18-03296-E

Madison, Wilton

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Saturday, March 17, 2018 11:40 AM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.8 to the Form S-1 and amendments thereto, filed by Salix Pharmaceuticals, Inc. on 8/15/1997. 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

April 9, 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. 18-03291-E

Dear Mr. Edwards:

This letter is in response to your request, dated March 17, 2018 and received in this office on March 19, 2018, for access to Exhibit 10.8 to the Form S-1 and amendments thereto, filed by Salix Pharmaceuticals, Inc. on August 15, 1997.

The search for responsive records has resulted in the retrieval of 23 pages of records that may be responsive to your request. They are being provided to you with this letter.

No fees have been assessed in the processing of this request. If you have any questions, please contact me at osbornes@sec.gov or (202) 551-9371. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney 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,

Sonja Osborne

Sonja Osborne
FOIA Lead Research Specialist

Enclosure

Exhibit 10.8

Portions of this exhibit marked [ ] are requested to be treated confidentially.

AMENDED AND RESTATED LICENSE AGREEMENT

BY AND BETWEEN

SALIX PHARMACEUTICALS, INC.

AND

BIOREX LABORATORIES LIMITED

APRIL 16, 1993

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AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED LICENSE AGREEMENT (the "Agreement") is entered into effective as of April 16, 1993 between SALIX PHARMACEUTICALS, INC., a California corporation having its principal place of business at 3600 W. Bayshore, Suite 205, Palo Alto, California 94303 ("Salix"), and BIOREX LABORATORIES LIMITED, a United Kingdom corporation having its principal place of business at 2 Crossfield Chambers, Gladbeck Way, Enfield, Middlesex EN2 7HT ("Biorex"),

RECITALS :

Biorex and Salix have entered into a License Agreement dated as of January 17, 1991, as amended by an Amendment Agreement dated as of September 17, 1992 (collectively, the "Original Agreement"). Salix and Biorex desire to amend and restate the Original Agreement to make certain modifications thereto as set forth below.

NOW, THEREFORE, for good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, the parties hereto mutually agree to amend, restate and supersede the Original Agreement in its entirety to read as set forth below:

Article 1. DEFINITIONS

For the purposes of this Agreement, the terms defined in this Article shall have the meanings specified below:

1.1 **"Affiliate"** means any corporation or other entity which controls, is controlled by, or is under common control with, a party to this Agreement. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity.

1.2 **"Astra"** means AB Astra, a company incorporated under the laws of Sweden, whose principal place of business is at Kvarnbengagatan 16, S-151 Sodertalje, Sweden.

1.3 **"Balsalazide"** means 5-[4(2-Carboxyethylcarbamoyl)-phenylazo]-salicylic acid disodium salt dihydrate, and prodrugs, analogs and isomers thereof, and improvements to any of the foregoing, owned by or licensed to Biorex during the term of this Agreement.

1.4 **"Biorex/Astra Agreement"** means the Agreement of even date herewith by and between Astra and Biorex.

1.5 **"Commercial Introduction"** of any Product shall mean the first sale for use or consumption by the general public of such Product in a country after required marketing and, if required, pricing approval has been granted by the governing health authority of such country.

1.6 **"Launch"** means a commercial launch by Salix, its Affiliates and/or sublicensees of the Product throughout the Territory supported by such marketing expense and supported and launched in such quantities as may be reasonably be appropriate for the Product to have a significant effect on total sales of any similar or competitive product.

1.7 **"Manufacturing Technology"** shall mean all methods, processes, designs, data, procedures and other information owned by or licensed to Biorex or its Affiliates during the term of this Agreement that are reasonably required for pilot production or commercial manufacturing of Products, including, without limitation, final quality assurance-quality control procedures, manufacturing procedures (including conditions, times, temperatures, pressures and rates), product and raw material specifications, and other technology related thereto, including all patent and other intellectual property rights thereto.

1.8 **"Net Sales"** with respect to any Product means the invoiced sales price of such Product received from independent customers (including distributors) who are not an Affiliate or sublicensee, less, to the extent such amounts are included in the invoiced sales price: (a) actual credited allowances to such independent customers for spoiled, damaged, out-dated and returned Product; (b) freight and insurance costs incurred in transporting such Products to such customer; (c) quantity and other trade discounts actually allowed and taken; (d) sales, value-added and other direct taxes; and (e) customs duties and surcharges and other governmental charges.

1.9 **"Patent Rights"** means all rights of Biorex in the Territory to any subject matter described by, claimed in or covered by any of the following:

1.9.1 United States Patent Number 4,412,992 entitled "2-Hydroxy-5-Phenylazobenzoic Acid Derivatives and Methods of Treating Ulcerative Colitis Therewith," issued November 1, 1983, and any substitutions, renewals, reissues, and extensions of the foregoing.

1.9.2 Any and all other patent rights, now existing or hereafter acquired (including applications therefor), pertaining to the subject matter described in Section 1.9.1 above, or that are otherwise related to Balsalazide, obtained in any country within the Territory.

1.10 **"Products"** means products incorporating Balsalazide, or any other material whose manufacture, use or sale by an unlicensed third party would constitute an infringement of any Valid Claim (as defined below) included within the Patent Rights.

1.11 **"Royalty Term"** means, with respect to each Product in the Territory, the period of time equal to the longer of: (a) nine (9) years from the date of Launch of such Product in the Territory; or (b) if the manufacture, use or sale of such Product in the Territory is covered by a Valid Claim, the term of such Valid Claim.

