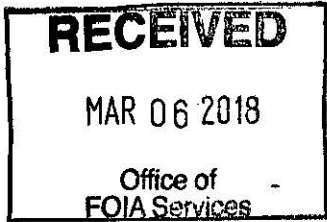


18-03038-E



Debra Smetana
kTMINE
940 West Adams
Suite 100
Chicago, IL 60607

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibit 10.10 to Form 10-Q filed on 08/09/2010 by Genzyme Corp

We authorize \$0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

A handwritten signature in black ink, appearing to be "Debra Smetana". The signature is stylized and cursive.

Debra Smetana



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 16, 2018

Ms. Debra Smetana
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-03038-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this office on March 6, 2018, for access to Exhibit 10.10 to Form 10-Q filed on August 9, 2010 by Genzyme Corp.

The search for responsive records has resulted in the retrieval of 15 pages of records that may be responsive to your request. They are being provided to you in their entirety with this letter.

No fees have been assessed in this instance. If you have any questions, please contact Sonja Osborne of my staff at osbornes@sec.gov or (202) 551-8371. You may also contact Ms. Osborne at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from me at McInerneyR@sec.gov or (202) 551-6249 as a FOIA Public Liaison for this office, or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink that reads "Ray J. McInerney".

Ray J. McInerney
FOIA Branch Chief

Enclosure



LICENSE AGREEMENT

This Agreement, effective as of the first day of January, 1995 (the "Effective Date") by and between:

GENZYME CORPORATION, a corporation organized and existing under the laws of the Commonwealth of Massachusetts and having its principal office at One Kendall Square, Cambridge, Massachusetts 02139 (hereinafter referred to as "GENZYME") and

MOUNT SINAI SCHOOL OF MEDICINE OF THE CITY UNIVERSITY OF NEW YORK, a not-for-profit corporation organized and existing under the laws of the State of New York and having its principal office at One Gustave L. Levy Place, New York, New York 10029 (hereinafter referred to as "MSSM").

WITNESSETH

WHEREAS, MSSM has certain clinical and preclinical data, information and patent rights relating to the production and use of recombinant x-galactosidase A for the treatment of Fabry Disease;

WHEREAS, MSSM desires to have recombinant x-galactosidase A developed and made available for general use to patients for the treatment of Fabry Disease, and for these purposes is willing to grant an exclusive license to GENZYME upon the terms and conditions set forth below;

WHEREAS, GENZYME has or has access to the research and development capability, the manufacturing capacity and the marketing ability needed to manufacture and sell recombinant a galactosidase A therapeutic products in the United States and abroad;

WHEREAS, GENZYME desires to obtain an exclusive, worldwide license under MSSM technology upon the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, the parties hereto agree as follows:

ARTICLE I - DEFINITIONS

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

1.1 "Affiliate" shall mean any corporation which directly or indirectly controls, is controlled by or is under common control with GENZYME, control being the ownership of at least 50% of the outstanding voting stock of such corporation.

1.2 "First Commercial Sale" shall mean the first arms-length transaction pursuant to this Agreement to one or more third party of any Product following receipt of approval to commence manufacturing and selling such Product from the applicable regulatory agency in the applicable country.

1.3 "Licensed Patents" shall mean the United States and foreign patents and patent applications set forth in Schedule A attached hereto and owned or controlled by MSSM, and the United States patents and foreign patents issuing from said United States and foreign patent applications or later-filed foreign applications based upon any of said United States patents and application and any divisions, continuations, continuations-in-part, reissues or extensions of any of the foregoing.

1.4 "Product" shall mean an enzyme replacement product for the treatment of Fabry disease, which includes recombinant x-galactosidase A.

1.5 "Net Sales" shall mean GENZYME's gross invoice price for Product less (a) normal cash and quantity discounts and rebates actually allowed; (b) sales actually made, but deemed uncollectible; (c) sales and excise taxes and duties directly imposed, or other governmental charges; (d) outbound transportation and insurance prepaid or allowed; (e) amounts actually allowed or credited on account of returns; and (f) other contractual allowances such as distribution fees.

1.6 "Technical Information" shall mean any and all proprietary technical data, know-how, information and material relating to the Product, its manufacture or use, and set forth in Schedule B attached hereto.

