UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-Q/A AMENDMENT NO. 1

/X/ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 1998

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware 83-0221517
----(State of Incorporation) (I.R.S. Employer I.D. No.)

2600 Stemmons Frwy, Suite 176, Dallas, TX 75207
------(Address of principal executive offices)

Telephone Number (214) 905-5100

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirement for the past 90 days.

Yes X No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Common stock outstanding as of August 14, 1998 3,426,695 shares, \$0.01 par value

PART II -- OTHER INFORMATION

ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

Exhibits: 3.8 Certificate of Amendment of Certificate of Incorporation filed June 18, 1998 (previously filed)

10.13 Agreement between Access Pharmaceuticals, Inc. and Block Drug Company, Inc. (Confidential Treatment Requested)

10.14 Sales Agency Agreement (previously filed)

10.15 Registration Rights Agreement (previously filed)

27.1 Financial Data Schedule (previously filed)

Reports on Form 8-K: None

SIGNATURES

registrant has duly caused this Amendment No. 1 to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCESS PHARMACEUTICALS, INC.

Date: December 4, 1998 By: /s/ Kerry P. Gray

Kerry P. Gray

President and Chief Executive Officer

(Principal Executive Officer)

Date: December 4, 1998 By: /s/ Stephen B. Thompson

Stephen B. Thompson

Chief Financial Officer

(Principal Financial and Accounting Officer)

AGREEMENT BETWEEN ACCESS PHARMACEUTICALS, INC. AND BLOCK DRUG COMPANY, INC

ADTICLE 1 DEEDUTIONS	1
ARTICLE 1 DEFINITIONS 1.1 Access 1	1
1.2 Access Know-How	2
1.3 Access Net Sales	2
1.4 Affiliate 3	•
	3
1.6 Block 1.7 Block-Chemex Agreement	3
1.8 Block Know-How	4
	4
1.10 Dermatological Use	5
	5
1.12 First Sale 5	=
1.13 Formulation 1.14 Improvement	5 5
1.14 Improvement 1.15 Improvement Patent	5
1.16 Licensed Patents	5
1.17 Notice 6	
1.18 Product 6	
1.19 Revenue 6	
1.20 Sublicense Net Sales	8
1.21 Takeda 8 1.22 Takeda License Agreement	8
1.23 Takeda Sublicensed Patents	8
1.24 Takeda Supply Agreement	9
1.25 Term 9	
1.26 Territory 9	
A DELICI E A COD A NET	
ARTICLE 2 GRANT 2.1 Grant 9	9
2.1 Grant	
ARTICLE 3 ACCESS ROYALTIES	10
3.1 Royalty Rate for Direct Sales by Access	10
3.2 Royalty Rate in all Other Instances	10
3.3 No Offset on Other Royalties	10
ARTICLE 4 ADDITIONAL OBLIGATIONS	S OF THE PARTIES 11
4.1 Access to Pay Registration Fees and Costs	11
4.2 Access to Pay Takeda Royalties to Block	11
4.3 Advance Notice of Studies	11
4.4 Access to Provide Data	11
	11
ARTICLE 5 ACCESS PAYMENT TERMS	12
5.1 Quarterly payments	12 12
	12
5.1 Quarterly payments	12 12
5.1 Quarterly payments5.2 Set-Off for Registration Fees	12 12
5.1 Quarterly payments5.2 Set-Off for Registration Feesi	12 12 12
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies	12 12 12 13 13 13
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data	12 12 12 13 13 13 13
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs	12 12 12 13 13 13 13
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data	12 12 12 13 13 13 13
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs	12 12 12 13 13 13 13 13 14
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block	12 12 12 13 13 13 13 13 14
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO	12 12 12 13 13 13 13 13 14 DYALTIES 14
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO 7.1 Royalties from Access to Block	12 12 12 13 13 13 13 13 13 14 DYALTIES 14
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO 7.1 Royalties from Access to Block 7.2 Royalties in Other Instances 7.3 Royalty Reduction	12 12 12 13 13 13 13 13 14 DYALTIES 14 14 14
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO 7.1 Royalties from Access to Block 7.2 Royalties in Other Instances 7.3 Royalty Reduction ARTICLE 8 BLOCK IMPROVEMENT RIG	12 12 12 13 13 13 13 13 14 DYALTIES 14 14 14 14 14 14 15HTS AND OBLIGATIONS 15
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO 7.1 Royalties from Access to Block 7.2 Royalties in Other Instances 7.3 Royalty Reduction ARTICLE 8 BLOCK IMPROVEMENT RIG 8.1 Grant of Rights to Block	12 12 12 13 13 13 13 13 13 14 DYALTIES 14 14 14 14 14 14 15 HTS AND OBLIGATIONS 15
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO 7.1 Royalties from Access to Block 7.2 Royalties in Other Instances 7.3 Royalty Reduction ARTICLE 8 BLOCK IMPROVEMENT RIG 8.1 Grant of Rights to Block 8.2 Royalties from Block to Access	12 12 12 13 13 13 13 13 14 DYALTIES 14 14 14 14 14 14 15HTS AND OBLIGATIONS 15
5.1 Quarterly payments 5.2 Set-Off for Registration Fees i ARTICLE 6 IMPROVEMENTS 6.1 Improvements by Access 6.2 Advance Notice of Studies 6.3 Access to Provide Data 6.4 Access to Pay Registration Fees and Costs 6.5 Access to Pay Takeda Royalties to Block ARTICLE 7 ACCESS IMPROVEMENT RO 7.1 Royalties from Access to Block 7.2 Royalties in Other Instances 7.3 Royalty Reduction ARTICLE 8 BLOCK IMPROVEMENT RIG 8.1 Grant of Rights to Block	12 12 12 13 13 13 13 13 13 14 DYALTIES 14 14 14 14 14 15 HTS AND OBLIGATIONS 15 15 15

