.

Development and License Agreements

Genetics Institute has entered into development and license agreements with various corporate sponsors. See "Business — Products under Development". While the terms of each agreement differ, the agreements generally provide that Genetics Institute will perform research on a specific product or in a specific field and will use its best efforts to develop a specified product or group of products. Under most of the development agreements, the Company is either reimbursed for its research and development costs or paid fixed fees for attaining specified technical benchmarks. Some of the agreements provide for additional cash payments by the sponsor upon the achievement by the Company of certain product development objectives.

Generally, upon the completion of the Company's research and development efforts, the corporate sponsor agrees to use its best or reasonable efforts, subject to certain conditions, to conduct clinical testing and obtain regulatory approvals and to manufacture and market the developed product. Under most of the agreements, the corporate sponsor acquires the exclusive right to exploit the developed technology for specified products or within specified fields of use, and the Company retains the right to use such technology for other products or outside such fields of use. Genetics Institute is generally entitled to receive royalties based on sales of products derived from the technology developed by the Company. Royalty rates for patented products in some cases are higher than those for unpatented products. Genetics Institute has retained the right, subject to certain conditions, to manufacture commercial quantities of products pursuant to its agreements with Baxter Travenol (relating to Factor VIII:C) and Boehringer-Mannheim (relating to EPO), although it does not currently have the capacity to undertake such manufacturing.

Patents and Proprietary Rights

As of March 1, 1986, the Company had on file approximately 210 patent applications worldwide, of which 54 were on file in the United States. To date, the Company has been issued two United States patents. There can be no assurance as to how many patents will be issued to the Company or whether any issued patents will provide the Company and its corporate sponsors with significant protection against competitors. United States patent office interference proceedings are likely with respect to a number of the Company's patent applications, and the costs of such proceedings may be significant. Moreover, there can be no assurance that any patents issued to the Company will not be infringed upon or designed around by others.

The patent position of biotechnology firms generally is highly uncertain and involves complex legal and factual questions. A number of products and processes currently under development by the Company, such as GM-CSF, EPO, Factor VIII:C and tPA, are subject to this uncertainty. Competitors have filed applications for, or have been issued, patents and may obtain additional patents and other proprietary rights relating to products or processes competitive with those of the Company. The scope and validity of such patents are presently unknown. Companies who have or obtain patents relating to products or processes competitive with those of the Company could bring legal actions against the Company or its corporate sponsors claiming damages and seeking to enjoin them from manufacturing, marketing and, in some countries other than the United States, clinically testing the affected product. If any such action were successful, in addition to any potential liability for damages, the Company or

its sponsor would be required to obtain a license in order to continue to manufacture or market the affected product. No assurance can be given that the Company or its corporate sponsor would be able to prevail in any such action or that any license required under any such patent would be made available or, if available, on acceptable terms. See "Business — Products Under Development — Tissue Plasminogen Activator".

Existing patents, including several owned by competitors of the Company, claim basic aspects of genetic engineering technology. A number of pending patent applications filed by such competitors make similar claims. It is unclear whether patents will issue from these applications, or whether the broad claims made in such applications will be allowed. If broad claims of existing or future patents are upheld as valid by courts, certain companies whose business consists of genetic engineering, such as Genetics Institute, would be required to obtain licenses. There can be no assurance that such licenses will be available or, if available, on acceptable terms. If the Company's corporate sponsors are required to pay royalties or make similar payments to a third party in order to obtain any such licenses which are required to market and sell the products developed for such sponsors, such sponsors are generally entitled to deduct a portion of such payments from royalties otherwise payable to the Company. In a few cases, the Company is required to indemnify the corporate sponsor against certain costs or liabilities incurred by the sponsor as the result of any patent infringement or similar claim asserted by a third party with respect to technology or products developed by the Company.

The Company intends to continue to apply for patent protection in appropriate cases. However, the Company believes that it may be better served in certain instances by relying on trade secret protection and continuing technological development to maintain its competitive position. All key employees and consultants of the Company, as well as its corporate sponsors, have agreed to maintain the confidentiality of the Company's proprietary information. The Company's sponsors may be competitors of the Company with respect to products other than those covered by their development agreements with the Company and many of the Company's consultants may be engaged in research projects outside the scope of their consulting agreements with the Company. There can be no assurance that the Company's confidentiality agreements will be honored or that others will not independently develop similar or superior technology.

The Company has entered into agreements with certain companies and institutions, including Stanford University and Harvard University, under which the Company has obtained royalty-bearing licenses to use certain products and processes. The Company cannot at this time make a meaningful estimate of its total future costs under these licenses.

Government Regulation

The production and marketing of the Company's products and its ongoing research and development activities are subject to regulation by numerous governmental authorities in the United States and other countries.

The federal government oversees certain recombinant DNA research activity through the National Institutes of Health guidelines for research involving recombinant DNA molecules (the "NIH Guidelines"). The Company voluntarily complies with the NIH Guidelines which, among other things, restrict or prohibit certain recombinant DNA experiments and establish levels of biological and physical containment of recombinant DNA molecules that must be met for various types of research.

Pharmaceutical products intended for therapeutic or diagnostic use in humans are governed by FDA regulations in the United States and by comparable agency regulations in foreign countries. The process of obtaining FDA approval for a new human drug or biological product is likely to take a number of years and requires the expenditure of substantial resources.

