

# EXHIBIT 10

REC'D S.E.C.  
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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Technical Assistance Services  
Baltimore, Maryland

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

For the fiscal year ended November 30, 1989 Commission file no. 0-14587

GENETICS INSTITUTE, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

04-2718435  
(I.R.S. Employer  
Identification No.)

87 Cambridge Park Drive, Cambridge, MA  
(Address of principal executive offices)

02140  
(Zip Code)

Registrant's telephone number, including area code (617) 876-1170

Securities registered pursuant to Section 12(b) of the Act:

None

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

Common Stock, \$0.01 par value  
(Title of class)

\$4.00 Convertible Exchangeable Preferred Stock, \$1.00 par value  
(Title of class)

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

The approximate aggregate market value of voting stock held by non-  
affiliates of the registrant was \$169,605,944 as of February 15, 1990. (A)

The number of shares of Common Stock outstanding as of February 15, 1990  
was 14,177,770.

Page 1 of 423  
Exhibit Index Begins on Page 42

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SUBJECT TO PROTECTIVE ORDER

Exhibit 10.29

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CONFIDENTIAL MATERIAL OMITTED AND  
FILED SEPARATELY WITH THE SECURITIES  
AND EXCHANGE COMMISSION.  
ASTERISKS DENOTE SUCH OMISSIONS.

WHEREAS, the PARTIES have entered into a Development and License Agreement for pharmaceutical compositions containing the chemical compound known as EPO of October 8, 1985 (hereinafter referred to as "LICENSE AGREEMENT") and

WHEREAS, BM has obtained manufacturing and marketing rights in the countries of the TERRITORY as listed in the LICENSE AGREEMENT for such pharmaceutical compositions and

WHEREAS, CI has agreed to supply BM with its requirements of INTERMEDIATE, as defined below, necessary for the production and formulation of pharmaceutical compositions containing the chemical compound EPO and

WHEREAS the PARTIES have entered into an agreement of May 5, 1988 which is superceded by this SUPPLY AGREEMENT.

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth, and other good and valuable consideration, the PARTIES agree as follows:

SECTION 1. DEFINITIONS

1.1 AFFILIATE shall mean any corporation, company, partnership, joint venture and/or firm which controls, is controlled by or is under common control with either PARTY or with either PARTY's shareholders; without limiting the generality of the foregoing, control shall mean:

- a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or share entitled to vote for the election of directors, and
- b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.2 GOVERNMENT REGULATORY AGENCY shall mean the governmental agency in each country in the TERRITORY responsible for reviewing and approving the development or marketing of LICENSED PRODUCTS.

*[Handwritten initials]*  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

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1.3 INTERMEDIATE shall mean the GMP-Material of LICENSED COMPOUND being produced meeting the specifications in accordance with the production and quality control procedures as agreed upon, and produced in GI's production plants in Cambridge and Andover, as outlined in this SUPPLY AGREEMENT and following strictly the Quality Assurance Plan as set forth in Schedule 1.

1.4 KNOW-HOW shall mean all technical information of GI, patentable or otherwise, relating to the expression and production of erythropoietin and as defined in the LICENSE AGREEMENT, Section 1.11.

1.5 LICENSED COMPOUNDS shall mean any and all kinds of human erythropoietin consisting of a polypeptide chain, the amino acid sequence of which is derived from erythropoietin encoding DNA or genomic DNA sequence isolated from human tissues or human cell lines, expressed and produced in mammalian cells and/or other host-vector systems as well as closely related derivatives which, or the making or use of which, is covered by a VALID CLAIM of any of the PATENT RIGHTS and/or embodies any KNOW-HOW.

1.6 LICENSED PRODUCTS shall mean any and all kinds of formulations, mixtures and/or compositions for whatever use which contain LICENSED COMPOUND.

1.7 NET SALES shall mean the amount invoiced (exclusive of value added taxes) by BM to wholesalers or final users of LICENSED PRODUCTS and LICENSED COMPOUNDS, less only a lump sum of % ( % percent) to cover all usual deductions, such as credits for returns, cash, trade or other discounts, transportation charges, allowances, etc.