1.12 **"Salix/Astra Agreement"** means the Co-Participation Agreement of even date herewith by and between Salix and Astra.

1.13 **"Technical Information"** means all formulae, raw material and product specifications, designs and procedures, formulation data, processes and methods, pharmacology, toxicology and other preclinical tests results, clinical trials data and results, know-how, trade secrets, inventions and other scientific, medical, technical and marketing data and information, including all patent and other intellectual property rights thereto, which: (a) are owned or controlled by, or licensed to, Biorex or its Affiliates during the term of this Agreement, and (b) that are reasonably necessary for the development, manufacture, sale or use of Products. Technical Information shall include information and methods relating to the characterization, synthesis, formulation, stability, manufacture or assay of Balsalazide.

1.14 **"Territory"** means the United States (including its territories, possessions and the Commonwealth of Puerto Rico).

1.15 **"Third Party"** means any entity other than Salix or Biorex and their respective Affiliates.

1.16 **"Trademarks"** means the trade name "Colazide" registered as a trademark for use on pharmaceutical preparations in the Territory and any other trade name designated by Biorex for use in the Territory in connection with the Products.

1.17 **"Valid Claim"** means a claim of an issued and unexpired patent included within the Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

Article 2. REPRESENTATIONS AND WARRANTIES

2.1 Authorization. Biorex represents and warrants that (i) it has the full right and authority to grant the licenses provided in the Agreement and perform its obligations hereunder; (ii) to the best of Biorex's knowledge, Salix may exercise the licenses granted to it under the Agreement without conflict with or infringement of any rights or alleged rights of any person or entity; (iii) Biorex has not, and will not during the term of this Agreement, make any commitment or incur any obligation in conflict with the licenses granted in the Agreement; (iv) Biorex is the sole legal owner of the Patent Rights; and (v) Biorex has obtained any and all governmental approvals, other than of the United States, that are required for Biorex to enter into and perform this Agreement.

2.2 No Other Representations. Except to the extent provided in this Article 2, Biorex makes no representations and extends no warranties of any kind, either expressed or implied, with respect to use, sale, or other disposition by Salix or its sublicensees or its vendees or other transferees of Products incorporating or made by use of subject matter licensed under this Agreement. THE WARRANTIES EXPRESSLY SET FORTH IN THIS ARTICLE 2 BY EITHER PARTY ARE EXCLUSIVE AND NO OTHER WARRANTY, WRITTEN OR ORAL, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS EXPRESSED OR IMPLIED.

Article 3. GRANT

3.1 Grant. Biorex hereby grants to Salix and its Affiliates (a) an exclusive license under the Patent Rights, the Technical Information and Manufacturing Technology to develop, use, and sell and have sold Products within the Territory; and (b) a nonexclusive license under the Patent Rights (including foreign counterparts thereof), the Technical Information and the Manufacturing Technology to make and have made Products anywhere in the world, but solely for sale or use within the Territory. Notwithstanding the foregoing, Salix shall not manufacture the Product outside the Territory without first obtaining Biorex's consent, which shall not be unreasonably withheld.

3.2 Sublicenses. The license granted to Salix under Section 3.1 above shall include the right to grant sublicenses, subject to this Section 3.2. To the extent applicable, such sublicenses shall include all of the rights and obligations due Biorex that are contained in this Agreement. Salix shall provide Biorex with a copy of any sublicense issued hereunder, which copy shall be maintained in confidence pursuant to Section 11 hereof. Notwithstanding the foregoing, Salix shall not grant a sublicense for the manufacture, sale and use of a Product in the Territory without first obtaining Biorex's consent, which shall not be withheld unreasonably. For the purposes of this Agreement, the Salix/Astra Agreement shall be deemed to be a sublicense and not a subcontract.

3.3 Subcontracts. The following types of arrangements shall not be deemed to be sublicenses hereunder:

3.3.1 appointment of third parties to market, sell, use or otherwise dispose of Products;

3.3.2 subcontracting of third parties to develop new Products; or

3.3.3 subcontracting of third parties to manufacture the Products.

3.4 Milestone Payments.

3.4.1 Salix has paid to Biorex the amounts set forth below:

Milestone	Amount
January 17, 1991	$50,000
First Approval by Food and Drug Administration ("FDA") of an Investigational New Drug ("IND") for a Product, or 1 June, 1992, whichever is earlier	$100,000

3.4.2 Salix shall pay to Biorex, within thirty (30) days after the events described below, the amounts set forth opposite such event:

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First Filing with FDA of a New Drug Application ("NDA") for a Product, or 1 June 1995, whichever is earlier	$100,000
First Approval by FDA of NDA for a Product	$250,000

The amount paid under this Section 3.4 with respect to approval of an NDA by the FDA shall be carried forward and offset against royalties accruing under Article 7 below.

