18-01415-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, December 15, 2017 5:26 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibits 10.58 and 10.60 to the 12/31/11 10-K, as amended, filed by ViroPharma Inc. on 2/28/2012. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark

Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

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

Office of FOIA Services

January 09, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-01415-E

Dear Mr. Edwards:

This letter is in response to your request, dated December 15, 2017 and received in this office on December 18, 2017, for information regarding Exhibits 10.58 and 10.60 to the form 10-K (dated December 31, 2011), as amended, filed by ViroPharma Inc. on February 28, 2012.

The search for responsive records has resulted in the retrieval of 16 pages that may be responsive to your request. They are being provided to you with this letter in their entirety at no cost.

If you have any questions, please contact me at Luetkenhausj@SEC.GOV or (202) 551-8352. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Aaron Taylor as a FOIA Public Liaison 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,

Jason Luetkenhaus

Jason Luetkenhaus
Lead FOIA Research Specialist

Enclosures

EXCLUSIVE CLINICAL STUDY AND DATA LICENSE AGREEMENT

THIS EXCLUSIVE CLINICAL STUDY AND DATA LICENSE AGREEMENT (the "**Agreement**") is made as of June 12, 2009 (the "**Effective Date**") between **VIROPHARMA INCORPORATED**, a Delaware corporation ("**ViroPharma**"), and **GENZYME CORPORATION**, a Massachusetts corporation ("**Genzyme**").

WHEREAS, Genzyme has performed and/or sponsored certain clinical studies related to Genzyme's proprietary product, tolevamer, and such clinical studies have generated data; and

WHEREAS, ViroPharma desires to exclusively license such clinical studies and the data generated from such studies from Genzyme;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by each party, it is agreed by and between the parties as follows:

1. **Definitions**. As used in this Agreement, the following capitalized terms shall have the meanings set forth in this Article 1 or as otherwise defined elsewhere in this Agreement.

   (a) "**Affiliate**" means, in relation to a party, any Person which directly or indirectly through one or more intermediaries controls, is controlled by or is under common control with such party. A Person shall be deemed to control another Person if it: (i) owns, directly or indirectly, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest; or (ii) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.

   (b) "**Confidential Information**" means, with respect to a party, all information of any kind whatsoever (including compilations, data, formulae, models, patent disclosures, procedures, processes, projections, protocols, results of experimentation and testing, specifications, strategies and techniques), and all tangible and intangible embodiments thereof of any kind whatsoever (including documents, drawings, machinery, patent applications, records and reports). For the avoidance of doubt, the Data and the Studies shall be considered Confidential Information.

   (c) "**Data**" means all information and data included in, generated in connection with, or made a part of either or both of the Studies, and further including all meta-data about the Studies (*e.g.*, the data dictionary and database structures), as well as final study reports, manuscripts and correspondence and other records of regulatory interactions related to the Studies.

   (d) "**Documentation**" means all materials, manuals, file descriptions and other written information or computer software provided by Genzyme to ViroPharma that describes or facilitates access to, or the organization and use of, the Studies or Data

including, but not limited to, financial disclosure statements from clinical investigators who participated in the Studies.

(e) "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

(f) "**Initiation Date**" shall have the meaning set forth in Section 4(b)(3).

(g) "**NDA**" means ViroPharma's New Drug Application Number 50-606 for the Product, as such application type is defined in the United States Federal Food, Drug and Cosmetic Act, and applicable regulations promulgated thereunder, as amended from time to time.

(h) "**Net Sales**" means the gross invoiced sales price of the Product billed to independent Third Parties including, without limitation, distributors, less the following items as applicable to the Product to the extent such items are customary under industry practices and to the extent such amounts are included in the gross invoiced sales price: (a) estimates of credits or allowances granted upon returns, rejections or recalls (due to spoilage, damage, expiration of useful life or otherwise), retroactive price reductions, billing corrections or allowances for bad debt; (b) freight, shipping and insurance costs; (c) estimates of quantity, cash and other trade discounts, credits or allowances; (d) customs duties, taxes and surcharges and other governmental charges incurred in connection with the production, sale, transportation, delivery, use, exportation or importation of Products; (e) estimates of amounts incurred for government mandated rebates and discount programs; (f) estimates of Third Party rebates and charge backs, hospital buying group/group purchasing organization administration fees or managed care organization rebates; and (g) distribution fees and sales commissions paid to Third Parties; all calculations of deductions will be in accordance with standard allocation procedures, allowance methodologies and accounting methods consistently applied in accordance with GAAP. The transfer of any Product by ViroPharma or one of its Affiliates to another Affiliate of ViroPharma shall not be considered a sale; in such cases, Net Sales shall be determined based on the gross invoiced sales price by the Affiliate to the independent Third Party, less the deductions allowed under this Section 1(h).