In case of distribution of the LICENSED PRODUCTS by AFFILIATES or sublicensees of BM, NET SALES shall have the meaning as defined above.

For countries where BM is only represented by unrelated distributors supplied by BM with finished goods, the royalties shall be calculated on BM's NET SALES to such distributor.

NET SALES shall not include any transfer between BM and any of its AFFILIATES or sublicensees for resale but shall include the resale from an AFFILIATE or sublicensee to an independent third party or use by the AFFILIATE or sublicensee.

Any commercial use of the LICENSED COMPOUNDS or LICENSED PRODUCTS by BM, its AFFILIATES or sublicensees in a commercial transaction with a third party, in which no invoice is issued, shall be considered a sale hereunder for royalty and accounting purposes and NET SALES for such use shall be the average price of arm-length sales by BM, its AFFILIATES and sublicensees during the royalty reporting period in which such use occurs, or if no

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such sales occurred in such period, in the last period in which such arms' length sales occurred.

1.8 PARTY shall mean GI or BM; PARTIES shall mean GI and BM.

1.9 PATENT RIGHTS shall mean all patent rights in the TERRITORY corresponding to the US patent applications US Serial Nos. \* and \* and all patents throughout the world based on subject matter used in the PROJECT and required to enable BM to manufacture and/or sell the LICENSED COMPOUND or LICENSED PRODUCT, including any additions, divisions, continuations, continuations-in-part, substitutions, extensions, renewals or reissues thereof or therefore.

1.10 PROJECT shall mean the research program commencing on the effective date of the LICENSE AGREEMENT and terminating with the completion of the Final Benchmark conceived, planned, organized, controlled and performed by GI for development of production technology as well as manufacture of LICENSED COMPOUND by means of recombinant DNA following the latest standard of science and GMP.

1.11 SUPPLY AGREEMENT shall mean this Agreement.

1.12 TERM. This Agreement shall become effective upon full execution and shall continue in full force and effect unless modified or terminated in accordance with any provision hereof for a period of 10 years as of BM's first commercial sale after approval in any country in the TERRITORY and/or the last patent to expire or until expiry of the License granted pursuant to Article 6 of the LICENSE AGREEMENT, whichever is longer. Articles 9.2 and 9.3 of the LICENSE AGREEMENT shall also apply.

1.13 TERRITORY shall mean the countries and territories specified in Schedule B and C of the LICENSE AGREEMENT.

1.14 VALID CLAIM shall mean a claim of an unexpired patent or inventor's certificate which shall not have been withdrawn, cancelled or disclaimed, nor held invalid by a court of competent jurisdiction in an unappealed or unappealable decision.

1.15 WEIGHTED AVERAGE NET SELLING PRICE shall mean the selling price per gram ( \* activity units/mg of protein) of LICENSED PRODUCT communicated to GI by BM on January 31 of each YEAR and defined as total NET SALES of LICENSED PRODUCT over the previous YEAR divided by grams of LICENSED PRODUCT sold by BM, its AFFILIATES and sublicensees over the same period. Schedule 2 of this SUPPLY AGREEMENT illustrates the calculation of WEIGHTED AVERAGE NET SELLING PRICE and its use in calculating payment due GI for supply of INTERMEDIATE.

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1.16 YEAR shall mean the calendar year.

SECTION 2. PURCHASE AND SALE OF INTERMEDIATE

2.1 During the TERM of this SUPPLY AGREEMENT, GI shall make its best reasonable efforts to sell and supply to BM and BM shall purchase from GI such quantity of INTERMEDIATE as BM may require, in accordance with Paragraph 7.2 of this SUPPLY AGREEMENT, during each YEAR of this SUPPLY AGREEMENT, commencing with the execution of this SUPPLY AGREEMENT, subject to the provisions hereinafter set forth.

2.2 GI hereby represents to BM that GI has ability and access necessary to fulfill BM's requirements for the INTERMEDIATE.

2.3 BM shall supply to GI as far as available any data, certifications, and material necessary for GI to obtain and maintain export approval from the U.S..