ARTICLE 9 TERM AND TERMINATI	
9.2 Termination for Breach	16 17
	17
9.3 Rights to Survive9.4 Reversion and Termination for Failure	- '
Takeda License Fees	18
	18
9.5 Termination by Takeda	18
ARTICLE 10 WARRANTIES	18
10.1 Exploitation of Licensed Rights	18
10.2 Access Indemnity	19
10.3 Block Indemnity	19
10.4 Obligations Regarding Patent Infring	
10.5 Claims by Third Parties	22
10.6 No Restrictions on Product	22
10.7 Power to Enter Into Agreement	22
10.8 No Other Warranties or Representation	
10.6 No Other warranties of Representative	ons 23
ARTICLE 11 MISCELLANEOUS	23
11.1 New Jersey Law Applies	23
11.2 Alternative Dispute Resolution	23
11.3 No Agency or Employment	26
11.4 Notice	26
11.5 Severability	28
11.6 Entire Agreement/Merger	28
11.7 Amendment	28
11.8 Counterparts	29
11.9 No Waiver of Rights	29
8	
ii	
11.10 Force Majeure	29
11.11 Further Assurances	29
11.12 Audit Rights	29
11.13 Binding Effect	30
11.14 No Strict Construction	30
11.15 Consent Not Unreasonably Withhel	-
11.16 Bankruptcy	31
11.17 Assignment	31
11.18 Taxes	31
11.19 Cooperation on Publicity	31
11.20 Costs of Agreement	32
11.21 Headings for Convenience Only	32
11.22 Independent Contractor	32
11.23 No Finder's Fee	33
11.24 Notification of Infringement	33
11.25 References	33
11.26 Singular and Plural	33
11.27 Successors and Assigns	33
11.28 Validity and Severability	34
11.29 Waiver	34
11.30 Takeda Agreement Controlling	34
ARTICLE 12 TAKEDA CONSENT	35
12.1 Takeda Approval	35
12.1 Takeda Appiovai	33

111

This Agreement, dated this 5th day of March, 1998, is by and between Block Drug Company, Inc., 257 Cornelison Avenue, Jersey City, New Jersey 07302 ("Block") and Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207 ("Access").

WHEREAS Block has certain rights in and to a topical product for treating aphthous ulcers containing amlexanox;

WHEREAS Access wishes to develop such product itself in various countries and to seek partners in various countries to develop such product;

NOW THEREFORE, in consideration of the following mutual promises and obligations and intending to be legally bound, the parties agree as follows:

1.1 Access: means Access Pharmaceuticals, Inc. The term "Access" shall, as required by the circumstances, also mean and include any company or business entity that controls or is controlled by, either directly or indirectly, Access Pharmaceuticals, Inc., its officers, agents and employees or any partnership or joint venture in which Access Pharmaceuticals, Inc. is a participant or any company or business entity that is under common control with Access Pharmaceuticals, Inc. The term "control" means the power to direct the affairs of such entity by

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reason of ownership of at least fifty percent (50%) of such entity by voting stock, equity interest, contract or otherwise.