(i) "**Orange Book**" means the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations.

(j) "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

(k) "**Product**" means ViroPharma's oral capsule vancomycin hydrochloride product marketed on the date hereof under the trademark Vancocin®.

(l) "**Quarter**" means one of the four three-month periods in a calendar year, commencing in January.

(m) "**Regulatory Approval**" means any approved New Drug Application, Supplemental New Drug Application (as such application types are defined in the United States Federal Food, Drug and Cosmetic Act or applicable regulations promulgated thereunder), and all other government or regulatory approvals (including, without limitation, where applicable, pricing and reimbursement approval and schedule classifications), product and/or manufacturing facility licenses, conformity assessments, registrations or authorizations.

(n) "**Representatives**" means employees, directors, consultants, and contractors of a party and/or a party's Affiliates.

(o) "**sNDA**" means ViroPharma's Supplemental New Drug Application for the expansion of the label for the Product, as such application type is defined in the United States Federal Food, Drug and Cosmetic Act, or applicable regulations promulgated thereunder, as amended from time to time, and which incorporates any of the Studies and/or the Data pursuant to the license granted hereunder.

(p) "**Studies**" means the clinical studies of Genzyme's proprietary product, tolevamer, conducted by, or on behalf of, Genzyme under Protocol Numbers GD3-170-301 and GD3-170-302.

(q) "**Territory**" means the fifty (50) states and the District of Columbia and any territories and commonwealths constituting the United States of America, including Puerto Rico.

(r) "**Third Party**" means any Person other than Genzyme or ViroPharma and their respective Affiliates.

2. **License**.

(a) **License Grant**. Genzyme hereby grants to ViroPharma a royalty-bearing, exclusive (even as to Genzyme) right and license in the Territory, with no right to sublicense except with Genzyme's prior written approval, which approval shall not be unreasonably withheld, delayed or conditioned, under all of Genzyme's rights and interests in and to the Studies and Data, including without limitation, patents, copyrights, database rights, and any other intellectual property rights it may have in the Studies and Data, for all purposes. For clarity, ViroPharma shall have the right, in good faith, to use, process, reformat, manipulate, adopt, create derivative works, copy, display, import, export, and store, in whole or in part, the Data, or portions thereof, in any way it desires; *provided, however,* that, for the avoidance of doubt, it is understood that ViroPharma shall not misrepresent the Data or the Studies or present the Data in any way that is false or misleading. Upon the expiration of the Royalty Term (defined below), the license described in this Section 2(a) shall automatically become nonexclusive, perpetual (subject to termination as set forth in Section 8 below), and royalty-free, and shall be limited to a license under Genzyme's rights and interests in the Data that are contained or referred to in the sNDA, but otherwise subject to all of the terms and conditions set forth herein.

(b) **Covenant Not to Sue**. ViroPharma acknowledges that, during the Term, copies of the Data will reside at Genzyme, and will otherwise be known generally by certain Genzyme employees. Accordingly, during the Term, ViroPharma covenants not to enforce against Genzyme any rights under the Data or the Studies, and shall not initiate any action asserting that Genzyme does not have the right to use the Data and/or Studies, solely to the extent that Genzyme is using the Data and/or Studies for internal research and development purposes only, specifically, for preparing and reviewing manuscripts for publication in accordance with Section 5(f)(1) hereof. Any other internal use of the Data and/or Studies by Genzyme shall only be with ViroPharma's prior written consent, which consent shall not be unreasonably withheld or delayed.

(c) **Non-use**. Genzyme and its Affiliates shall not, directly or through any other Person(s), make use of or dispose of the Studies or Data in any way prior to the expiration of the Royalty Term, other than as set forth herein, including, but not limited to, licensing or otherwise providing the Studies or Data to any Third Party. In addition, prior to the expiration of the Royalty Term, Genzyme shall not use, or permit any Third Party to use, any of the Studies or Data in seeking any Regulatory Approvals.

3. **Delivery of Studies and Data**. As soon as possible, but no later than thirty (30) days, after the Effective Date, Genzyme shall provide ViroPharma with a copy of all of the Studies and Data in a manner mutually acceptable to the parties, together with all Documentation.

4. **Financials**.