SECTION 3. INITIAL PRODUCTION AND PURCHASE OF 130 GRAMS INTERMEDIATE AND SUBSEQUENT ORDERS

3.1 BM hereby places an order for 130 grams of INTERMEDIATE to be manufactured at GI's Cambridge facility. GI shall supply this material to BM according to the following special terms and conditions and in accordance with the Erythropoietin Quality Assurance Plan as defined in Schedule 1.

3.2 BM shall pay GI for this INTERMEDIATE at the rate of US \$ per gram in recognition of a) the significant costs involved in converting such Cambridge facility to a commercial GMP and FDA-inspected manufacturing site, b) its comparatively high operating cost, and c) GI's lost opportunity cost.

3.3 BM agrees to indemnify GI for all losses exceeding \$ of GI's manufacturing revenue which results or arises from an event or occurrence in a facility owned or controlled by GI with respect to the INTERMEDIATE (as described in Section 1.1 of the LICENSE AGREEMENT), arising out of GI's manufacture of the aforesaid 130 grams, except for the portion of any loss which is based solely on GI bad faith or similar conduct. In any event, BM shall not be responsible for GI's losses in any such event. Any such losses must be agreed upon beforehand in writing by BM.

3.4 If a change in the manufacturing process is required by the Committee of Proprietary Medical Products of the European Community or one of its member States (hereinafter referred to as

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CPMP) such that INTERMEDIATE produced by that process cannot be sold by BM, BM shall have the right to suspend production of the 130 gram order at GI until such a time as the necessary process modifications have been made. Quantities already produced shall be shipped and invoiced to BM and paid for by BM. In such event, as soon as possible, the Parties shall review the changes proposed by the CPMP regulatory authorities and shall develop a plan to implement the necessary process modifications at GI.

3.5 GI shall share one-half in the inventory carrying cost of any unused material should first market approval of INTERMEDIATE in the TERRITORY be delayed beyond \* provided, however, that GI's share shall not be more than \* per annum of the value of the inventory and such obligation shall not extend beyond \*

#### SECTION 4. FORECASTING AND ORDERING

4.1 BM's planning procedure for all its supplies is based on a rolling twelve-month forecast whereby BM gives its suppliers a twelve-month forecast for material to be supplied which is updated on a quarterly basis. Beginning on September 1, 1988 and continuing for the TERM of this SUPPLY AGREEMENT, BM shall supply to GI such twelve-month forecasts of BM's anticipated requirements of INTERMEDIATE for the following twelve-month period. Such twelve-month forecasts shall be binding upon GI and BM to the extent that GI shall be obligated to supply up to \* percent of the amount of INTERMEDIATE stated in such forecasts for the applicable twelve-month periods, and BM shall be obligated to purchase at least \* percent of the amount of such forecast for the applicable twelve-month periods.

4.2 Except for the initial order of 130 grams, all orders for INTERMEDIATE by BM shall be made by submission to GI of a purchase order specifying the quantity of INTERMEDIATE ordered. Such purchase orders shall be submitted to GI not later than \* prior to the date on which GI is requested to make the first delivery of INTERMEDIATE.

4.3 GI shall not be required to accept purchase orders calling for delivery of less than \* of INTERMEDIATE or, with respect to any particular twelve-month period, more than \* percent of the amount of INTERMEDIATE set forth in the relevant twelve-month forecast. In the event that, with respect to any particular twelve-month period, BM shall submit purchase orders calling for delivery of less than \* percent of the amount of INTERMEDIATE set forth in the relevant twelve-month forecast, BM shall remain obligated to pay GI for such shortfall in an amount equal to \* times the WEIGHTED AVERAGE NET SELLING PRICE of LICENSED PRODUCT times the amount of INTERMEDIATE that would comprise the balance of \* percent in the relevant twelve-month

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period.

SECTION 5. QUALITY CONTROL

5.1 BM shall analyze each shipment immediately upon receipt. Shipments shall be considered to comply with BM Certificate of Analysis specifications (attached hereto as Schedule 1) unless BM gives GI notice in writing and supporting documentation that it does not consider a particular shipment to comply within \* days of receipt of that shipment. If BM gives GI such notice, GI will thereupon be given access to the shipment in question to conduct its own analysis thereof, and the PARTIES will endeavour to agree amicably as to whether or not the shipment does comply with the specifications.