- 1.2 Access Know-How: means (a) any and all information in the possession of Access at any time during the Term of this Agreement which Access has the right to license or sublicense relating to the physical and chemical analysis and stability of the Product, its clinical effects and indications for use, and (b) any and all information in the possession of Access as of the date of execution of this Agreement which Access the right to license or sublicense relating to the method of use, packaging, formulation, or method of administration of the Product that, at the time it is communicated to Block, was not rightfully in Block's possession and was not common general knowledge. Information relating to Takeda's process of manufacture of amlexanox shall be excluded from the scope of Access Know-How.
- 1.3 Access Net Sales: For purposes of determining compensation to Block for direct sales of Access under Paragraph 3.1 and Paragraph 7.1 of this Agreement, "Access Net Sales" means gross revenues received by Access on the sale of any Product less (a) trade discounts actually allowed; and (b) when borne by Access in connection with the sale, transportation and handling charges; sales, use and excise taxes; import duties, tariffs or other governmental charges; and credits for claim or allowances, retroactive price reductions, refunds, returns, and recalls. There shall not be any imputed gross revenue for samples, free goods or other marketing programs whereby the Product is given away to induce sales thereof. For purposes of determining Net Sales, a sale shall be deemed to have occurred when the sale is invoiced or

2

when the Product is delivered, whichever occurs first. In the case of the transfer or sale of Product by Access to an Affiliate or distributor of Access for sales by such Affiliate or distributor, Net Sales shall be based upon the greater of the total invoice price charged by Access to such Affiliate or distributor or the total invoice price charged by such Affiliate or distributor to its customers. Net Sales for countries outside the U.S. shall be calculated by converting to U.S. currency using the exchange rate in effect on the last business day of each month as published in the Wall Street Journal.

- 1.4 Affiliate: means any corporation or business entity controlled by, controlling, or under common control with Access or Block, respectively. For this purpose, "control" shall mean the direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock, or at least a fifty percent (50%) interest in the income of such corporation or other business entity, or such other relationship as, in fact, constitutes actual control.
- 1.5 Amlexanox: means 2 amino 7 isopropyl 5 oxo 5H [1] benzopyrano [2,3 b] pyridine 3 carboxylic acid (Takeda Code No. AA-673).
 - 1.6 Block: means Block Drug Company, Inc.
- 1.7 Block-Chemex Agreement: means that asset purchase and royalty agreement between Block Drug Company, Inc. and Chemex Pharmaceuticals, Inc., dated as of June 7, 1995.

3

1.8 Block Know-How: means (a) any and all information in the possession of Block at any time during the Term of this Agreement which Block has the right to license or sublicense relating to the physical and chemical analysis and stability of the Product, its clinical effects and indications for use, and (b) any and all information in the possession of Block as of the date of execution of this Agreement which Block the right to license or sublicense relating to the method of use, packaging, formulation, or method

of administration of the Product that, at the time it is communicated to Access, was not rightfully in the possession of Access and was not common general knowledge. Information relating to Takeda's process of manufacture of Amlexanox shall be excluded from the scope of Block Know-How.

1.9 Block Net Sales: means gross revenues received by Block on the sale of any Product less (a) trade discounts actually allowed; and (b) when borne by Block in connection with the sale, transportation and handling charges; sales, use and excise taxes; import duties, tariffs or other governmental charges; and credits for claim or allowances, retroactive price reductions, refunds, returns, and recalls. There shall not be any imputed gross revenue for samples, free goods or other marketing programs whereby the Product is given away to induce sales thereof. For purposes of determining Net Sales, a sale shall be deemed to have occurred when the sale is invoiced or when the Product if delivered, whichever occurs first. In the base of the transfer or sale of Product by Block to an Affiliate or distributor of Block for sales by such Affiliate or distributor, Net Sales shall be based upon the greater of the total invoice price charged by

4

Block to such Affiliate or distributor or the total invoice price charged by such Affiliate or distributor to its customers.

- 1.10 Dermatological Use: means all uses for the treatment of diseases and disorders of the integument including, but not limited to, therapeutic, prophylactic and immunological uses. For the purposes of this definition, integument is skin and its appendages, including hair, hair follicles, sebaceous glands, sweat glands, nails, and component and migratory cells of the skin.
 - 1.11 Effective Date: means the date first set forth above.
- 1.12 First Sale: means the date on the first invoice to any customer purchasing a Product or an Improvement on a country by country basis after the Effective Date of this Agreement.
- 1.13 Formulation: means the topical formulation containing Amlexanox attached hereto as Exhibit A.
- 1.14 Improvement: means all inventions, developments or improvements, whether or not patentable, originated or acquired by either party hereto that relate to the Product.
- 1.15 Improvement Patent: means any patent or patent application covering any Improvement.