Article 4. DEVELOPMENT

4.1 Technical Information. Insofar as it has not already done so, Biorex shall promptly provide to Salix all Technical Information, including all regulatory filings made by or for Biorex with respect to Balsalazide and any other products that would be covered by the Patent Rights if made, used or sold within the Territory ("Biorex Products"), and a description of Biorex's development program for such products, including without limitation descriptions of all tests, trials, development steps, protocols, clinical investigators and the like. Biorex shall promptly provide to Salix, and in any event at least quarterly, all Technical Information (including such regulatory filings) and information that it develops or acquires after the date hereof. In addition, Biorex shall use all reasonable efforts to so provide to Salix all similar items and information generated or developed by or for other licensees of Biorex and to permit Salix to use such items and information to the same extent it may use Technical Information hereunder. Salix shall have a right to use all such Technical Information and information of such licensees for purposes of this Agreement, and to cross-reference all such regulatory filings. In the event that Biorex does not obtain from any other licensee of Biorex the right to permit Salix to use such items or information, Biorex shall not provide to such licensee any information of Salix provided to Biorex under Section 4.2 below.

4.2 Exchange of Data. Each party shall keep the other informed as to its progress in the development and testing of all Products and Biorex Products and the preparing, filing and obtaining of the approvals necessary for marketing such products. Each party shall notify the other at least thirty (30) days in advance of, and make available to the other party for review prior to submittal of, all filings and correspondence to be submitted to regulatory authorities with respect to marketing approval of such a product, and all proposed publications of test data or results related to such products. Such items shall be made available at such party's principal place of business, or if reasonable to do so, they shall be sent to the other party. In addition, each party shall provide the other with copies of such other documents as it reasonably requests promptly after such request. Until the date of the Commercial Introduction of each such product, each party shall provide to the other quarterly reports summarizing in reasonable detail its activities related to the development and securing of the requisite marketing and other regulatory approvals for such products. After the Commercial Introduction of any such product, each party shall keep the other informed of any further communications or activities concerning such products by, with or involving governmental health agencies. Throughout the term of this Agreement, each party shall promptly supply the other with all information regarding adverse drug experiences.

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4.3 Visit of Facilities. Representatives of Salix and Biorex may, upon reasonable notice and at times reasonably acceptable to the other party (a) visit the facilities where the preclinical tests or clinical trials are being conducted with respect to Products or Biorex Products, and the facilities where the other party manufactures any Product, Biorex Product or active compound contained therein (or has such a product or compound manufactured, but subject always to the consent of the relevant subcontractor) to the extent relating to such product or compound; and (b) consult informally, during such visits and by telephone, with personnel of the other party performing work on such tests, trials or manufacturing.

4.4 Conferences. Until the filing of an NDA with respect to a Product, the parties shall meet periodically, at times and locations to be agreed, to discuss their respective development programs with respect to such Product and related Biorex Products.

4.5 Technical Assistance. Biorex shall provide to Salix such reasonable technical assistance as is in Biorex's control, if appropriate at Salix's facilities, with respect to the development, preclinical and clinical testing and manufacturing of Products.

4.6 Progress Reports. Salix shall provide to Biorex semiannual reports describing in reasonable detail its progress in developing Products hereunder. Such obligation shall continue until the Commercial Introduction of the first Product.

Article 5. DUE DILIGENCE; NONCOMPETITION

5.1 Regulatory Approvals. Salix shall use its best efforts to conduct such additional preclinical studies and clinical trials as are necessary to obtain regulatory approval to market at least one Product in the Territory. In this connection, and subject to Section 5.4 below, Salix shall use its best efforts to achieve the following objectives:

5.1.1 Commencing human clinical trials with respect to a Product on or before June 1, 1993;

5.1.2 Substantially completing human clinical trials necessary to file with the FDA an NDA with respect to a Product on or before March 31, 1994; and

5.1.3 Filing with the FDA an NDA with respect to a Product on or before June 30, 1994.

5.2 Commencement of Marketing. Subject to the provisions of Section 5.4 below, with respect to each Product for which Salix has received necessary regulatory approvals to market such Product in the United States, Salix shall use commercially reasonable efforts to:

5.2.1 Commence marketing such Product in such country within four (4) months of receiving approval (including, if required, pricing and reimbursement approval) to market such Product in that country;

5.2.2 After commencing marketing of such Product in such country, to meet the market demand for such Product in such country; and

5.3 Biorex's Remedies.

5.3.1 Failures Relating to Clinical Development. In the event that Salix fails to meet its obligations under Section 5.1 above, and does not remedy such failure within 60 days of notice by Biorex, Salix shall pay to Biorex [$10,000 per month] until such failure is cured; provided, however, that failure to meet the time schedules set forth in Section 5.1 above shall not alone constitute a failure to meet Salix's obligations under Section 5.1, so long as Salix is using its best efforts to meet the objectives set forth therein as soon as is reasonably practicable. Any amounts paid by Salix hereunder may be carried forward and offset against royalties or minimum royalties that accrue under Article 7 below.

5.3.2 Failure to Market. If Salix fails to fulfill its obligations under Section 5.2 with respect to any country, and does not remedy such failure within one hundred eighty (180) days after receiving a written request to do so, Salix's rights to sell that Product in such country shall thereafter be nonexclusive, and Biorex shall have the right to grant one additional license to sell such Product in such country (which license shall not include the right to grant further sublicenses), unless Salix promptly commences to pay the minimum royalties required under Section 7.3.

5.3.3 Sole Remedy. This Section 5.3 sets forth Biorex's sole remedies for a failure by Salix to meet its obligations under Sections 5.1 and 5.2 above.