INTERMEDIATE shall be manufactured in accordance with the Erythropoietin Quality Assurance Plan (Schedule 1). This Quality Assurance Plan may be revised by the PARTIES in order to conform with regulatory changes or procedures in a manner mutually agreed upon by the PARTIES. In particular, compelling regulatory reasons for such modification of the Quality Assurance Plan will be immediately addressed by BM and GI.

5.2 In the event that the PARTIES are unable to agree as to whether or not a given shipment complies with the specifications given in Schedule 1, the question will be submitted to an independent quality control laboratory agreed upon by both PARTIES. In the event that GI concedes or the independent quality control laboratory finds that the shipment in question does not comply with the specifications given in Schedule 1, GI shall promptly and without cost to BM supply BM with the same quantity of INTERMEDIATE complying with the specifications as outlined in this SUPPLY AGREEMENT or otherwise agreed upon in writing as contained in the shipment in question. Such shipment shall satisfy and discharge any claims or potential claims of BM against GI in regard to such shipment. Cost for the independent quality control laboratory shall be borne by the PARTY whose results are wrong.

5.3 During the pendency of a dispute that requires settlement by an independent laboratory under the above Paragraph, GI will make its best reasonable efforts to replace promptly the portion of such shipment under dispute until such dispute is resolved. GI shall endeavour to maintain an emergency inventory of INTERMEDIATE for this purpose of at least the magnitude of the shipment under dispute.

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SECTION 6. PRICES AND PAYMENT

6.1 GI shall invoice BM for each shipment upon delivery of INTERMEDIATE and corresponding GI Certificate of Analysis (Schedule 1). BM shall pay \* of each shipment within x days following receipt by BM of such invoice as well as shipment and shall pay \* of such invoice within # days of receipt of such shipment.

6.2 All shipments shall be made C.I.F. Frankfurt.

6.3 BM shall deliver to GI on January 1 of each year a written report showing its computation of the WEIGHTED AVERAGE NET SELLING PRICE per gram for LICENSED PRODUCT in the TERRITORY over the previous twelve-month period. Such annual WEIGHTED AVERAGE NET SELLING PRICE per gram shall be used by GI in the calculation of payment due from BM hereunder.

6.4 For INTERMEDIATE produced at GI's Cambridge facility exceeding the 130 grams to be supplied pursuant to Section 3.1, above, BM shall pay GI x percent of BM's WEIGHTED AVERAGE NET SELLING PRICE of LICENSED PRODUCT in the TERRITORY or US % per gram of INTERMEDIATE, whichever is greater. However, if the total of the royalties due GI under Section 7.1 of the LICENSE AGREEMENT and the payment for INTERMEDIATE is more than x percent of the WEIGHTED AVERAGE NET SELLING PRICE of LICENSED PRODUCT in the TERRITORY then the PARTIES shall negotiate in good faith a reduced supply price for INTERMEDIATE.

6.5 For INTERMEDIATE produced at GI's Andover facilities, BM shall pay GI % percent of BM's WEIGHTED AVERAGE NET SELLING PRICE OF LICENSED PRODUCTS.

6.6 Should for any compelling regulatory reasons supply of INTERMEDIATE out of Cambridge be necessary, GI shall be obligated to maintain production in the Cambridge facility.

6.7 Except as modified in Paragraphs 6.1-6.5, above, the provisions of Section 8.2 of the LICENSE AGREEMENT shall remain in effect.

6.8 (a) For supply of material pursuant to Paragraph 6.4 of this SUPPLY AGREEMENT, the initial invoice price per gram for INTERMEDIATE shall be US \*

(b) For supply of material pursuant to Paragraph 6.5 of this SUPPLY AGREEMENT, the initial invoice price per gram for INTERMEDIATE shall be agreed upon by the PARTIES prior to placement of the first order. Such initial invoice price per gram shall be calculated as x percent of the WEIGHTED AVERAGE NET SELLING PRICE per gram of LICENSED PRODUCT in the TERRITORY.