- 1.16 Licensed Patents: means all patents and applications set forth in Exhibit B to this Agreement and all Takeda Sublicensed Patents.
- 1.17 Notice: shall have the meaning set forth in Paragraph 11.4 hereof. "Notify" shall mean to provide Notice in accordance with Paragraph 11.4 hereof.
- 1.18 Product: means the Formulation and any topical formulation containing Amlexanox for Dermatological Use, excluding any formulation for treatment of the cause or symptoms of oral mucositis, covered by any claim or any Licensed Patent in any country, whether or not granted.
- 1.19 Revenue: for purposes of determine compensation to Block for sales to or by a sublicensee or other party of Access under Paragraph 3.2 and Paragraph 7.2 of this Agreement, "Revenue" means the net profits received by Access for the sale of the Products by Access or by any third party. As used herein, "net profits" shall mean:
- (a) the full amount of any nonrecurring or nonperiodic payments made to Access by any third party as full or partial payment for any rights granted to such third party relating to any Product or Improvement including, but not limited to, milestone payments and reimbursement for fees expended to obtain permission from any governmental authority to make, use or sell a Product or Improvement (unless such fees have not been deducted under Paragraph 5.2 or 7.3 of this Agreement;

- (b) the full amount of any royalties, including advance royalties, or other periodic or recurring payments, paid to Access by any third party as full or partial payment for any rights granted to such third party relating to any Product or Improvement;
- (c) the full fair market value of any non-monetary consideration paid to Access by any third party as full or partial payment for any rights granted to such third party relating to any Product or Improvement; and
- (d) the net consideration received by Access for sales of any Product or Improvement to any third party for resale. As used herein, "net consideration" means the gross consideration received by Access for sales of any Product or Improvement less either: (1) if Access manufactures such Product or Improvement, Access' direct and indirect manufacturing costs incurred in making such Product or Improvement, recorded on Access' books in accordance with generally accepted principles; or (2) if Access has such Product or Improvement made by a third party, Access' out-of-pocket payments to such third party for such Product or Improvement. All manufacturing costs and out-of-pocket payments are subject to audit by Block. This audit right is in addition to and separate from Block's audit right pursuant to Paragraph 11.12. Any royalties paid by Access to Block under this Agreement or any other agreement and royalties paid be Access to any other party for sales hereunder may also be deducted from gross consideration;

7

- (e) net profits shall not include any royalties or other payments made by Block to Access under any provision of this Agreement, or any other agreement.
- 1.20 Sublicensee Net Sales: means gross revenues received by the sublicensee on the sale of any Product less (a) trade discounts actually allowed; and (b) when borne by the sublicensee in connection with the sale, transportation and handling charges; sales, use and excise taxes; import duties, tariffs or other governmental charges; and credits for claim or allowances, retroactive price reductions, refunds, returns, and recalls. There shall not be any imputed gross revenue for samples, free goods or other marketing programs whereby the Product is given away to induce sales thereof. For purposes of determining Net Sales, a sale shall be deemed to have occurred when the sale is invoiced or when the Product is delivered, whichever occurs first. In the case of the transfer or sale of Product by the sublicensee to an Affiliate or distributor of the sublicensee for sales by such Affiliate or distributor, Net Sales shall be based upon the greater of the total invoice price charged by the sublicensee to such Affiliate or distributor or the total invoice price charged by such Affiliate or distributor to its customers.
- 1.21 Takeda: means Takeda Chemical Industries, Ltd., a Japanese corporation and all parents, subsidiaries and affiliates thereof.

- 1.22 Takeda License Agreement: means that agreement between Chemex and Takeda dated November 12, 1987 regarding licensing of patent rights from Takeda to Chemex. A copy of that agreement is set forth in Exhibit C to this Agreement.
- 1.23 Takeda Sublicensed Patents: means any and all patent applications and patents now or hereafter owned or controlled by Takeda in the Territory relating to the Product, including any and all patents issuing or maturing from such patent applications, or any reissue application, divisions extensions, Improvements, and continuations-in-part thereof. Such current Takeda Patents and patent applications in the Territory are listed in Exhibit D to this Agreement.
- 1.24 Takeda Supply Agreement: means that agreement between Chemex and Takeda dated November 12, 1987 regarding supply of material from Takeda to Chemex. A copy of that agreement is set forth in Exhibit E to this Agreement.
- 1.25 Term: means the term of this Agreement, as set forth in Article 9 hereof.
- 1.26 Territory: means all countries in the world in which Block has been granted rights by Takeda except the United States of America and Israel. Block has not been granted rights in Japan and other countries.