1.7 "Valid Claim" means a claim of an issued patent within the Licensed Patents that has not expired or been withdrawn, canceled, disclaimed or held invalid by a court or governmental agency of competent jurisdiction in an unappealed or unappealable decision.

ARTICLE II - GRANT

2.1 MSSM hereby grants to GENZYME an exclusive, worldwide right and license, and subject to approval by MSSM, which shall not be unreasonably withheld, the right to sublicense third parties, (a) to make, have made, use, and sell Product under the Licensed Patents; and (b) to use the Technical Information provided by MSSM. MSSM agrees that [it shall not license to any party] other than GENZYME [any technology for the treatment of Fabry disease developed] by or under [the direction of Dr. Robert Desnick] during the term of this Agreement.

2.2 GENZYME agrees to forward to MSSM a copy of any and all sublicense agreements, and further agrees to forward to MSSM annually a copy of royalty reports related to royalties received by GENZYME from its sublicensees during the preceding twelve (12) month period.

2.3 GENZYME agrees to use its reasonable best efforts to substantially manufacture in the United States that Product which is intended for sale in the United States.

ARTICLE III - REPRESENTATIONS AND WARRANTIES

3.1 MSSM represents and warrants that MSSM is the owner of the entire right, title and interest in and to Licensed Patents, and has the right to grant the license as described herein,

and that the grant of such license will not result in a breach of any agreement or other undertaking to which MSSM is a party.

3.2 MSSM represents that the United States Government retains rights to the Licensed Patents and Technical Information. All rights granted to GENZYME hereunder are subject to said retained rights as provided in 37 CFR 401 and 45 CFR 8.

ARTICLE IV - CONSIDERATION

4.1 For the rights, privileges and license granted hereunder, GENZYME shall pay or cause to be paid to MSSM a royalty of [six percent (6%)] of the Net Sales of Product sold by GENZYME and its Affiliates and [fifty percent (50%)] of the royalties payable to GENZYME by any sublicensees for the longer of (i) the life of the Licensed Patents for Product covered by Valid Claims in the country of sale, or (ii) [ten (10)] years after the First Commercial Sale of Product. The royalty payable to MSSM shall be reduced to [three percent (3%)] of the Net Sales in any country in which a recombinant x-galactosidase A product derived from mammalian cells is commercially available from a third party.

4.2 No multiple royalties shall be payable because Product, its manufacture, lease or sale, is or shall be covered by more than one Valid Claim, patent application or patent licensed under this Agreement.

4.3 Royalty payments shall be paid to MSSM in United States dollars in New York, N.Y. Any taxes which GENZYME or any Affiliate or sublicensee shall be required by law to withhold or pay on remittance of the royalty payments shall be deducted from royalty paid to MSSM. GENZYME shall furnish MSSM upon request, copies of all official receipts for such taxes. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate as reported by the Wall Street Journal on the last business day of the calendar quarterly reporting period to which such royalty payments relate or when such conversion rate is next reported.

ARTICLE V - REPORTS AND RECORDS

5.1 GENZYME shall keep full, true and accurate accounts containing all particulars that may be necessary for the purpose of showing the amount payable to MSSM. Said books of account shall be kept at GENZYME 's principal place of business or at such other location that is reasonably accessible. Said books and the supporting data shall be open at all reasonable times, for three (3) years following the end of the calendar year to which they pertain, to inspection no more often than once a year by an independent certified public accountant retained by MSSM, at its expense, solely for the purpose of verifying, under suitable confidentiality obligations, GENZYME's royalty statement to MSSM. If GENZYME's royalty statement is found to be in error by [seven percent (7%)] or more, such inspection expenses shall be paid by GENZYME.

5.2 Beginning with the First Commercial Sale, GENZYME, within sixty (60) days after March 31, June 30, September 30 and December 31, of each year, shall deliver to MSSM true and accurate reports, giving such particulars of the business conducted by GENZYME during the preceding quarter under this Agreement as shall be pertinent to a royalty accounting

hereunder. Reports shall include: (a) total billings for Product sold; (b) deductions applicable as provided in Paragraph 1.5; and (c) total royalties due.

5.3 With each such report submitted, GENZYME shall pay to MSSM the royalties then due and payable. If no royalties shall be due, GENZYME shall so report.