(a) **Maintenance Fee**. In partial consideration of the rights and licenses granted pursuant to Article 2, commencing on the Effective Date and continuing until the Initiation Date, ViroPharma shall pay Genzyme a maintenance fee on a Quarterly basis equal to one-hundred fifty thousand dollars (U.S. $150,000) per Quarter (the "**Maintenance Fee**"); provided, that the Maintenance Fee shall be pro-ratable for the Quarters in which the Effective Date and the Initiation Date occur, meaning that the Maintenance Fees for such Quarters shall be calculated based on, with respect to the Quarter during which (i) the Effective Date occurs, the number of days remaining in such Quarter following (and including) the Effective Date, and (ii) the Initiation Date occurs, the number of days preceding (and excluding) the Initiation Date in such Quarter). The Maintenance Fee shall be due and payable within thirty (30) days after the conclusion of each Quarter commencing with the Quarter during which the Effective Date occurs and continuing through to (and including) the Quarter during which the Initiation Date occurs.

(b) **Royalties**.

1. As further consideration for the rights granted hereunder, during the Royalty Term (as defined below), ViroPharma shall pay Genzyme a

royalty on Net Sales of the Product in the Territory ("**Royalties**") as follows:

Year Following Initiation Date	Royalty Rate
1	10%
2	10%
3	16%

For the avoidance of doubt, "Year Following Initiation Date" shall mean the 12-month periods commencing on the Initiation Date, the first anniversary of the Initiation Date and the second anniversary of the Initiation Date.

2. Within forty-five (45) calendar days following the end of each Quarter during the Royalty Term, ViroPharma shall provide Genzyme for such Quarter a report setting forth the Net Sales with respect to the Product and a calculation of the amount due on such Net Sales in accordance with Section 4 (each, a "**Sales Report**"), along with the Royalties due pursuant to this Section 4.

3. Royalties due under this Section 4 shall commence upon the day (the "**Initiation Date**") subsequent to the day that ViroPharma's sNDA is approved by the FDA and will continue until the third anniversary of the Initiation Date (the "**Royalty Term**"); *provided, however*, that the Royalty Term shall immediately expire upon the first commercial sale of an oral capsule vancomycin hydrochloride product approved pursuant to Section 505 of the United States Federal Food, Drug and Cosmetic Act and determined by the FDA to be therapeutically equivalent to the Product, as evidenced by a therapeutic equivalence code published in the Orange Book ("**Other Vancomycin Product**"). If the Royalty Term expires prior to the third anniversary of the Initiation Date for the reason set forth in the preceding sentence, and subsequent to such expiration the Other Vancomycin Product (as well as any additional Other Vancomycin Products approved after the first Other Vancomycin Product) ceases to be sold commercially, then the Royalty Term shall recommence, but shall expire on the third anniversary of the Initiation Date.

(c) **Late Payments**. Any payments by ViroPharma that are not paid on or before the date such payments are due under this Agreement shall bear interest, to the extent permitted by applicable laws, at the Prime Rate of interest plus three percent (3%) as reported in the *Wall Street Journal* on the date payment is due, with interest calculated based on the number of days that payment is delinquent.

(d) **Method of Payment**. All payments under this Agreement shall be made by wire transfer in immediately available funds to such account(s) as Genzyme may designate in writing to ViroPharma.

(e) **Taxes**. If taxes, assessments, fees or other charges are required to be withheld from payments to Genzyme under this Agreement by the tax or revenue authorities in any country, ViroPharma shall make such payments to the applicable taxing authority as required to fulfill such requirement and pay to Genzyme the net amount due, provided, that ViroPharma shall promptly notify Genzyme so that Genzyme may take lawful actions to avoid and minimize such withholding. Receipts for payment of all such withholdings shall be provided to Genzyme, together with an accounting of the calculations of such taxes, within fifteen (15) calendar days after such withholding taxes are remitted to the proper authority. The parties will cooperate reasonably in completing and filing documents required under the provisions of any applicable laws in connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of, or credit for, any such payment.

(f) **Audit**. Genzyme shall have the right, upon reasonable written notice during the Royalty Term and for two (2) years after expiration or termination of the Royalty Term, at Genzyme's expense, through an independent certified public accountant reasonably acceptable to ViroPharma and pursuant to the confidentiality provisions in Article 5 of this Agreement, to examine the basis for the Sales Reports during regular business hours; provided, however, that (i) such examination shall not take place more often than once per year, (ii) such examination shall not cover a period of time that has previously been audited, and (iii) such accountant shall report to the parties only as to the accuracy of the Sales Reports and the Royalties paid by ViroPharma. Any undisputed adjustments required as a result of overpayments or underpayments identified through Genzyme's exercise of its audit rights shall be made by subtracting or adding, as appropriate, amounts from or to the next payment or, if no further payments are due, by payment to the party owed such adjustment within thirty (30) days after identification of such adjustment. Genzyme shall bear the full cost of the audit; provided, however, ViroPharma shall reimburse Genzyme for such fees and expenses in the event an audit reveals an error of understatement equal to or exceeding five percent (5%).