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(c) Thereafter, during each December after the first bona fide commercial sale following regulatory approval the initial invoice price per gram of the LICENSED PRODUCT shall be based on the WEIGHTED AVERAGE NET SELLING PRICE per gram of LICENSED PRODUCT in the TERRITORY during the previous twelve-month period.

(d) For supply of material pursuant to either Paragraph 6.4 or 6.5 of this SUPPLY AGREEMENT, any adjustments and resulting payments to GI or BM necessary due to variance between actual payments to GI for INTERMEDIATE in a given YEAR and the calculation of the amount due to GI based on the WEIGHTED AVERAGE NET SELLING PRICE per gram of LICENSED PRODUCT in the TERRITORY over the previous YEAR, shall be settled by January 31 of the following year.

6.9 Monetary conversions from the currency of a foreign country in which INTERMEDIATE is sold into currency of the Federal Republic of Germany shall be made at the average official exchange rate in force in the country over the calendar quarter for which the supplies are made. If there is no such official rate, the conversion shall be made at the rate for such remittances on that date as certified by Deutsche Bank AG, Frankfurt, Federal Republic of Germany. The average shall be computed by dividing the sum of the rates on the first business day of each month of that quarter by three.

6.10 Should the average buying rate of DM per US dollar vary by more than X percent from the current exchange rate X, during a given calendar quarter, then the price to be paid for any supply as calculated at the above-listed exchange rate shall be adjusted by X the excess over said X percent variation to cushion the affect of said fluctuation. The relevant currency exchange rate shall be that listed in the Wall Street Journal.

SECTION 7. TECHNOLOGY TRANSFER AND PRODUCTION RIGHTS

7.1 Technology Transfer

In accordance with Paragraph 8.3 of the LICENSE AGREEMENT, GI undertakes the following activities:

(a) GI will continue to provide documentation relating to its process for manufacturing INTERMEDIATE as soon as available, commencing immediately.

(b) GI will provide certain technical assistance to BM for BM to initiate the manufacturing process at BM's

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facilities.

(c) When practical, GI will invite BM's technical personnel to be present during the production of INTERMEDIATE in the Cambridge facility. Such visit shall be arranged and agreed upon by the technical staff of the PARTIES.

(d) Technical assistance requiring a commitment from GI in excess of \* man-hours will be compensated to GI by BM at US \* per man-month.

7.2 Production Rights

(a) The PARTIES agree to replace Schedule C of the LICENSE AGREEMENT with the following language:

(i) GI shall supply 100 percent of BM's INTERMEDIATE requirements for each of the first three twelve-month periods following the first bona fide commercial sale of LICENSED PRODUCT following approval in any country in the TERRITORY. Thereafter, GI and BM shall each have the right to supply fifty percent of INTERMEDIATE requirements in the TERRITORY in each following twelve-month period.

(ii) Upon twelve months advance written notice to GI, BM can request GI to supply additional quantities of INTERMEDIATE which exceed the quantity otherwise allocated to GI above.

SECTION 8. MANUFACTURE

8.1 If GI is prevented or unable to produce INTERMEDIATE for any reason, BM will instead manufacture 100 percent of its requirements and will, in order to compensate GI for its inability to manufacture INTERMEDIATE, pay GI an additional \* percent royalty on NET SALES pursuant to Section 8.1 of the LICENSE AGREEMENT.

SECTION 9. VALIDATION OF MATERIAL FROM ALTERNATIVE MANUFACTURING SITES

9.1 Both PARTIES shall commit to qualify both Andover and Pensberg as approved manufacturing sources for INTERMEDIATE. GI shall be responsible for supplying BM in time with the necessary documentation relating to the identity and homogeneity of INTERMEDIATE produced from the Andover and Cambridge facilities. BM shall be responsible for all documentation necessary to obtain regulatory approval for both the Andover and the Pensberg facilities in the same Product License Application ("PLA") amendment for all Government Regulatory Agencies. The PARTIES shall agree on a detailed plan to allow timely execution of such PLA.

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SECTION 10. WARRANTY

10.1 GI warrants that any INTERMEDIATE delivered under this SUPPLY AGREEMENT shall conform to the specifications outlined in Schedule 1. GI's sole obligation and BM's sole and exclusive remedy for a breach of the warranty contained in this Section 10.1 shall be limited to replacement of the nonconforming INTERMEDIATE as set forth in Section 5.2.