The steps required before a new human pharmaceutical product can be produced and marketed include preclinical studies, the filing of an Investigational New Drug ("IND") application, human clinical trials and the approval of a New Drug Application ("NDA"). Preclinical studies are conducted

in the laboratory and in animal model systems to gain preliminary information on the drug's efficacy and identify significant safety problems. The results of these studies are submitted to the FDA as part of the IND application before approval can be obtained for the commencement of testing in humans. The human clinical testing program is designed to collect data relating to the dosing and side effects of the new product, the product's efficacy and comparisons with currently available drugs or biologics. Upon completion of clinical testing, if the applicant believes the drug is safe and effective under specific conditions, it must submit an NDA to the FDA. The NDA includes summaries of the manufacturing and testing processes, preclinical studies and clinical trials. FDA approval of the NDA is required before the applicant may market the new product.

Even after initial FDA approval has been obtained, further studies may be required to provide additional data on safety or to gain approval for the use of a product as a treatment in clinical indications other than those for which the product was initially tested. Also, the FDA may require post-marketing testing and surveillance programs to monitor the drug's effects. Side effects resulting from the use of pharmaceutical products may prevent or limit the further marketing of the products.

At present, pharmaceutical products generally may not be exported from the United States for other than research purposes until the company obtains FDA approval for marketing in the United States. While certain pending federal legislation would provide some relief from these restrictions, there can be no assurance that such legislation will be enacted.

The field testing, manufacturing and marketing of various agricultural products, such as new crop strains or insecticides, may require the approval of the United States Department of Agriculture ("USDA"), as well as the Environmental Protection Agency. The commercial manufacture and marketing of animal health products generally requires approval by the USDA or the FDA.

In addition, Genetics Institute is subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Federal Insecticide, Fungicide and Rodenticide Act and the Research Conservation and Recovery Act, national restrictions on technology transfer, import, export and customs regulations and other present or possible future local, state or federal regulation. From time to time other federal agencies and Congressional Committees have indicated an interest in implementing further regulation of biotechnology applications. The Company is unable to predict whether any such regulations will be adopted or whether, if adopted, such regulations will adversely affect the Company's business.

Competition

Competition in the biotechnology industry is intense. Genetics Institute competes with specialized biotechnology firms in the United States and elsewhere, as well as an increasing number of large pharmaceutical, agricultural, energy, food and chemical companies which are seeking to apply biotechnology to their operations.

Competition is particularly intense in the area of pharmaceutical and diagnostic products. Many biotechnology companies have focused their development efforts in these areas, and many major pharmaceutical companies have developed or acquired substantial internal biotechnology capabilities or have made commercial arrangements with other biotechnology companies.

The Company believes that it is likely to encounter significant competition with respect to the principal pharmaceutical products currently under development by the Company. Companies which are able to complete human clinical trials, obtain required regulatory approvals, and commence commercial sales of their products before their competitors are able to do so may achieve a significant competitive advantage. One of the Company's competitors has announced that it has commenced human clinical testing of a recombinant EPO product, and another competitor is in an advanced clinical testing stage of a recombinant tPA product.

Significant levels of research in biotechnology are carried out in universities and other non-profit research organizations. These entities have become increasingly active in seeking patent protection

and licensing revenues for their research results. Moreover, these institutions continue to compete with companies, such as Genetics Institute, in recruiting skilled scientific personnel.

Genetics Institute believes that its ability to compete effectively in the biotechnology industry will be based on its ability to create and maintain scientifically advanced technology, attract and retain scientific personnel with a broad range of expertise, obtain patent protection or otherwise develop proprietary products or processes, obtain required government approvals on a timely basis, select and pursue research and development projects in areas in which significant market opportunities exist or are likely to develop, manufacture its products on a cost-effective basis and successfully market its products either alone or through third parties. Many of the Company's competitors have substantially greater financial resources, experience, manufacturing facilities and sales organizations than Genetics Institute.

Human Resources

As of March 1, 1986, the Company had 255 full-time employees, of which 172 were engaged in research, process development and product development, 54 in operations support and 29 in general administration. In addition, as of such date, the Company had approximately 43 scientific consultants on retainer. Of the Company's employees, 68 have Ph.D. degrees and another 51 hold other advanced degrees.

None of the Company's employees is covered by a collective bargaining agreement. Genetics Institute considers its relations with its employees to be excellent.

The Company's ability to maintain its competitive position will depend, in part, upon its continued ability to attract and retain qualified scientific and managerial personnel. Competition for such personnel is intense.

Facilities

The Company's executive, administrative, research and development and production facilities, comprising approximately 125,000 square feet, are located in three buildings in Cambridge, Massachusetts. Construction or renovation of all three buildings was completed during 1985.

Each of the three buildings is leased. The lease term for the Company's principal facility extends through 2009. The Company has options to extend the terms of the leases on the other two buildings through 1994 and 1997. In addition, in mid-1985 the Company opened a branch office in Tokyo where it leases approximately 2,000 square feet of office space. This branch office was established to develop business opportunities in Japan. See Note 8 of Notes to Consolidated Financial Statements for information regarding the Company's obligations under these leases.

Litigation

In December 1985, Genetics Institute was joined as a defendant in litigation previously commenced by John Moore against the Regents of the University of California (the "University") and others in the Superior Court of the State of California for the County of Los Angeles. The plaintiff is seeking to recover unspecified damages against all of the defendants as the result of research conducted on cells derived from the plaintiff's surgically-removed cancerous spleen. These cells had been made available to Genetics Institute under an agreement with the University and were used by the Company in the course of its research in the field of immune mediators. This litigation is presently in the discovery stage. The Company believes that the claims against the Company lack merit and will not have a material adverse effect on the Company's business or financial condition.