5. **Confidential Information**.

(a) **Limitations on Disclosure & Use**. The party receiving Confidential Information (the "**Recipient**") of the other party ("**Disclosing Party**") shall use such information solely as authorized hereunder. Recipient shall hold Confidential Information in strict confidence and shall not disclose any Confidential Information to any Person, provided, that Confidential Information may be disclosed to those Representatives of Recipient who (i) have a need to know the Confidential Information in connection with the Recipient's obligations hereunder, (ii) have been informed by Recipient of the confidential nature of the Confidential Information and of the confidentiality undertakings of Recipient contained herein and (iii) are bound in writing by obligations of confidentiality no less stringent than those contained herein. Recipient

shall use commercially reasonable efforts to hold the Disclosing Party's Confidential Information in a secure location so as to ensure that unauthorized Persons do not gain access to any Confidential Information. Recipient shall promptly notify the Disclosing Party of any unauthorized release of, access to or use of Confidential Information of the Disclosing Party. Such notice shall not remedy any breach of this Agreement resulting from such unauthorized release, access or use.

(b) **Permitted Disclosures**. This Agreement imposes no obligation upon Recipient with respect to Confidential Information that Recipient can demonstrate through written documentation:

1. was in Recipient's possession before receipt from the Disclosing Party;

2. is or becomes available to the public through no fault, act or omission of Recipient;

3. is furnished to Recipient by a Third Party who is under no obligation of confidentiality and has the right to make such disclosure without any restriction; or

4. is independently discovered or developed by Recipient without access to or use of the Disclosing Party's Confidential Information as evidenced by written records.

(c) **Required Release**. In the event that Recipient is required by judicial or administrative process to disclose Confidential Information, Recipient shall promptly notify the Disclosing Party and allow the Disclosing Party a reasonable time to oppose such process or to seek limitations on the portion of the Confidential Information that is required to be disclosed. For clarity, such disclosure pursuant to this Article 5 shall not cause the information so disclosed to lose its confidential nature and in all other instances and circumstances such information shall remain Confidential Information.

(d) **Use of Names**. Neither party shall use the name of the other party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other party; provided, however, that (i) either party may use the name of the other party in connection with the Product, the Studies, and/or the Data in any document filed with any regulatory agency or authority, including the FDA, the United States Securities and Exchange Commission (in accordance with Section 5(e) hereof) and any stock exchange and (ii) ViroPharma shall have the right to identify Genzyme as the original sponsor of the Studies and the party responsible for originally generating the Data.

(e) **Confidentiality of this Agreement**. The terms of this Agreement shall be Confidential Information of each party and, as such, shall be subject to the provisions of this Article 5. Notwithstanding the foregoing, to the extent that either party determines that it or the other party is required to file or register this Agreement or a notification thereof to comply with the requirements of an applicable stock exchange

or Nasdaq regulation or any governmental authority including, without limitation, the United States Securities and Exchange Commission, such party shall promptly inform the other party thereof. Prior to making any such filing, registration or notification, the parties shall agree on the provisions of this Agreement for which the parties shall seek confidential treatment, it being understood that if one party determines to seek confidential treatment for a provision for which the other party does not, then the parties will use reasonable efforts in connection with such filing to seek the confidential treatment of any such provision. The parties shall cooperate, each at its own expense, in such filing, registration or notification, including, without limitation, submitting any such confidential treatment request, and shall execute all documents reasonably required in connection therewith.

(f) **Presentations, Publications and Publicity**.

1. Prior to the expiration of the Royalty Term, Genzyme shall not present or publish, or submit for publication, any work relating to the Studies or Data, without ViroPharma's prior written approval. Notwithstanding the immediately preceding sentence, to the extent that a Third Party has been granted publication rights with respect to the Studies in connection with such Third Party's participation as a clinical investigator in such Studies (**"Third Party Clinical Investigator"**), then this Agreement shall not prevent such publication. Genzyme shall provide any proposed publication authored in whole or in part by a Third Party Clinical Investigator to ViroPharma for review at least thirty (30) days prior to submission for publication; *provided, however*, that ViroPharma shall not have the right to delay or prevent such publication.

2. ViroPharma may not present or publish, or submit for publication, any information relating to the Studies or Data prior to the Initiation Date. After the Initiation Date, ViroPharma may only present or publish, or submit for publication, any information relating to the Studies or Data with Genzyme's prior written consent, which consent shall not be unreasonably withheld, delayed or conditioned. A copy of the proposed publication shall be submitted to Genzyme for review at least thirty (30) days prior to submission for publication. Any publication by ViroPharma relating to the Studies or Data shall, at Genzyme's request, include as authors those Genzyme employees who were involved with the Studies and the generation of the Data, whose names shall be provided by Genzyme to ViroPharma.