5.4 Excused Performance. In addition to the provisions of Article 15, Salix's obligations with respect to any Product under this Article 5 are expressly conditioned upon the continuing absence of any adverse condition relating to the safety, quality or efficacy of that Product or any other restrictions or delays imposed or caused by governmental authorities, or other condition or event beyond Salix's control that would reasonably justify Salix, after consulting with Biorex, in exercising prudent and justifiable business judgment, to conclude that development or marketing of such Product should be delayed, suspended or stopped altogether, and Salix's obligation to develop or market any such Product shall be delayed or suspended so long as any such condition or event exists. In addition, Salix shall not be responsible for any delays caused by failure of the FDA to accept data provided by Biorex or by inability of Salix to obtain, or delays in obtaining, sufficient quantities of clinical materials on reasonable terms.

5.5 Noncompetition. During the term of this Agreement, Biorex shall not market in the Territory, itself or through licensees, distributors, agents or Affiliates, any product that competes or would compete with a Product.

5.6 Scientific Advisory Board. Until the Commercial Introduction of a Product, Salix may appoint to its Scientific Advisory Board one representative selected by Biorex; provided, however, that such scientific advisor nominated by Biorex shall enter into Salix's standard form of Scientific Advisor Agreement on the same terms and conditions generally proposed by Salix for its scientific advisors.

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Article 6. MANUFACTURING; TRADEMARKS

6.1 Clinical Materials. Biorex shall use its best efforts to supply, or to arrange for others to supply, Salix's requirements of Products for preclinical tests and human clinical trials on reasonable terms and conditions. In the event that Biorex arranges for Third Parties to develop formulations of, or supply, Products to Biorex under this Section 6.1, Biorex shall use all reasonable efforts to acquire the right to include the manufacturing processes and technology used by such Third Party for such Product in the Technical Information, Manufacturing Technology or the Patent Rights, so that Salix may use such process to manufacture such Product.

6.2 Manufacturing Technology. As soon as practicable following a request by Salix, Biorex shall disclose to Salix all Manufacturing Technology in existence at such time, and shall thereafter promptly (and in any event at least quarterly) provide Salix with updates or additions to such Manufacturing Technology that are subsequently developed or acquired by Biorex or its Affiliates. In addition, Biorex shall use all reasonable efforts to so provide to Salix all similar items and information generated or developed by or for other licensees of Biorex and to permit Salix to use such items and information to the same extent it may use Manufacturing Technology hereunder.

6.3 Trademarks. Biorex hereby grants to Salix an exclusive license, including the right to grant sublicenses, to use the Trademarks within the Territory in connection with sales of Products. Such license shall be royalty free and fully paid for the first six (6) years following Launch; thereafter Salix shall pay Biorex a royalty fee of [one percent (1%) of Net Sales] of all Products bearing the Trademarks sold or supplied by Salix, its Affiliates and/or sublicensees in the Territory. Except as provided below, Salix shall have the exclusive right to institute and pursue actions to prevent any use of the Trademarks within the Territory.

Article 7. ROYALTIES

7.1 Base Royalty Rate. In consideration of licenses granted to Salix herein, Salix shall pay to Biorex the following royalties with respect to Net Sales by Salix, its Affiliates and sublicensees of Products in the Territory during the Royalty Term for such Product (except as otherwise set forth in this Section 7);

Annual Net Sales For All Products	Royalty Rate
First $5,000,000	3%
$5,000,001-10,000,000	4%
$10,000,001-20,000,000	5%
$20,000,001-30,000,000	6%
$30,000,001-40,000,000	7%
Over $40,000,001	9%

For example, the parties acknowledge that the applicable royalties due Biorex hereunder at Annual Net Sales for All Products of $45,000,000 will be $2,600,000 (3% of the first $5,000,000; 4% of the next $5,000,000; 5% of the next $10,000,000; 6% of the next

[ ] Confidential treatment requested.

$10,000,000; 7% of the next $10,000,000; and 9% of the remaining $5,000,000). Annual Net Sales shall be determined on Salix's fiscal year basis for purposes of such royalty calculations.

7.2 Sales to Resellers. With respect to sales of Products to a wholesaler or distributor who are not Affiliates ("Distributors"), Net Sales shall be calculated based upon the price paid by such Distributor, and no royalty shall be payable upon the Distributor's sales of such Products by the Distributor. With respect to sales of Products in bulk form to sublicensees other than Distributors, royalties shall be payable only upon the sublicensee's resale of such Products and not upon Salix's sale to the sublicensee. For the purposes of this Agreement, Astra and any Astra Associates (as defined the Salix/Astra Agreement) shall be deemed to be sublicensees and not Distributors.

7.3 Minimum Royalties. Beginning with Salix's first full fiscal year after the Commercial Introduction of the first Product incorporating Balsalazide, and continuing for five (5) years thereafter, Salix shall pay to Biorex the following minimum royalties:

Year After Commercial Introduction	Minimum Royalty
First Year	$ 600,000
Second Year	1,300,000
Third-Fifth Years (per year)	1,500,000

Minimum royalties accrued under this Section 7.3 and earned royalties otherwise accruing under this Article 7 shall be offset against each other. In the event that earned royalties in any Salix fiscal year in the Territory do not exceed the minimum royalties for such year, the royalty report provided under Article 8 below for the final quarter of such year shall include a payment so that the total royalties paid for such year equals the minimum royalties for such year. In the event that Salix fails to pay the minimum royalties for any year within ninety (90) days of the date such payment is due, Biorex shall have the right to convert Salix's licenses hereunder into nonexclusive licenses. To exercise such right, Biorex must give Salix at least thirty (30) days prior written notice within such 90-day period of its intention to do so. Salix may cure any such failure by paying the minimum royalty within such ninety (90) day period (or if longer, within the 30-day notice period), in which case Biorex's right to convert Salix's licenses as a result of such nonpayment shall cease. Converting such licenses to be nonexclusive shall be Biorex's sole remedy upon a failure by Salix to pay such minimum royalties.