ARTICLE VI - TECHNICAL INFORMATION

6.1 Promptly after the effective date of this Agreement and periodically during the term thereof, MSSM, to the extent that it has all necessary legal and contractual rights to do so, shall disclose and furnish to GENZYME all Technical Information which is requested by GENZYME and which is known or possessed by MSSM. To enable GENZYME to assist in protecting the rights licensed to GENZYME hereunder, MSSM shall, provide to GENZYME a [(30) thirty] days prior right of review of MSSM publications relating to the Product. GENZYME may then delay submission up to an additional [thirty (30)] days to allow filing of appropriate patent applications. GENZYME agrees to review oral disclosures or abstracts within [seven (7)] days of notification, and MSSM agrees to delete proprietary information as requested by GENZYME.

6.2 Each of the parties, for itself and its Affiliates, undertakes during the term of this Agreement, to hold in confidence and not to disclose to any third party, the Technical Information received from the other, provided that such undertaking shall not apply to any portion of said Technical Information which:

- (a) was known to the receiving party or any of its Affiliates prior to its receipt by the receiving party or any of its Affiliates hereunder;
- (b) is received at any time by the receiving party or any of its Affiliates in good faith from a third party lawfully in possession of the same and having the right to disclose the same;
- (c) is as of the date of the receipt by the receiving party or any of its Affiliates in the public domain or subsequently enters the public domain other than by reason of acts or omissions of the employees or agents of the receiving party or any of its Affiliates;

and provided further that nothing contained herein shall prevent GENZYME or any of its Affiliates from using and disclosing the Technical Information received from MSSM in connection with applying for and securing governmental authorizations for the marketing of licensed products or otherwise in the performance of its obligations under this Agreement.

ARTICLE VII - PATENT SUPPORT AND PROSECUTION

7.1 GENZYME shall [reimburse MSSM] on a quarterly basis for [all reasonable out-of-pocket external expenses incurred by MSSM] after the date of this Agreement in connection with the filing, prosecution and maintenance of all Licensed Patents filed, prosecuted or maintained at the request of GENZYME. GENZYME shall not be required to [reimburse MSSM for any extension fees or, at its option, any costs incurred as a result of interferences

declared by the United States Patent and Trademark Office]. If GENZYME elects not to pay for the cost of a patent interference], MSSM shall be free to license such patent to any other party.

7.2 MSSM shall seek prompt issuance of, and maintain, at its expense (subject to reimbursement pursuant to Paragraph 7.1)], the Licensed Patents, and shall keep GENZYME informed of, and shall provide to GENZYME copies of, all official documents received from and sent to governmental patent offices. MSSM shall keep GENZYME apprised on a timely basis of the progress of any patent prosecution, and shall provide GENZYME with a reasonable opportunity to preview and comment upon prosecution responses. MSSM agrees to reasonably consider any such comments provided by GENZYME.

7.3 If MSSM shall decide to discontinue any such prosecution, or shall decide not to maintain any patent, or not to file a patent application on an invention relating to the Product, or not to file same in a particular country, it shall promptly notify GENZYME in writing and in reasonably sufficient time for GENZYME to assume such prosecution or maintenance, or file such patent application, and shall take the necessary steps and execute the necessary documents to permit GENZYME to assume the filing, prosecution, or maintenance of the same at GENZYME's expense and control, whereupon GENZYME shall possess a royalty-free, exclusive license to same for the life of any such patent.

ARTICLE VIII - INFRINGEMENT

8.1 MSSM shall have the first option to institute and prosecute [, at its expense,] suits for infringement of Licensed Patents. Any recovery of damages shall [belong solely to MSSM].

8.2 If MSSM elects not to bring an action for infringement, GENZYME shall have the power, but not the obligation, to institute and prosecute [, at its own expense,] suits for infringement of Licensed Patents. MSSM agrees to join as party plaintiff in any such suits instituted by GENZYME, and shall fully cooperate with GENZYME in the prosecution of such suits. GENZYME may withhold up to [fifty percent (50%)] of royalties due hereunder during the pendency of such suits and GENZYME may apply such withheld amounts toward reimbursement of its expenses, including reasonable attorney's fees in connection therewith. Any recovery of damages by GENZYME shall be applied first in satisfaction of any unreimbursed expenses and legal fees relating to the suit or settlement thereof, and then toward reimbursement of MSSM for any royalties withheld and applied pursuant to this Article VIII. Any remaining recoveries shall be deemed Net Sales for purposes of calculation of royalties hereunder.