3. Nothing contained in this Agreement shall be construed as precluding (i) either party from making, in its discretion, any disclosures of information of any type which relate to the safety, efficacy, toxicology, or pharmacokinetic characteristics of the Product and/or tolevamer to the extent that either party may be required by law to make disclosures of such information, (ii) ViroPharma from disclosing information relating to the Studies or Data to the FDA or other regulatory authorities in conjunction with the filing of the sNDA or (iii) ViroPharma from including information relating to the Studies or Data in investor presentations after the filing of the sNDA, in the revised label for the Product

after the Initiation Date, or in its promotional materials for the Product after the Initiation Date.

(g) **Survival**. Unless specified otherwise, the obligations of confidentiality set forth in this Article 5 shall survive the expiration or termination of this Agreement for a period of ten (10) years from the effective date of such expiration or termination.

6. **Representation, Warranties and Covenants**.

(a) **Mutual Representations**. Each party represents and warrants that it has the legal right and authority to enter into this Agreement, and the performance of its obligations under this Agreement will not result in a material violation or breach of any agreement, contract, commitment or obligation to which it is a party or by which it is bound and will not conflict with or constitute a default under its charter or bylaws or other organizational documents.

(b) **Genzyme Representations and Warranties**. Genzyme further represents, warrants and covenants that:

1. Genzyme exclusively owns all right, title and interest in and to the Studies and Data, free and clear of any encumbrances, and has the right to license and use the Studies and Data as contemplated by this Agreement.

2. The Studies and Data are not subject to any litigation or similar proceedings, and Genzyme has no knowledge of a Third Party threat of such a proceeding, or of facts that likely would be the basis for instituting such proceeding.

3. To Genzyme's knowledge, ViroPharma's use of the Studies and Data will not constitute an infringement or misappropriation of trade secrets, copyright, proprietary information or any other intellectual property rights of any Third Parties.

4. To Genzyme's knowledge, the Studies were performed in accordance with all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, including, without limitation, the FDA guidelines on good clinical practice and the International Conference on Harmonization Good Clinical Practice guidelines.

5. To Genzyme's knowledge and except as otherwise communicated to the FDA, informed consent was obtained in writing from each subject prior to any screening or participation in the Studies in accordance with all applicable laws, rules, regulations and guidelines, and all individually identifiable health information has been maintained in accordance with all applicable laws, rules, regulations and guidelines governing the confidentiality and privacy of individually identifiable health information including, without limitation, the Health Insurance Portability and Accountability Act of 1996.

6. To Genzyme's knowledge, no Person used in any capacity with respect to the Studies or Data was subject to any conflicting obligations that may impair the acceptance of the Studies or Data by the FDA.

7. To Genzyme's knowledge, no Person who was involved in any capacity with respect to the conduct of the Studies or the generation or collection of the Data has, as of the Effective Date, been debarred pursuant to Section 306 of the United States Federal Food, Drug and Cosmetic Act, or is the subject of a conviction described in such section.

(c) **ViroPharma Representations and Warranties**. ViroPharma further represents, warrants and covenants that:

1. ViroPharma will use the Data and Studies in compliance with all applicable laws and regulations.

2. ViroPharma will accurately represent the Data and the Studies in (i) any and all regulatory filings with the FDA and other regulatory authorities and (ii) any publications, scientific meetings, or other presentations of the Data and the Studies, which presentations shall be made in accordance with Section 5(f)(2) hereof.

3. ViroPharma will use reasonable commercial efforts to (i) file the sNDA in a timely manner, (ii) cooperate with the FDA to obtain approval of the sNDA, and (iii) obtain marketing exclusivity for the Product, as reflected in an exclusivity code for the Product in the Orange Book.

(d) **Limitation of Liability**. Neither party will under any circumstances be liable to the other party for incidental, special or consequential damages (including, but not limited to, loss of profits, revenue or business) resulting from or in any way related to a breach of any representation or warranty hereunder. This limitation does not apply to claims for indemnification under Sections 7(a) or 7(b) hereof.

(e) EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, THE NONINFRINGEMENT OF ANY THIRD-PARTY PATENTS OR PROPRIETARY RIGHTS, OR THE VALIDITY OR ENFORCEABILITY OF ANY OF THE PATENT RIGHTS.