7.4 Combination Product. In the event a Product is sold in a combination product with other biologically active components, Net Sales, for purposes of royalty payments on the combination product, shall be calculated by multiplying the Net Sales of that combination by the fraction A/B, where A is the gross selling price of the Product sold separately and B is the gross selling price of the combination product. In the event that no such separate sales are made by Salix or a permitted sublicensee, Net Sales for royalty determination shall be reasonably allocated between such Product and such other compensation, based upon their relative importance and proprietary protection.

[ ] Confidential treatment requested.

7.5 No Patent Protection. Notwithstanding anything to the contrary contained in Section 7.1:

7.5.1 In the event that Product is sold in a country in which the sale would not infringe a Valid Claim within the Patent Rights in the Territory, and significant sales of a substantially equivalent product are made by third parties in the Territory, the royalty otherwise applicable to such Product in the Territory shall be reduced by fifty percent (50%) (even though the Product is made in a country in which such manufacture infringes a Valid Claim) for so long as significant sales of the substantially equivalent product continue.

7.5.2 In the event that any patent or any claim thereof included within the Patent Rights shall be held invalid in a decision by a court of competent jurisdiction, Salix shall have the right to withhold fifty percent (50%) of the royalties payable with respect to such claim accruing after the date of such decision. In the event that such decision is reversed on appeal, Salix shall promptly remit to Biorex all such royalties so withheld.

7.5.3 In the event Astra is granted a license to manufacture as set forth in Schedule 5 of the Salix/Astra Agreement with the royalty rates specified in Sections 6.1, 6.2 or 6.3 of said Schedule 5, the royalties otherwise payable by Salix under Article 7 shall be limited the lesser amount of :

(A) the amounts due Biorex as otherwise provided in this Article 7; or

(B) the greater of (1) the sum of the amounts payable by Astra to Salix as provided in Section 6 of Schedule 5 to the Salix/Astra Agreement or (2) five percent (5%) of Net Sales of Products.

7.6 Third Party Royalties. In the event that Salix is required to pay to a Third Party any royalties or amounts determined by Net Sales of a Product with respect to technology incorporated in such Product other than the technology licensed hereunder, Salix may deduct from the royalty accruing to Biorex under Section 7.1 or 7.2 above with respect to such Product fifty percent (50%) of the amount paid to such Third Party, up to a maximum of fifty percent (50%) of the royalties that would otherwise accrue to Biorex with respect to such Product under Section 7.1 or Section 7.2.

7.7 Nonexclusivity. In the event that Salix's licenses under this Agreement become nonexclusive under Section 5.3 or Section 7.3 above, and Biorex grants another license with respect to a Product within the Territory on royalty terms more favorable than those set forth herein, Salix shall have the right and option to substitute such royalty terms for the royalty terms provided herein. In the event Salix's licenses herein become nonexclusive, its obligations to pay minimum royalties shall thereupon terminate.

Article 8. ROYALTY REPORTS AND ACCOUNTING

8.1 Reports, Exchange Rates. During the term of this Agreement, after the Commercial Introduction of a Product, Salix shall furnish to Biorex on a quarterly basis a written report covering Salix's fiscal quarters showing (i) the gross sales of all Products sold by Salix its Affiliates.

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and its sublicensees in the Territory during the reporting period and the calculation of Net Sales from such gross sales, (ii) the gross sales of all Products bearing the Trademark sold by Salix and its Affiliates & its sublicensees in the Territory during the reporting period and the calculation of Net Sales from such gross sales;; (iii) the sublicense royalties received by Salix during the reporting period; (iv) the royalties payable in U.S. dollars, which shall have accrued hereunder in respect of such sales and sublicense royalties; (v) withholding taxes, if any, required by law to be deducted in respect of such royalties, sales and sublicense royalties; and (vi) the dates of the Commercial Introductions of any Products in the Territory during the reporting period. Reports shall be due sixty (60) days following the close of each respective quarter. In case no royalty is due for any royalty period hereunder, Salix shall so report. Salix shall keep accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

8.2 Audits.

8.2.1 Upon the written request of Biorex, at Biorex's expense and not more than once each Salix fiscal year, Salix shall permit an independent public accountant selected by Biorex and reasonably acceptable to Salix to have access during normal business hours to such of the records of Salix as may be reasonably necessary to verify the accuracy of the royalty reports hereunder made not more than thirty-six (36) months prior to the date of such request.

8.2.2 In the event such accountant concludes that additional royalties were owed during such period, the additional royalty shall be paid promptly. The fees charged by such accountant shall be paid by Biorex unless the audit establishes that the royalties payable by Salix for the audited period are more than one hundred five percent (105%) of the royalties actually paid for such period, in which case Salix shall pay the reasonable fees and expenses charged by the accountant.

8.2.3 Upon the expiration of thirty-six (36) months following the date of any royalty report hereunder, the calculation of royalties payable with respect to the quarter covered by such report shall be binding and conclusive upon Biorex; and Salix shall be released from any liability or accountability with respect to royalties for such year.

8.3 Confidential Financial Information. Biorex agrees that all information subject to review under this Article 8 is confidential and shall cause its accountant to retain all such information in confidence.