8.3 If GENZYME does not bring action, and MSSM chooses not to bring action, to halt infringement, then the applicable royalty in such country shall be [fifty percent (50%)] of the rate otherwise applicable, provided that GENZYME has suffered at least a [ten percent (10%)] market share loss due to such infringement.

ARTICLE IX - TERM AND TERMINATION

9.1 This Agreement shall be effective as of the date first written above and shall continue in effect on a country-by-country basis until the later of (i) the expiration of the last to

expire of the Licensed Patents in a particular country, or (ii) ten (10) years after the date of the First Commercial Sale. Thereafter, Genzyme shall have a paid up license to the Technical Information.

9.2 Should GENZYME fail in its payment to MSSM of royalties due in accordance with the terms of this Agreement, MSSM shall have the right to serve notice upon GENZYME by certified mail at the address designated in Article XVI hereof, of its intention to terminate this Agreement within [sixty (60)] days after receipt of said notice of termination unless GENZYME shall pay to MSSM within the [sixty (60)] day period, all such royalties due and payable, or institute arbitration proceedings as provided herein. Upon the expiration of the [sixty (60)] day period, if GENZYME shall not have paid all such royalties due and payable, or implemented arbitration, the rights, privileges and license granted hereunder shall thereupon immediately terminate.

9.3 Upon any material breach or default of this Agreement by either party, other than those occurrences set out in Paragraph 9.2 above, the other party shall have the right to terminate this Agreement and the rights, privileges and license granted hereunder by [ninety (90)] days' notice including a detailed explanation of the reasons for termination, by certified mail to the defaulting party. Such termination shall become effective unless the defaulting party shall have cured any such breach or default prior to the expiration of the other party's notice of termination.

9.4 GENZYME shall have the right, upon [ninety (90)] days written notice, to terminate the license granted herein, on a country-by-country basis or to fully terminate the license and this Agreement.

9.5 Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. GENZYME and its Affiliates and sublicensees may, however, after the effective date of such termination, sell all Product, and complete Product in the process of manufacture at the time of such termination and sell the same, provided that GENZYME shall pay to MSSM the royalties thereon as required by Article IV of this Agreement and shall submit the reports required by Article V hereof on the sales of Product.

9.6 The provisions of Article VI shall survive termination of this Agreement for a period of five (5) years. The provisions of Article XII shall survive termination of this Agreement.

ARTICLE X - ARBITRATION

Except as to issues relating to the validity, construction or effect of any patent licensed hereunder, any and all claims, disputes or controversies arising under, out of, or in connection with this Agreement, which have not been resolved by good faith negotiations between the parties, shall be resolved by final and binding arbitration in Boston, Massachusetts by three arbitrators, one selected by each party within 30 days of receipt of notice to arbitrate, the remaining arbitrator to be selected by the party- selected arbitrators. If a party fails to select an arbitrator within the thirty day period, it shall forfeit its right to make such a selection. The arbitration shall be under the rules of the American Arbitration Association then obtaining. The

arbitrators shall have no power to modify any of the terms or conditions of this Agreement. Any award rendered in such arbitration may be enforced by any of the parties in the United States District Court for Massachusetts, to whose jurisdiction for such purposes MSSM and GENZYME each hereby irrevocably consents and submits. Each party shall bear its own costs.

ARTICLE XI - THIRD PARTY PATENTS

In the event that a patent of a third party should exist during the term of this Agreement, which such third party alleges is infringed by the manufacture, use or sale of Product by GENZYME, or in the event that GENZYME shall undertake to challenge the validity or infringement of such patent by litigation, GENZYME may withhold up to [fifty percent (50%)] of the royalties otherwise due to MSSM towards the reimbursement of its out-of-pocket costs and expenses incurred in such litigation, and/or if GENZYME is required to pay to such other patentee a royalty under such patent, GENZYME may deduct up to [fifty percent (50%)] of the royalties paid to such third party. In no event, however, shall the deductions allowed in this Article XI cause the total royalty payable to MSSM under Article 4.1 of this Agreement to be less than [three percent (3%)] of Net Sales.