7. **Indemnification and Insurance.**

(a) **Indemnification of Genzyme**. ViroPharma shall indemnify and hold Genzyme and its directors, officers, employees and agents harmless from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and expenses)

resulting from all claims, demands, actions and other proceedings by any Third Party ("Third Party Losses") to the extent arising from (a) the breach of any representation, warranty or covenant of ViroPharma under this Agreement, (b) the development, distribution, marketing, sale, storage, disposal or use of the Product, (c) the sNDA or ViroPharma's use of the Studies and/or the Data or (d) the negligence, recklessness or willful misconduct of ViroPharma or its Affiliates or their respective sublicensees, distributors, Representatives or agents in the performance of its or their obligations and/or permitted activities under this Agreement; in each case except to the extent that such Third Party Losses are subject to indemnification by Genzyme pursuant to Section 7(b) below.

(b) **Indemnification of ViroPharma**. Genzyme shall indemnify and hold ViroPharma and its directors, officers, employees and agents harmless from and against all Third Party Losses to the extent arising from (a) the breach of any representation, warranty or covenant of Genzyme under this Agreement, or (b) the negligence, recklessness or willful misconduct of Genzyme or its Affiliates; in each case except to the extent that such Third Party Losses are subject to indemnification by ViroPharma pursuant to Section 7(a) above.

(c) **Insurance**. Each party shall maintain General Liability insurance that is reasonably adequate to fulfill any potential obligation to the other party hereto, but in any event not less than one million U.S. dollars (U.S. $1,000,000) per occurrence and five million U.S. dollars (U.S. $5,000,000) aggregate limit, and Products Liability insurance with a two million U.S. dollars (U.S. $2,000,000) aggregate limit. Each party shall provide to the other party hereto, upon request, with a certificate of such insurance. Each party shall continue to maintain such insurance after the expiration or termination of this Agreement during any period in which ViroPharma continues to sell the Product in the Territory.

8. **Term and Termination**.

(a) **Term**. This Agreement shall become effective on the Effective Date, and will remain in effect unless terminated pursuant to this Article 8 ("**Term**").

(b) **Termination by ViroPharma**. ViroPharma shall have the right, provided that the Maintenance Fees are fully paid up as of such time, to terminate this Agreement at any time prior to the date the sNDA is filed with the FDA, or after the expiration of the Royalty Term, by providing thirty (30) days written notice thereof to Genzyme.

(c) **Termination by Either Party**. In the event that (i) ViroPharma withdraws the sNDA, (ii) ViroPharma receives notification of FDA's denial of the sNDA, or (iii) prior to filing the sNDA, an Other Vancomycin Product is sold commercially in the Territory, then ViroPharma shall communicate this information to Genzyme pursuant to Section 9(b) below, and either party shall have the right to terminate this Agreement upon thirty (30) days notice by providing written notice thereof to the other party. In addition, Genzyme may terminate this Agreement upon thirty (30)

days written notice if (i) ViroPharma has not filed the sNDA by the first anniversary of the Effective Date or (ii) the Product is no longer sold in the Territory.

(d) **Termination for Breach**. This Agreement may be terminated by a party if the other party commits a material breach or default of the terms of this Agreement and such breach or default is not cured within thirty (30) days after the giving of written notice by the non-breaching party specifying such breach or default.

(e) **Termination for Bankruptcy**. In case of the filing of a voluntary petition for bankruptcy, the failure to cause an involuntary petition in bankruptcy to be dismissed within sixty (60) days after the filing thereof, suspension of payment, assignment for the benefit of creditors, voluntary liquidation or otherwise of one party then the other party shall be entitled to terminate this Agreement by giving thirty (30) days written notice to the other party.

(f) **Effects of Termination**.

1. Upon expiration or termination of this Agreement, ViroPharma shall return to Genzyme all Data, Documentation and other Confidential Information provided by Genzyme to ViroPharma pursuant to this Agreement.

2. If ViroPharma terminates this Agreement, or if Genzyme terminates this Agreement under Sections 8(d) or 8(e) hereof, then if and when ViroPharma files the sNDA, Genzyme shall have the right to notify the FDA in writing that ViroPharma no longer has any rights to Genzyme's interests in the Data or the Studies, and therefore the sNDA does not qualify for marketing exclusivity under 21 CFR 314.108(b)(5)(ii), in that it does not contain reports of new clinical investigations that were "conducted or sponsored by the applicant," as defined by 21 CFR 314.108(a).

3. Upon expiration or termination of this Agreement, ViroPharma will have no further rights to, or license under, Genzyme's interests in the Data or the Studies.

(g) **Survival**. Expiration or termination of this Agreement shall not affect any rights or obligations which have accrued prior thereto or in connection therewith, or any obligations hereunder which by their terms should survive termination or expiration (including, but not limited to, any payment obligations of ViroPharma outstanding as of the effective date of expiration or termination of this Agreement). Notwithstanding anything herein, the provision of Articles 1, 4 (obligation to pay any Maintenance Fees or Royalties incurred prior to the termination or expiration date), 5 (for the period specified in Section 5(g)), 6 and 7 (for the period equal to the period proscribed statute of limitations for claims arising with respect thereto), and Sections 8(f) and 8(g) shall survive the expiration or termination of this Agreement.