Article 9. ROYALTY PAYMENTS

9.1 Payment Terms. Royalties shown to have accrued by each royalty report provided for under Article 8 of this Agreement shall be due and payable on the date such royalty report is due. Payment of royalties in whole or in part may be made in advance of such due date. Royalties determined to be owing, and any overpayments to be credited, with respect to any prior quarter shall be added, together with interest thereon under Section 9.3 below from the date of the report for the quarter for which such amounts are owing, or credited, as the case may be, to the next quarterly payment hereunder.

9.2 Exchange Control. Except as hereinafter provided in this Section 9.2, all royalties due shall be paid in U.S. currency. If at any time legal restrictions prevent the prompt remittance of part or all royalties with respect to any country of the Territory where the Product is sold, payment shall be made through such lawful means or methods as Biorex may designate.

9.3 Late Payments. Any payments 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 law at the prime rate of interest as reported by Bank of America NT&SA in San Francisco, California from time to time, calculated on the number of days such payment is delinquent. This Section 9.3 shall in no way limit any other remedy available to either party.

Article 10. INFRINGEMENT

10.1 Infringement Rights. The provisions of this Article 10 shall govern the parties' rights and obligations, as between themselves, with respect to actions against and by Third Parties for infringement of patents licensed under this Agreement or owned by such Third Parties. In the event that either party learns of a significant infringement of the Patent Rights, or corresponding patent rights outside of the Territory ("Foreign Patent Rights"), it shall promptly notify the other party.

10.2 Enforcement of Patent Rights.

10.2.1 Salix shall have the exclusive right to bring, direct and control any action to enforce the Patent Rights against infringers within the Territory.

10.2.2 Salix may deduct from royalties owing under Article 7 above all of its costs and expenses incurred in enforcing the Patent Rights, up to [a maximum of fifty percent (50%)] of the royalties accruing hereunder. After reimbursement to Salix for its unreimbursed expenses, all damages and other payments recovered from such infringing parties shall be retained by Salix and included in Net Sales for the quarter in which they are received. Biorex shall cooperate with Salix, at Salix's expense, in connection with any such litigation, including without limitation by joining as a party if necessary or appropriate and executing such documents as Salix may reasonably request.

10.3 Third Party Claims. In the event that Salix is sued by an unaffiliated third party alleging that the manufacture, sale or use of a Product infringes patent rights of such third party, then Salix may withhold up to [fifty (50%)] of the royalties payable hereunder and apply such royalties to any damages, costs, liabilities or expenses (including the reasonable fees of attorneys and other professionals) incurred as a result of such claim, up to [a maximum of fifty (50%)] of such damages, costs, liabilities and expenses.

Article 11. CONFIDENTIALITY

11.1 General. Except as expressly otherwise provided in this Agreement, each party shall hold in confidence and not use or disclose to any Third Party (other than employees, consultants, advisors, permitted sublicensees and third parties with whom such party is considering entering into a business relationship who are similarly bound in writing) any

[ ] Confidential treatment requested.

product, technical, manufacturing, process, marketing, financial, business or other information, ideas, cell lines or know-how identified in writing as confidential ("Proprietary Information") of or used by the other; provided, however, that Proprietary Information of a party shall not include:

11.1.1 Items which at the time of disclosure are published or otherwise generally available to the public;

11.1.2 Items which, after disclosure by the other party, are published or become generally available to the public through no breach of this Agreement by the other or the other's employees or agents; or

11.1.3 Items which the other can document were or are (i) in its possession at the time of disclosure and was not acquired directly or indirectly from such party, or (ii) independently developed.

11.2 Exceptions. A party may disclose Proprietary Information of the other:

11.2.1 In connection with the order of a court of law or in compliance with laws or regulations relating to registrations or sale of securities or product approval, or

11.2.2 If such information is also rightfully acquired from a third party who, to the best of such party's knowledge and belief, is entitled to rightfully make such disclosure, but only to the extent such party complies with any restrictions imposed by the third party.

11.2.3 After five (5) years from the date such information is disclosed to it hereunder.

11.3 Licensed Information. Any Proprietary Information of or used by Biorex which are or may be subject to an exclusive license to Salix hereunder shall not be disclosed by Biorex to any third party for use in the Territory except for purposes not inconsistent with such exclusive license and only pursuant to confidentiality and non-use restrictions at least as restrictive as those provided herein.

11.4 Terms of this Agreement. Salix and Biorex agree not to disclose the financial terms or conditions of this Agreement to any Third Party without the prior written consent of the other party hereto, except as required by applicable law or to persons with whom Biorex or Salix has entered into or proposes to enter into a business relationship.

Article 12. PATENT PROSECUTION AND MAINTENANCE

12.1 Control. Salix shall have the right to take such actions as are necessary or appropriate, with counsel of its choosing, to effect the patent applications within the Patent Rights and to obtain patent protection with respect to the subject matter therein in any country within the Territory. In the event that Salix elects not to prosecute or maintain a patent application or patent within the Patent Rights, Biorex shall have the right to do so at its own expense.

12.2 Expenses. The cost of Salix's preparing, filing, prosecuting and maintaining all patent applications and patents contemplated by this Agreement shall be borne by Salix.