SECTION 11. MISCELLANEOUS

11.1 This SUPPLY AGREEMENT as well as the LICENSE AGREEMENT including their respective schedules (which schedules are deemed to be a part of this SUPPLY AGREEMENT for all purposes) contains the full understanding of the PARTIES with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. No waiver, alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the PARTIES by their respective officers thereto duly authorized.

11.2 In case of contradiction between this SUPPLY AGREEMENT and Section 8.2 and Schedule C of the LICENSE AGREEMENT, the terms of the SUPPLY AGREEMENT shall control.

11.3 BM shall be responsible for any and all import duties and taxes associated with the supply and shipment and sale of INTERMEDIATE.

11.4 This SUPPLY AGREEMENT shall be governed by and interpreted in accordance with Swiss Law. Any dispute, controversy, or claim arising out of or relating to this SUPPLY AGREEMENT which cannot be amicably settled shall be referred to arbitration held in Zurich, Switzerland in the English language in accordance with the rules of the Chamber of Commerce of Zurich, Switzerland to the exclusion of any other court. The Court of Arbitration shall decide finally and exclusively.

11.5 In the event that either PARTY is prevented from performing or is unable to perform any of its obligations under this SUPPLY AGREEMENT due to any act of God, fire, casualty, flood, war, strike, lockout, failure of public utilities, injunction or any act, exercise, assertion or requirement of governmental authority, including any governmental law, order or regulation or any preliminary injunction permanently or temporarily prohibiting or reducing the level of research, development or production work hereunder or the manufacture, use or sale of LICENSED PRODUCTS; epidemic, destruction of production facilities, riots, insurrection, inability to procure or use materials, labor, equipment, transportation or energy sufficient

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to meet experimentation or manufacturing needs; or any other cause beyond the reasonable control of the PARTY invoking this Section 11.7 if such PARTY shall have used its best efforts to avoid such occurrence, such PARTY shall give notice to the other PARTY in writing promptly, and thereupon the affected PARTY's performance shall be excused and the time for performance shall be extended for the period of delay or inability to perform due to such occurrence.

IN WITNESS WHEREOF, the PARTIES, through their authorized officers, have executed this SUPPLY AGREEMENT as of the 11<sup>th</sup> day of January, 1988.

[Signature]  
BOEHRINGER MANNHEIM GmbH  
pps.

[Signature]  
GENETICS INSTITUTE, INC.

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Schedule 1  
Quality Assurance Plan

I. General

The quality of EPO as a drug manufactured by recombinant DNA technology is substantially determined by the production procedure. therefore, the basis of this Quality Control Agreement is the production procedure (including its process controls) which has been agreed upon by CI and BM, and which will be notified to the authorities in BM's application file. Any deviation from the agreed production and quality control procedures occurring in the course of the production must be brought to BM's attention, so that consequences can be driven jointly.

As basis for the agreed production and quality control procedures the following regulatory guidelines are acknowledged in their current version:

Commission of the European Communities "On the Production and Quality Control of Medicinal Products derived by Recombinant DNA Technology".

Commission of the European Communities "Notice to Applicants for Marketing Authorization for Proprietary Medicinal Products in the Member States of the European Community".

WHO "Acceptability of Cell Substrates for Production of Biologicals".

Pharmaceutical Inspection Convention (PIC) "Guidelines for the Manufacture of Active Pharmaceutical Ingredients (Bulk Drug Substances)".

FDA "Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology".

FDA "Guide to Inspection of Bulk Pharmaceutical Chemical Manufacturing".