9. **Miscellaneous**.

(a) **Genzyme Reporting Obligations**. Genzyme shall notify ViroPharma (i) of any Adverse Experience, Serious Adverse Experience or Unexpected Adverse Experience (as defined at 21 CFR § 312.32(a)) arising from the Studies, by telephone within twenty-four (24) hours after Genzyme receives information about the experience, to be confirmed in writing within two (2) business days and (ii) immediately in writing if the FDA, the European Medicines Agency (EMEA) or any other regulatory authority inspects, requests an inspection, or makes written or oral inquiries regarding the Studies or Data (including, without limitation, in the event that any Person who was involved in any capacity with respect to the Studies or Data is, on or after the Effective Date, debarred or is the subject of a conviction described in Section 306 of the United States Federal Food, Drug and Cosmetic Act, or if any action, suit, claim, investigation or legal administrative proceeding is pending or, to the best of Genzyme's knowledge, is threatened, relating to the debarment of any Person used in any capacity with respect to the Studies or Data). ViroPharma shall have the right, at its discretion, to be present at any meeting with any regulatory authority with respect to the Studies or Data. Within ten (10) days after the Effective Date, ViroPharma shall provide Genzyme with the name and contact information of the individual at ViroPharma who shall receive all notices and information provided by Genzyme under this Section 9(a).

(b) **ViroPharma Reporting Obligations**. ViroPharma shall notify Genzyme within three (3) business days of (i) any written communication from the FDA or any other regulatory authority relating to the Studies, the Data, the sNDA, the award of marketing exclusivity for the Product or the publication of an exclusivity code for the Product in the Orange Book, and provide Genzyme with copies of any such written communications within three (3) business days of receipt, (ii) prior to the Initiation Date, any written communication by ViroPharma to the FDA or any other regulatory authority relating to the Studies, the Data, the sNDA, the award of marketing exclusivity for the Product or the publication of an exclusivity code for the Product in the Orange Book (but not including any memoranda that ViroPharma may provide to FDA or any other regulatory authority that discusses the label for the Product), and provide Genzyme with copies of any such written communication or filing including, without limitation, the sNDA, within three (3) business days of the date of such communication or filing, and (iii) any meeting between ViroPharma and the FDA relating to the Studies, the Data, the sNDA, the award of marketing exclusivity for the Product or the publication of an exclusivity code for the Product in the Orange Book, and provide Genzyme with a written summary of such meeting within three (3) business days of the date of the meeting, and a copy of any FDA minutes of the meeting within three (3) business days of receipt from the FDA. Within ten (10) days after the Effective Date, Genzyme shall provide ViroPharma with the name and contact information of the individual at Genzyme who shall receive all notices and information provided by ViroPharma under this Section 9(b).

(c) **Assignment**. Neither party shall assign this Agreement without the prior written consent of the other party, provided, that either party may assign this Agreement without the prior written consent of the other party (i) to an Affiliate or (ii) to a party in connection with the sale or transfer of substantially all of its assets with respect to

the subject matter of this Agreement. Any permitted assignee shall assume all obligations of its assignor under this Agreement. This Agreement and the rights granted in this Agreement shall be binding upon and shall inure to the benefit of ViroPharma, Genzyme and their respective successors and permitted assigns.

(d) **Entire Agreement**. This Agreement constitutes and contains the entire understanding and agreement of the parties respecting the subject matter of this Agreement, and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements between the parties, whether oral or written, regarding such subject matter, including, but not limited to, the Confidential Disclosure Agreement dated January 29, 2009 between the parties; *provided, however*, that the parties' obligations of confidentiality under the Confidential Disclosure Agreement shall remain in full force and effect with respect to any and all information disclosed thereunder. No modification, alteration or change in any of the terms of this Agreement shall be valid or binding upon the parties hereto unless made in writing and signed by both parties.

(e) **Notices and Deliveries**. Any formal notice, request, delivery, approval or consent required or permitted to be given under this Agreement (except as otherwise set forth in Sections 9(a) and 9(b) hereof) shall be in writing in English and shall be deemed to have been sufficiently given, whether delivered in person, transmitted by facsimile with contemporaneous confirmation by mail, or delivered by internationally recognized overnight courier service (receipt required), to the party to which it is directed at its address shown below or such other address as such party shall have last given by notice to the other party.