ARTICLE 2 GRANT

2.1 Grant: Block hereby grants Access the exclusive right under the Licensed Patents and the Block Know-How to make, use, have made and sell or have sold any Product within the Territory during the Term, including the right to make or have made outside the Territory for sale in the Territory. The rights granted hereunder, however, are subject to the rights granted to Block by Takeda as set forth in the Takeda License Agreement and the Takeda Supply Agreement. Access agrees to be bound by the royalty provisions in such agreements, as amended from time to time. Access shall have the right to sublicense the rights granted hereunder within the Territory at its sole discretion subject to approval by Takeda.

ARTICLE 3 ACCESS ROYALTIES

- 3.1 Royalty Rate for Direct Sales by Access: On a country by country basis, if Access sells a Product directly to retail pharmacies or other dispensaries, then Access shall pay to Block a royalty of * of Access Net Sales of such Product in such country.
- 3.2 Royalty Rate in all Other Instances: For any consideration received by Access for sales to or by a sublicensee or other party other than as set forth in Paragraph 3.1, Access shall pay Block * of any Revenue received by Access on any Product.
- * Confidential portions have been omitted and are on file separately with the Commission

10

3.3 No Offset on Other Royalties: No payment received by Block from Access in accordance with Paragraphs 3.1 or 3.2 shall reduce or offset any amounts paid as an advance royalty in the Block-Chemex Agreement. No Access Net Sales of any Product or any sales by any party resulting in any Revenue under Paragraph 3.2 shall be considered as any form of sale covered by the Block-Chemex Agreement.

ARTICLE 4 ADDITIONAL OBLIGATIONS OF THE PARTIES

- 4.1 Access to Pay Registration Fees and Costs: Access or its sublicensees shall pay all registration fees, clinical evaluation costs and any other costs associated with obtaining approval to market any Product within any country in the Territory.
- 4.2 Access to Pay Takeda Royalties to Block: Access shall pay all royalties due to Takeda for sales of Products within the Territory directly to Block, and Block shall be solely responsible for remitting all such payments due to Takeda for sales of Product within the Territory under the terms of the Takeda License Agreement.
- 4.3 Advance Notice of Studies: Access shall provide Block with no less than sixty (60) days' advance written Notice of the commencement of any study or other sponsored research relating to any Product. Access shall not proceed with any study or other sponsored research without the written approval of Block, which shall not be unreasonably withheld or delayed.

11

4.4 Access to Provide Data: Access shall supply Block, without compensation, with all clinical and other technical and scientific data that it develops relating to any Product. Block may use this data at its discretion for any purpose, including, but not limited to, filing of such data with regulatory authorities outside the Territory for any purpose. Information pertaining to side effects resulting from any use of Amlexanox in any type of application will be exchanged by both parties hereto on an emergent basis, whenever such information is obtained.

ARTICLE 5 ACCESS PAYMENT TERMS

5.1 Quarterly payments: Within thirty (30) days of the end of each calendar quarter, commencing with the first full calendar quarter following the Effective Date, Access shall submit to Block a written report setting forth the Access Net Sales for such quarter and the calculation of the royalty payment

due Block for such quarter, provided however that the first such quarterly report shall include Net Sales from the Effective Date to the end of the first full calendar quarter. Access shall, with said written quarterly reports, pay to Block the royalty amount due as indicated in said reports. In the event that Access sublicenses a third party hereunder, the written report and payment to Block shall be due within thirty (30) days of receipt of such third party royalty report, which third party royalty report shall be due not later than thirty (30) days after the end of each calendar quarter. The report from Access to Block shall contain a copy of any such sublicensee royalty report.

12

5.2 Set-Off for Registration Fees: On a country basis, Access shall be entitled to reduce the amounts paid to Block in any quarterly payment by up to * for all out-of-pocket expenses incurred under Paragraph 4.1, up to an aggregate total off-set for all quarterly payments on Access Net Sales of any Product or Revenue for any Product of * . Any reduction made in any quarterly payment as a result of this Paragraph 5.2 shall be accompanied by a written report setting forth the basis for such reduction.

ARTICLE 6 IMPROVEMENTS

- 6.1 Improvements by Access: Access may develop and register any Improvement in the Territory. Access may not develop or register any Improvement for the treatment of the cause or symptoms of oral mucositis under the terms of this Agreement.
- 6.2 Advance Notice of Studies: Access shall provide Block with no less than sixty (60) days' advance written Notice of the commencement of any study or other sponsored research relating to any Improvement. Access shall not proceed with any such study or other sponsored research without the written approval of Block, which shall not be unreasonably withheld or delayed.
- 6.3 Access to Provide Data: Access shall supply Block, without compensation, with all clinical and other technical and scientific data that it develops relating to any Improvement.
- * Confidential portions have been omitted and are on file separately with the Commission

13

Block may use this data at its discretion for any purpose, including filing such data with regulatory authorities outside the Territory for any purpose.