12.3 Cooperation. Salix shall provide Biorex with copies of all material documentation after receipt from or prior to submission to any governmental agency with jurisdiction to issue such patents, as appropriate, so that Biorex may be informed and apprised of the continuing prosecution. Salix shall consult with Biorex and its counsel concerning prosecution of any patent application and adopt reasonable suggestions made with respect thereto, and shall use its best efforts to amend any patent application to include claims reasonably requested by Biorex and required to protect the product contemplated to be sold under this Agreement. Biorex shall make available to Salix or its authorized attorneys, agents or representatives, Biorex's employees, agents or consultants necessary or appropriate to enable Salix to file, prosecute and maintain patent applications and resulting patents within the Patent Rights. Biorex shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to Salix.

Article 13. TERM; TERMINATION

13.1 Expiration. Unless terminated earlier pursuant to Section 13.2 or 13.3 below, the provisions of this Agreement with respect to a Product shall expire on the expiration of the last Royalty Term applicable under this Agreement with respect to such Product. Upon expiration of each Royalty Term with respect to each Product in the Territory, Salix shall have the following irrevocable, royalty-free licenses (with right to sublicense): (a) a nonexclusive license (with right to grant sublicenses) under the Patent Rights, Technical Information and Manufacturing Technology to make, have made, use, sell and have sold such Products in the Territory; and (b) the exclusive license to use the Trademarks in connection with the marketing and sale of such Products in the Territory, subject to Salix's payment to Biorex of the royalty stated in Section 6.3 for so long as Salix, its Affiliates and sublicensees shall continue to use the Trademarks.

13.2 Termination for Cause. Either party may terminate this Agreement following the material breach of any material provision of this Agreement by the other party if the breaching party has not commenced to cure such breach within ninety (90) days after written notice thereof by the other party and thereafter proceeded diligently to cure such breach within a reasonable time; provided, that in no event shall such reasonable time to cure such breach exceed 180 days from the date of such notice. In determining whether there has been a material breach of a material provision of this Agreement for purposes of this Section 13.2, all of the circumstances of the breach shall be considered, including the breaching party's conduct, the hardship of termination, the extent to which the breaching party has performed its obligations, the extent to which the nonbreaching party will obtain the benefits it reasonably anticipated, and similar factors.

13.3 Termination by Salix. Salix shall have the right to terminate this Agreement or the licenses granted herein, in whole or as to any specified Product, at any time, and from time to time, by giving notice in writing to Biorex. Such termination shall be effective ninety (90) days from the date Biorex receives such notice and all Salix's rights associated therewith shall cease as of that date; provided, however, that if Salix revokes in writing its notice of termination before the end of such 90-day period, such notice of termination shall have no effect and the rights specified in such notice of termination shall not terminate.

13.4 Effect of Termination.

13.4.1 Upon a termination of this Agreement by Salix under Section 13.3 above, or by reason of a material breach by Salix, all licenses granted to Salix hereunder (or, in the event of a partial termination under Section 13.3, the licenses to the Products to which such termination pertains) shall terminate, and Salix shall promptly return to Biorex all tangible materials provided by Biorex incorporating Technical Information and Manufacturing Technology pertaining to the terminated Product. In the event of such a termination, Salix shall assign to Biorex its filings with the FDA and all other regulatory authorities within the Territory that pertain to the terminated Products.

13.4.2 Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination.

13.4.3 Upon termination of this Agreement by either party, Salix shall provide Biorex with a written inventory of all Products in process of manufacture or in stock, and Salix (and its Affiliates and sublicensees) shall have the privilege of disposing of such Products within a period of one hundred eighty (180) days; provided, however, that Salix shall pay royalties on any Net Sales of such Products at the rate and at the time herein provided and shall render reports thereon in the manner herein provided.

13.4.4 Upon the expiration or termination of this Agreement for any reason, the parties rights and obligations under the following provisions shall survive: Sections 8.2, 8.3, and 10.3 and Articles 9, 11, 13, 14 and 17; provided, that the indemnification provision of Article 14 shall survive only with respect to claims that are made prior to three (3) years after expiration or termination of this Agreement. In addition, upon expiration of this Agreement under Section 13.1 above, the parties rights and obligations under Article 4 and Sections 6.2 and 6.3 shall survive.

13.4.5 If the Biorex /Astra Agreement comes into force in accordance with Clause 2.1 thereof, then this Agreement shall terminate automatically forthwith and the provisions of Clause 13.4.1-13.4.4, inclusive, of this Agreement shall apply upon such termination.

Article 14. INDEMNITY

14.1 Salix. Subject to Biorex's compliance with its obligations set forth in Section 14.3 below, Salix agrees to indemnify and hold Biorex, its Affiliates and their employees and agents harmless from and against any losses, claims, damages, liabilities or actions

(including reasonable attorneys' fees and court and other expenses of litigation) (collectively, the "Liabilities") suffered or incurred in connection with Third Party claims for personal injuries or any product recall to the extent caused by: (a) any failure to test for or provide adequate warnings of adverse side effects to the extent such failure arises out of acts or omissions in connection with the performance of Salix's preclinical or clinical testing obligations hereunder, (b) any manufacturing defect in any Product or other material manufactured by Salix or its sublicensee, or subcontractors, or (c) any other act or omission (without regard to culpable conduct) of Salix or its sublicensee, or subcontractors in connection with the activities contemplated under this Agreement, except to the extent such Liabilities resulted from negligence, recklessness or intentional misconduct of Biorex.