*Frederic Engel*  
Dr. Frederic Engel

1 Dec 88  
Date

*M. Engel*  
Prof. Dr. Marion Engel

25. Nov. 88  
Date

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- 13 -

II. Specification of EPO Final Bulk Product

A. GI Certificate of Analysis Assays for Commercial Erythropoietin

Assay<sup>1</sup>

Target specification:<sup>2</sup>

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

Yes GI

\*

\*

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Yes GI  
Yes GI

\*

1 Assays conducted and paid for by Genetics Institute  
2 Units expressed in mg protein

Fredric Bader  
Dr. Fredric Bader

1 Dec 88  
Date

M. Krüger  
Prof. Dr. Dietrich Krüger

15 Nov 88  
Date

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B. AM Certificate of Analysis for Commercial Erythropoietin

<u>Assay</u>	<u>Target Specification</u>
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\*

\*

\*

\*

All assays listed above are conducted in the responsibility of BM, and paid for by BM.

\* In the event that a sample assays \* BM shall re-assay such sample and average the results of the assays.

Frederic Bader  
Dr. Fredric Bader

1 Dec 88  
Date

Mu...  
Name

25 Nov. 88  
Date

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III. Characterization of EPO Final Bulk Product

\*

\*

GI

GI

GI

BK

BH

SM

BH

BH

BH

\*

\*

GI

GI

GI

All Assays will be conducted by Genetics Institute.

*Frédéric Hader*  
Dr. Frédéric Hader

*Dec 24, 1988*  
Date

Prof. Dr. Dietrich Kruger

Date

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IV. Cell Testing (Microbiological Associates and GI)

Adventitious Virus:

Retrovirus: \*

Microbial: \*

Identity: \*

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\* Will not be performed on \* and \*  
 \*\* Will only be performed on \* and \*

Fredric Bador Date: 1 Apr 88  
 Dr. Fredric Bador

D. Neugebauer Date: 25. Nov. 88  
 Prof. Dr. Dierkrich Neugebauer

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- 19 -

<u>Schedule of Call Testings:</u>			<u>Paid By:</u>
KWCSI	Full	*	GI
*	Full	*	GI
*	Full	*	EM
*	Modif.	*	EM
Final:	Modif.	*	GI

*Fredrick Bader*  
 Dr. Fredrick Bader

*December 16, 1988*  
 Date

*M. Kröger*  
 Prof. Dr. Dietrich Kröger

*15. Nov. 88*  
 Date

*HK*

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- 19 -

Schedule 2

CALCULATION OF WEIGHTED AVERAGE NET SALES PRICE  
AND PAYMENT DUE GI FOR SUPPLY OF INTERMEDIATE

ASSUMPTION: BM SELLS 200 million AU LICENSED COMPOUND in YEAR A  
as follows:

		(Millions)	
		AU	\$
*	vials x	* AU/vial (¢*/vial) =	* *
*	vials x	* AU/vial (¢*/vial) =	= *
*	vials x	* AU/vial (¢*/vial) =	* *
		Total	= 200 *

THEREFORE: Total NET SALES YEAR A

= \* x sales = \* x \* = \* million

LICENSED PRODUCT sold YEAR A

= 200 million AU/ \* AU/mg = \* mg

WEIGHTED AVERAGE NET SELLING PRICE in YEAR A

= \* / \* mg = \* /mg

EXAMPLE: For supply of material in YEAR A:

WTD AVERAGE NET SELLING PRICE x \* = SUPPLY PRICE

= \* x \* = \* /mg

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SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Technical Information Services  
Bethesda, Maryland

FORM 10-K

Annual Report Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

For the fiscal year ended November 30, 1989 Commission file no. 0-14587

GENETICS INSTITUTE, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

04-2718435  
(I.R.S. Employer  
Identification No.)

87 CambridgePark Drive, Cambridge, MA  
(Address of principal executive offices)

02140  
(Zip Code)

Registrant's telephone number, including area code (517) 876-1170

Securities registered pursuant to Section 12(b) of the Act:

None

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

Common Stock, \$0.01 par value  
(Title of class)

\$4.00 Convertible Exchangeable Preferred Stock, \$1.00 par value  
(Title of class)

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

The approximate aggregate market value of voting stock held by non-  
affiliates of the registrant was \$369,605,944 as of February 15, 1990. (A)

The number of shares of Common Stock outstanding as of February 15, 1990  
was 12,177,770.

Page 1 of 423  
Exhibit Index Begins on Page 42

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CONFIDENTIAL  
SUBJECT TO PROTECTIVE ORDER