- 6.4 Access to Pay Registration Fees and Costs: Access shall pay for all registration fees, clinical evaluation costs and any other costs associated with obtaining approval for it to market any Improvement within any country within the Territory.
- 6.5 Access to Pay Takeda Royalties to Block: Access shall pay all royalties due to Takeda for sales of Improvements within the Territory directly to Block, and Block shall be solely responsible for remitting all such payments due to Takeda for sales of any Improvement within the Territory under the terms of the Takeda License Agreement.

ARTICLE 7 ACCESS IMPROVEMENT ROYALTIES

- 7.1 Royalties from Access to Block: On a country by country basis, if Access sells any Improvement directly to retail pharmacies or other dispensaries, then Access shall pay to Block a royalty of * of Access Net Sales on such Improvement in such country. Payment shall be made in accordance with the procedures set out in Paragraph 5.1.
- 7.2 Royalties in Other Instances: For any consideration received by Access for sales to or by a sublicensee or other party other than as set forth in Paragraph 7.1, Access shall pay
- * Confidential portions have been omitted and are on file separately with the Commission

Payment shall be made in accordance with the procedures set out in Paragraph 5.1.

7.3 Royalty Reduction: On a country by country basis, Access shall be entitled to reduce the amounts paid to Block in any quarterly payment by for the * out-of-pocket expenses incurred under Paragraph 6.4 to develop and register the Improvement in such country up to an aggregate total off-set of * of all such costs in such country. Any reduction made in any quarterly payment as a result of this Paragraph shall be accompanied by a written report setting forth the basis for such reduction.

ARTICLE 8 BLOCK IMPROVEMENT RIGHTS AND OBLIGATIONS

- 8.1 Grant of Rights to Block: Access hereby grants Block the exclusive right under any Improvement Patent, if any, and Access Know-How, if any, now existing or subsequently developed, to make, use, have made and sell any Improvement outside the Territory during the Term, including, but not limited to, the right to make or have made the Improvement, or any part thereof, within the Territory for sale outside the Territory. Block shall have the right to sublicense the rights granted hereunder outside the Territory at its sole discretion.
- 8.2 Royalties from Block to Access: On a country by country basis, Block shall pay Access a royalty of * of Block Net Sales or any Sublicensee Net Sales (of any Block sublicensee) of any Improvement outside the Territory.
- * Confidential portions have been omitted and are on file separately with the Commission

- 8.3 Set-Off for Advance or Other Royalties: Block shall be entitled to offset any royalties otherwise due under Paragraph 8.2 by * . In no event shall Block be required to pay royalties to Access under both the Block-Chemex Agreement and Paragraph 8.2 of this Agreement for Block Net Sales hereunder.
- 8.4 Block Royalty Reports: Within thirty (30) days of the end of each calendar quarter, commencing with the first full calendar quarter following the First Sale of any Improvement by Block or a Block sublicensee outside the Territory, Block shall submit to Access a written report setting forth the Block Net Sales for such quarter and the calculation of the royalty payment due Access for such quarter including any setoff under Paragraph 8.2, provided however, that the first such quarterly report shall include Block Net Sales from the date of First Sale to the end of the first full calendar quarter. Block shall, with said written quarterly report, pay to Access the royalty amount due as indicated in said report. In the event that Block sublicenses a third party hereunder, the written report and payment to Access shall be due within thirty (30) days of receipt of such third party royalty report, which third party royalty report shall be due no later than thirty (30) days after the end of each calendar quarter. The report from Block to Access shall contain a copy of any such sublicensee royalty report.
- * Confidential portions have been omitted and are on file separately with the Commission

16 ARTICLE 9 TERM AND TERMINATION

9.1 Term: The Term of this Agreement for any Product commences on the Effective Date hereof and ends, on a country by country basis upon the later of ten (10) years from the date of First Sale of a Product in such country or the expiration, lapse, termination or unappealed or unappealable determination of invalidity, unenforceability or nonallowability of the last Licensed Patent in each country, if any. The Term for Improvements shall commence on the Effective Date and shall end, on a country-by-country basis, upon the later of ten (10) years from the date of First Sale of an Improvement in such country or the expiration, lapse, termination or unappealed or unappealable determination of invalidity, unenforceability or nonallowability of the last Licensed Patent, if any, or Improvement Patent, if any, in each country. In no event, however, shall the duty to pay royalties under this Agreement for either party extend beyond twenty (20) after the Effective Date. Royalties payable to Takeda under the Takeda License Agreement shall not be At the conclusion of the Term, each party shall have a fully paid-up worldwide nonexclusive license with respect to any Licensed Patent, Improvement Patent, Block Know-How and Access Know-How, and no further payments shall be made or required under this Agreement.