14.2 Biorex. Subject to Salix's compliance with its obligations set forth in Section 14.3, Biorex agrees to indemnify and hold Salix, its Affiliates, and licensees and their employees and agents harmless from and against any Liabilities suffered or incurred in connection with third party claims for personal injuries or any product recall to the extent caused by: (a) any failure to test for or provide adequate warnings of adverse side effects to the extent such failure arises out of acts or omissions in connection with Biorex's preclinical or clinical testing obligations hereunder, (b) any manufacturing defect in any Product or other material manufactured by Biorex or its sublicensees or subcontractors, or (c) any other act or omission (without regard to culpable conduct) of Biorex or its sublicensees or subcontractors in connection with the activities contemplated under this Agreement, except to the extent such Liabilities resulted from negligence, recklessness or intentional misconduct of Salix. Notwithstanding the foregoing, Biorex shall not be obligated to indemnify Salix with respect to Liabilities incurred in the course of human clinical trials conducted by Salix (itself or through subcontractors), or with respect to Liabilities resulting from the use of Products supplied by Biorex as clinical trials materials for use in such clinical trials.

14.3 Procedure. A party (the "Indemnitee) that intends to claim indemnification under this Article 14 shall promptly notify the other party (the "Indemnitor") in writing of any loss, claim, damage, liability or action in respect of which the Indemnitee or any of its Affiliates, employees or agents intend to claim such indemnification, and the Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, jointly with any other Indemnitor similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceeding. The indemnity agreement in this Article 14 shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, which consent shall not be withheld unreasonably. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the indemnitee under this Article 16, but the omission so to deliver written notice to the Indemnitor shall not relieve it of any liability that it may have to any Indemnitee otherwise than under this Article 14. The Indemnitee under this Article 14, its employees and agents, shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by this indemnification.

Article 15. FORCE MAJEURE

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected party or from fire, floods, embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other party.

Article 16. ASSIGNMENT

This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned or transferred, by either party without the written consent of the other party; provided, however, that either Biorex or Salix may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, if such assets include substantially all of the assets relating to its performance of its respective obligations hereunder, or in the event of its merger or consolidation with another company at any time during the term of this Agreement. Any purported assignment in violation of the preceding sentence shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either party of responsibility for the performance of any accrued obligation which such party then has hereunder.

Article 17. MISCELLANEOUS

17.1 Notices. Any notice or report required or permitted to be given or made under this Agreement by one of the parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery or courier) or courier, postage prepaid, addressed to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee.

Salix Pharmaceuticals, Inc.
3600 W. Bayshore Road
Palo Alto, CA 94303
Attention: Randy W. Hamilton

Biorex Laboratories Limited
2 Crossfield Chambers
Gladbeck Way
Enfield, Middlesex EN2 7HT
Attention: Miss L. Baxendale

17.2 Applicable Law; Arbitration.

17.2.1 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of California, without regard to conflicts of laws provisions.

17.2.2 Arbitration. Any dispute arising between the parties relating to, arising out of or in any way connected with this Agreement or any term or condition hereof, the performance by either party of its obligations hereunder, whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other party. The party giving such notice shall refrain from instituting the arbitration proceeding for a period of sixty (60) days following such notice. Any arbitration hereunder shall be conducted under the UNCITRAL Arbitration Rules. Each such arbitration shall be conducted in the English language by a panel of three arbitrators appointed in accordance with such rules. Any such arbitration initiated by Biorex shall be held in Santa Clara County California, in which case the appointing authority shall be the American Arbitration Association, and any such arbitration initiated by Salix shall be in London, in which case the appointing authority shall be the London Court of International Arbitration. The arbitrators shall have the authority to grant specific performance, and to allocate between the parties the costs of arbitration in such equitable manner as they determine. Any monetary award shall bear interest at a rate fixed by the arbitrators from the date an arbitration proceeding is commenced to the date on which the award is paid in full. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. Neither Salix nor Biorex shall be entitled to exercise its respective remedies hereunder until the conclusion of any arbitration proceeding seeking such remedy; provided, that the party against whom the breach is asserted notifies the other party that it disputes the breach within the time provided to cure the asserted breach under the applicable Section.

17.3 Export Laws. Biorex shall procure and maintain all export licenses required for it to transfer to Salix and its sublicensees all Technical Information, Patent Rights, Manufacturing Technology and other technical data, and shall comply with all other laws, regulations and governmental directives relating to the export of technical data, goods and services including, without limitation, those enforced by the United States Departments of Commerce and Defense.

17.4 No Consequential Damages. EXCEPT AS PROVIDED IN SECTION 14, IN NO EVENT SHALL EITHER SALIX OR BIOREX OR THEIR AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY.

17.5 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both parties hereto.

17.6 Headings. The captions to the several Articles hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles hereof.

17.7 Independent Contractors. It is expressly agreed that Salix and Biorex shall be independent contractors and that the relationship between the two parties shall not constitute a

partnership, joint venture or agency. Neither Salix nor Biorex shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written authorization of the party to do so.

17.8 Waiver. The waiver by either party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver or any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise.

17.9 Severability. In case any one or more of the provisions contained in this Agreement shall for any reason be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions hereof, but this Agreement shall be construed as if such invalid or illegal or unenforceable provisions had never been contained herein.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

SALIX PHARMACEUTICALS, INC.

By: _____
Randy W. Hamilton

Title: PRESIDENT

BIOREX LABORATORIES LIMITED

By: _____

Title: Managing Director