ARTICLE XII - INSURANCE AND INDEMNIFICATION

12.1 GENZYME shall at all times during the term of this Agreement and thereafter, defend, indemnify and hold MSSM, its affiliates and their trustees, directors, officers, employees, medical staff, agents, volunteers and students harmless from any and all claims, demands, lawsuits, actions, settlements, judgments, and expenses (including legal expenses and attorney's fees), arising from or in connection with the negligent acts or omissions or product liabilities of GENZYME, its Affiliates, employees or other agents committed in connection with this Agreement. MSSM shall be required to provide GENZYME with prompt notice of any such claims, as well as such reasonable assistance and cooperation as GENZYME may request in the defense of such claims. GENZYME'S obligation to protect, defend, indemnify and hold harmless hereunder shall Survive the expiration and termination of this Agreement.

12.2 GENZYME shall purchase and keep in force the following minimum insurance coverages, naming MSSM as additional insured with such insurers as shall be acceptable to MSSM:

1) Comprehensive General Liability, including:

- (a) Personal injury and bodily injury and Broad form property damage liability with a combined single limit of not less than \$[2,000,000].
- (b) Coverage for the contractual liability assumed by this Agreement.

2) Product liability insurance in an amount not less than [ten million dollars (\$10,000,000)] per occurrence, with an aggregate yearly limit of [ten million dollars (\$10,000,000)]. Prior to any work being performed under this Agreement, GENZYME shall deliver to MSSM certificates of insurance evidencing that the coverages specified in these sections are in effect. Such certificates shall show that:

- (a) MSSM is an additional named insured;
- (b) the insurer shall give MSSM thirty (30) days written notice sent by registered mail of any material change in, or cancellation of, such insurance.

ARTICLE XIII - ASSIGNMENT

13.1 GENZYME shall be entitled to assign its rights hereunder, with the written consent of MSSM, which consent shall not be unreasonably withheld. At GENZYME's request, MSSM shall enter into a separate counterpart agreement with any such assignee, it being expressly agreed that GENZYME shall remain bound by the obligations hereof until such separate counterpart agreement is signed. Such counterpart agreement shall be the same in form and substance except for necessary changes to reflect the extent of the assignment.

13.2 MSSM shall be entitled to assign its rights hereunder with the written consent of GENZYME, which consent shall not be unreasonably withheld.

ARTICLE XIV - NON-USE OF NAMES AND TRADEMARKS

14.1 Neither party shall use the names or trademarks of the other party for any advertising, promotional or sales literature without prior written consent which consent shall not be unreasonably withheld, except that GENZYME may disclose that it is exclusively licensed by MSSM hereunder. In all cases, GENZYME shall be permitted to make such disclosures as required by state and federal law.

14.2 It is understood that MSSM has selected the trademark ["FABRase"] for use in connection with the Product. GENZYME agrees to reasonably consider said trademark for use in connection with its commercialization of the Product, and MSSM agrees to assign its rights to said trademark to GENZYME at no cost, upon GENZYME's request.

ARTICLE XV - DUE DILIGENCE

GENZYME shall use its reasonable efforts to develop the Product for commercialization. Such efforts shall include the following:

- (a) within [three (3)] years of the Effective Date, to initiate [pre-clinical safety/toxicology] studies on the Product which is intended for use in clinical trials;
- (b) within [five (5)] years of the Effective Date to initiate [human clinical trials] for the Product; and
- (c) within [nine (9)] years of the Effective Date to [file a New Drug Application for the Product with the United States Food and Drug Administration].

ARTICLE XVI - PAYMENTS, NOTICES AND OTHER COMMUNICATIONS

Any payment, notice or other communication pursuant to this Agreement shall be sufficiently made or given on the date of mailing if sent to such party by certified first class mail, postage prepaid, addressed to it as its address below or as it shall designate by written notice given to the other party:

In the case of MSSM:

Office of Science and Technology Development Mount Sinai School of Medicine
One Gustave L. Levy Place
New York, NY 10029
Attention: Dr. Frank Landsberger
Fax. No. (212) 348-3116

In the case of GENZYME:

Genzyme Corporation One Kendall Square
Cambridge, MA 02139
Attention: Senior Vice President and General Counsel
Fax. No. (508) 872-5415

ARTICLE XVII - MISCELLANEOUS PROVISIONS

17.1 This Agreement shall be construed, governed, interpreted and applied in accordance with the laws of the State of New York, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent was granted.