If to Genzyme, address to:
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
Attn: President, Cardiometabolic and Renal
Fax: 617-768-9718

With a copy to:
Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142
Attn: General Counsel
Fax: 617-252-7553

If to ViroPharma, address to:
ViroPharma Incorporated
730 Stockton Drive
Exton, PA 19341
Attn: Vice President, Business Development
Fax: 610-458-7380

With a copy to:
ViroPharma Incorporated
730 Stockton Drive
Exton, PA 19341
Attn: General Counsel
Fax: 610-458-7380

Any such notice shall be deemed to have been given: (i) on the next business day after delivery if personally delivered or sent by facsimile or (ii) on the business day after dispatch if sent by internationally recognized overnight courier.

(f) **Other**. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each party. 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. This Agreement has been prepared jointly by the parties and any ambiguities in this Agreement shall not be strictly construed against either party. This Agreement may be executed in counterparts, or facsimile versions, each of which shall be deemed to be an original, and both of which together shall be deemed to be one and the same agreement. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the application of principles of conflicts of law.

[Signature page follows.]

IN WITNESS WHEREOF, ViroPharma and Genzyme, by their duly authorized officers, have executed this Agreement as of the Effective Date.

VIROPHARMA INCORPORATED	**GENZYME CORPORATION**
By: /s/ Vincent J. Milano	By: /s/ John P. Butler
Name: Vincent J. Milano	Name: John P. Butler
Title: President and Chief Executive Officer	Title: President, Cardiometabolic and Renal

10.60

AMENDMENT NO. 2 TO EXCLUSIVE CLINICAL STUDY AND DATA LICENSE AGREEMENT BETWEEN GENZYME CORPORATION AND VIROPHARMA INCORPORATED

This Amendment No. 2 (the "Amendment") to the Exclusive Clinical Study and Data License Agreement dated June 12, 2009 (the "Agreement") by and between Genzyme Corporation ("Genzyme") and ViroPharma Incorporated ("ViroPharma"), as amended on October 21, 2009, is effective as of April 5, 2010 ("Amendment Effective Date").

WHEREAS, Genzyme and ViroPharma are parties to the Agreement, pursuant to which Genzyme granted ViroPharma a license to certain clinical studies and data related to Genzyme's proprietary product, tolevamer;

WHEREAS, Genzyme and ViroPharma now wish to amend certain provisions of the Agreement to allow Genzyme to receive a royalty in the event that ViroPharma, or its distributor, launches an authorized generic version of the Product;

NOW, THEREFORE, in consideration of the promises and agreements set forth herein, and for other good and valuable consideration, the parties hereby agree as follows:

1. Capitalized terms not defined herein shall have the meaning ascribed to such terms in the Agreement.

2. The following language shall be added as Section 4(b)(4) of the Agreement:

   In the event that ViroPharma, either alone or pursuant to an agreement with an authorized generic distributor (**"AG Distributor"**),distributes an authorized generic version of the Product (**"AG Product"**) during the Royalty Term, ViroPharma will pay Genzyme a royalty on all revenue (excluding transfer payments which are at or less than ViroPharma's cost of goods) from sales of the AG Product in the Territory received by ViroPharma (either directly or from an AG Distributor) (the **"AG Royalty"**) as follows:

Year Following Initiation Date	AG Royalty Rate
1	8%
2	8%
3	12.8%

If, in addition to the AG Product, two (2) Third Parties are selling an Other Vancomycin Product to a wholesaler, distributor, consumer or any other Third Party, the AG Royalty will be as follows during the Royalty Term:

Year Following Initiation Date	AG Royalty Rate
1	7.5%
2	7.5%
3	12%

If, in addition to the AG Product, three (3) or more Third Parties are selling an Other Vancomycin Product to a wholesaler, distributor, consumer or any other Third Party, the AG Royalty will be as follows during the Royalty Term:

Year Following Initiation Date	AG Royalty Rate
1	7%
2	7%
3	11.2%

The AG Royalty shall be in addition to the Royalties paid to Genzyme under Section 4(b)(1). ViroPharma shall pay Genzyme the AG Royalty in accordance with the terms of the Agreement and ViroPharma shall include the revenues received by ViroPharma from the AG Product, and the calculation of the AG Royalty, in the Sales Reports provided in accordance with Section 4(b)(2).

Except as expressly modified hereby, the terms of the Agreement remain in full force and effect and shall govern and apply to all matters contemplated by this Amendment.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

VIROPHARMA INCORPORATED	GENZYME CORPORATION
By: /s/ Vincent J. Milano	By: /s/ John P. Butler
Name: Vincent J. Milano Title: President & CEO	Name: John P. Butler Title: President, Cardiometabolic & Renal
Date:_____	Date:_____