17.2 The parties hereto acknowledge that this Agreement and the Research Agreement dated of even date sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change or modification except by the execution of a written instrument subscribed to by the parties hereto.

17.3 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way effect the validity or enforceability of the remaining provisions hereof.

17.4 The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party.

17.5 Neither party shall, without the consent of the other, which consent shall not be unreasonably withheld, originate any publicity, news release, or other public announcement, written or oral, whether to the public press, to stockholders, or otherwise, relating to this Agreement, any amendment hereto or performance hereunder, save any such announcement as in the opinion of legal counsel to the party making such announcement is required by law to be made. Both parties acknowledge the likelihood that GENZYME may be required to make a

general announcement regarding the existence of this Agreement as a material event. The party making such announcement will give the other party an opportunity to review the form of the announcement before it is made.

17.6 Both parties acknowledge and recognize the presence of risk regarding the development and sale of the Product contemplated hereunder, that potential markets discussed have only been estimated and are not being relied upon, and that the Product may be unsuccessful in any such market.

IN WITNESS WHEREOF, the parties hereto have caused this License Agreement to be executed by their duly authorized representatives as of the day and year first set forth above.

MOUNT SINAI SCHOOL OF MEDICINE

GENZYME CORPORATION

BY: /s/[illegible] Katz

BY: /s/ Gregory D. Phelps

TITLE: [illegible]

TITLE: Senior Vice President

DATE: 1-27-95

DATE: 2-3-95

ACCEPTED AND AGREED TO:

NAME: /s/ Robert J. Desnick
Robert J. Desnick, Ph.D., M.D.

DATE: 1-26-95

**Schedule B
Technical Information**

1. Purification and Isolation of Native and Recombinant Human α -Gal A:

- Artificial and natural substrate assays
- Characterization of α -Gal A physical and kinetic properties
- Characterization of active site
- N-Glycosylation site occupancy and structures of oligosaccharide chains
- Methods for sequential deglycosidation of α -Gal A
- FPLC methods for rapid purification; use of affinity column and perfusion chromatography
- Separation of α -Gal A and α -N-acetylgalactosaminidase (α -Gal B)
- Affinity-purified monospecific polyclonal antibodies for α -Gal A

2. Development of Assays for Globotriaosylceramide (GL-3):

- HPLC quantitation
- Development of a rapid assay using verotoxin binding

3. Isolation and Characterization of the α -Gal A and B cDNA and Genomic Sequences:

- Human α -Gal A and B cDNA and entire genomic sequences
- Murine α -Gal A and B cDNA and genomic organization
- CHO α -Gal A cDNA and genomic organization
- Human mutations and polymorphisms for α -Gal A
- Alterations to increase transcription and translation of α -Gal A

4. Overexpression of α -Gal A in COS and CHO Cells: -

- Engineering sialotransferase to produce sialylated recombinant α -Gal A

5. Design of Overexpression Vectors for α -Gal A Enzyme and Gene Therapy: -

- Development of Pol-I-based vectors
- Development of Simlike Forest Virus-based vectors

6. Generation of Knock-Out Mice for α -Gal A:

- Generation of knock-out mice for α -Gal A and α -N-acetylgalactosaminidase (α -Gal B)

7. In Vivo Administration of α -Gal A Glycoforms to Mice:

- Secreted recombinant α -Gal A
- Sialylated recombinant α -Gal A
- Acid phosphatase-treated α -Gal A glycoforms

8. Experience in the Diagnosis, Management and Treatment of Patients with Fabry Disease:

FIRST AMENDMENT TO LICENSE AGREEMENT

This is the First Amendment to the January 1, 1995 License Agreement between Genzyme Corporation ("GENZYME") and Mount Sinai School of Medicine of the City University of New York ("MSSM"). This Amendment shall be effective as of October 7, 2003.

WHEREAS, in the License Agreement, MSSM has granted to GENZYME an exclusive license under certain Technical Information and Licensed Patents rights, including U.S. patent No. 5,356,804 ("the '804 patent"), in connection with the commercialization of recombinant α -galactosidase A for the treatment of Fabry Disease; and

WHEREAS, MSSM and Genzyme are co-plaintiffs and appellants in a suit against Transkaryotic Therapies, Inc. ("TKT") alleging infringement of the '804 patent (the "Infringement Suit"), which Infringement Suit was originally brought in the United States District Court for the District of Delaware (Civil Action No. 00-677 GMS) and is now on appeal to the Court of Appeals for Federal Circuit (Appeal No. 02-1312);

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which each party acknowledges, MSSM and GENZYME hereby agree as follows:

1. **Definitions.** Capitalized terms not defined in this First Amendment shall have the meaning given them in the License Agreement.
2. **Restatement of Section 2.1.** Section 2.1 of the License Agreement shall be amended and restated to read as follows:

"2.1 Except as provided in Article XVIII, MSSM hereby grants to GENZYME an exclusive, worldwide right and license, and subject to approval by MSSM, which shall not be unreasonably withheld, the right to sublicense third parties, (a) to make, have made, use, and sell Product under the Licensed Patents; and (b) to use the Technical Information provided by MSSM. MSSM agrees that [it shall not license to any party] other than GENZYME [any technology for the treatment of Fabry disease developed] by or under [the direction of Dr. Robert Desnick] during the term of this Agreement."

3. **Addition of Article XVIII.** New Article XVIII shall be added to the License Agreement, which Article shall read as follows:

"ARTICLE XVIII — INFRINGEMENT SUIT AGAINST TKT

18.1.1 In the event that GENZYME withdraws as plaintiff-appellant from the Infringement Suit, MSSM shall have the right (i) to continue the proceedings and maintain the Infringement Suit as the sole plaintiff [at MSSM's sole expense] and (ii) to solely bring, defend or maintain any other proceeding relating to the Licensed Patents or Technical Information in which TKT is a party or has an

interest [at MSMM's sole expense]. Notwithstanding the foregoing, GENZYME shall [indemnify and hold MSSM harmless] from any [costs or expenses (including attorneys' or expert fees)] for which [MSSM may be liable] to the extent arising out of or related to (i) [any actions or omissions of GENZYME or its agents (including the actions or omissions of Pennie & Edmonds, LLP before the date of GENZYME's withdrawal) in connection with the Infringement Litigation] or (ii) any agreement between [GENZYME and TKT relating to GENZYME's withdrawal from the Infringement Suit ("Settlement Agreement")]. In addition, only to the extent permitted by any Settlement Agreement, GENZYME [at its own cost] shall reasonably cooperate with MSSM's prosecution of the Infringement Suit or any other action related to the Licensed Patents or Technical Information. Such cooperation includes making available to MSSM any documents, witnesses, or other information in GENZYME's control.

18.2 Any [recovery of damages] in the Infringement Suit or any other proceeding between [MSSM and TKT relating to any of the Licensed Patents or Technical Information shall belong solely to MSSM].

18.3 Notwithstanding the provisions of Section 2.1, MSSM shall have [the right to grant a license to TKT under the Licensed Patents and Technical Information in connection with TKT's current gene-activated Replagal™ product and to collect any proceeds from such license for its own account]."

4. **Acknowledgements.** GENZYME and MSSM acknowledge that, if GENZYME withdraws from the Infringement Suit:

- a. Effective as of the date GENZYME withdraws, GENZYME confirms that, [as stated in Section 8.2 of the License Agreement, GENZYME will no longer be able to withhold any amounts from royalties otherwise due MSSM]. For the avoidance of doubt, amounts previously [withheld under Section 8.2 may be applied to GENZYME's expenses incurred in connection with the Infringement Suit, with any remainder paid over to MSMM].
- b. Section 8.3 of the License Agreement shall not apply to [any activities of TKT or its Affiliates], or their respective successors, assigns or licensees.

Except as provided herein, the License Agreement shall remain in full force and effect. Any capitalized terms used herein but not otherwise defined shall have the meanings ascribed to them in the License Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be executed and delivered as of the effective day and year set forth above.

MOUNT SINAI SCHOOL OF MEDICINE

GENZYME CORPORATION

By: /s/ Kenneth L. Davis
Kenneth L. Davis, M.D.

By: /s/ Thomas DesRosier

Title: Dean

Title: Senior Vice President

Date: 10-7-2003

Date: 10-7-2003