9.2 Termination for Breach: Either party may terminate this Agreement on sixty (60) days' written Notice to the other if the other is in default or breach of any material provision,

17

provided, however, that if the party receiving such Notice cures or diligently commences to cure the breach or default within such sixty (60) day period, this Agreement shall continue in full force and effect. If such default or breach of a material provision is a failure to pay any amount due and owing hereunder, the terminating party may terminate this Agreement on thirty (30) days' written Notice. If, however, the party receiving such Notice cures such default or breach within such thirty-(30) day period, this Agreement shall continue in full force and effect. Failure to terminate this Agreement for any default or breach shall not constitute a waiver by the aggrieved party of its right to terminate the Agreement for any other default or breach.

- 9.3 Rights to Survive: Termination shall not affect the rights of the parties accruing up to the effective date of termination and thereafter as to provisions which expressly survive termination.
- 9.4 Reversion and Termination for Failure to Pay Takeda License Fees: If Access fails to make any payment to Block under Paragraph 4.2 or Paragraph 6.5, then all rights granted to Access in this Agreement shall revert to Block thirty (30) days after Notice to Access from Block of such failure to pay. If Access makes all payments to Block required under Paragraphs 4.2 and 6.5 and any other required payments hereunder as set forth in such Notice within the thirty (30) days, then such rights shall not revert to Block.

18

9.5 Termination by Takeda: If the Takeda License Agreement or the Takeda Supply Agreement is terminated or canceled by Takeda or by operation of the Takeda License Agreement or the Takeda Supply Agreement for any reason, this Agreement shall also terminate, effective as of the date of termination of such agreement. Provide, however, Block shall give Access Notice at least thirty (30) days prior to any such termination, and Access shall have the right to cure any breach that is the cause of any termination. Block shall use its reasonable commercial efforts to keep the Takeda License Agreement and the Takeda Supply Agreement in effect during the Term of this Agreement.

ARTICLE 10 WARRANTIES

- 10.1 Exploitation of Licensed Rights: Block makes no warranty or representation that the use of any products, the practice of the Licensed Patents, or the use of any trademark will result in the successful promotion, marketing or sale of the Products. Access makes no warranty or representation that the use of any Improvements, the practice of the Improvements, or the use of any trademark will result in the successful promotion, marketing or sale of the Improvements.
- 10.2 Access Indemnity: Access shall indemnify and hold Block harmless against any and all liability, damage, loss, cost or expense (including attorney's fees and expenses), hereinafter "Damages," resulting from any third party claim made or suit brought against Block to the extent that such claim or suit (i) is caused by Access' negligence or willful misconduct;

19

(ii) is caused by Access' breach of any of the representations or warranties set forth herein; or (iii) is caused by Access' breach of this Agreement. As the parties intend fully indemnification, all costs, expenses and fees, including attorney's fees and disbursements, incurred in enforcing this Paragraph 10.2 shall also be reimbursed. Upon filing of any such claim or suit, Block shall

immediately Notify Access thereof and shall permit Access at its cost to handle and control such claim or suit. Block shall have the right to participate in the defense of such claim or suit at its own expense.

- 10.3 Block Indemnity: Block shall indemnify and hold Access harmless against any and all liability, damage, loss, cost or expense (including attorneys' fees and expenses), hereinafter "Damages," resulting from any third party claim made or suit brought against Access to the extent that such claim or suit (i) is caused by Block's negligence or willful misconduct; (ii) is caused by Block's breach of any of the representations and warranties set forth herein; or (iii) is caused by Block's breach of this Agreement. As the parties intend full indemnification, all costs, expenses and fees, including attorneys' fees and disbursements, incurred in enforcing this Paragraph 10.3 shall also be reimbursed. Upon filing of any such claim or suit, Access shall immediately Notify Block thereof and shall permit Block at its cost to handle and control such claim or suit. Access shall have the right to participate in the defense of such claim or suit at its own expense.
- 10.4 Obligations Regarding Patent Infringement: In the event of alleged infringement of one or more patents licensed hereunder by a third party:

20

- (a) each party shall Notify the other of any perceived or threatened infringement of the Takeda patents by any third party as such party becomes aware of such perceived or threatened infringement. Block shall Notify Takeda of any such perceived or threatened infringement, and all actions with respect to the Takeda Sublicensed Patents will be governed by Paragraph 12.1 of the Takeda Agreement;
- (b) In the event of infringement of any patent owned or licensed by Block and licensed under this Agreement, the party discovering the infringement shall Notify the other party of such infringement. Block shall have sixty (60) days from the date of such Notice to Notify Access of its decision to enforce or not to enforce the patent. If Block elects not to enforce such patent within such sixty (60) day period, then Access may, at its option, enforce such patent. In the event of any legal action seeking to enforce any patent owned by Block, both Access and Block may be named as party plaintiff. No settlement, consent judgement or other voluntary final disposition of such suit may be entered into by Block without the consent of Access, which consent shall not be unreasonably withheld or delayed.
- (d) In the event of infringement of any patent owned by Access and licensed under this Agreement, the party discovering the infringement shall Notify the other party of such infringement. Access shall have sixty (60) days from the date of such Notice to Notify Block of its decision to enforce or not to enforce the patent. If Access elects not to enforce such patent within such sixty (60) day period, then Block may, at its option, enforce such patent. In

21

the event of any legal action seeking to enforce any patent owned by Access, both Access and Block may be named as party plaintiff. No settlement, consent judgment or other voluntary final disposition of such suit may be entered into by Block without the consent of Access, which consent shall not be unreasonably withheld or delayed.

(e) In the event of any lawsuit against a third party hereunder, the parties agree to cooperate with each other in all respects relating to the lawsuit. Damages or any amount received in settlement of claims of infringement, shall be apportioned as follows: (1) the party that actively asserted the patent or patents found to be infringed or were covered by any settlement of claims shall first be reimbursed for * of its out-of-pocket expenses, including attorneys' fees, expended in actively asserting such patent or patents; (2) out of the remainder, the party that did not actively assert such patent or patents shall be reimbursed for * of its out-of-pocket expenses, including attorneys' fees, expended in such lawsuit; and (3) the party that actively asserted such patent or patents shall then receive any remaining funds from such damage award or settlement. If both parties actively asserted such patent or patents, then the parties will divide funds from such damage award or settlement as follows: each party shall receive of its out-of-pocket expenses, including attorneys' fees, expended in such lawsuit and the parties shall share any remaining funds equally. If the funds from such damage award or settlement are not sufficient to compensate both

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20

shall be divided in a ratio equal to the ratio of the out-of-pocket expenses, including attorneys' fees, of each party.

- 10.5 Claims by Third Parties: In the event a party to this Agreement is sued or threatened with suit by a third party and such action pertains to the Products, the party being threatened shall give prompt Notice to the other party. The parties agree to confer together in such event and consult with one another with respect to the action to be taken.
- 10.6 No Restrictions on Product: Each party represents to the other that it has no knowledge of violations of any law or regulation or restrictions on the ability to make, use or sell the Product, other than ordinary restrictions imposed in countries in which governmental approval is required, but has not yet been obtained, to market in such countries and other than restrictions imposed by the Takeda License Agreement and the Takeda Supply Agreement.
- 10.7 Power to Enter Into Agreement: Each party represents that it has no knowledge of any impediment to it entering into this Agreement except for the required consent by Takeda to the Agreement.
- 10.8 No Other Warranties or Representations: Nothing in this Agreement shall be construed as (a) a warranty or representation by Block or Access as to the validity or scope of any patent; (b) a warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this agreement is or will be free from infringement of

23

patents of third parties; (c) an obligation to bring or prosecute actions or suits against third parties for infringement; or (d) conferring a right to use in advertising, publicity or otherwise any trademark or tradename of Block.

Neither party makes any representation, extends any warranties of any kind, either express or implied, or assumes any responsibilities whatever with respect to use, sale, or other disposition by and party of any Product or Improvement.

ARTICLE 11 MISCELLANSOUS

- 11.1 New Jersey Law Applies: This Agreement shall be interpreted and construed in accordance with the laws of the State of New Jersey.
- 11.2 Alternative Dispute Resolution: All disputes relating to or arising out of this Agreement or its subject matter shall be resolved by the parties as set forth in this Paragraph 11.2 (a) In the event of a dispute, Notice of a demand for a meeting of the parties to discuss and settle a dispute ("Notice of meeting") may be given by either Party. Such Notice shall be in writing and shall set a date no more than (10) business days from the date of the Notice of Meeting on which the parties shall meet during normal business hours at a mutually acceptable place. If within five (5) days after the date of the meeting the parties have not resolved their dispute(s), then the parties shall proceed as provided below. Notwithstanding anything in this

24

Paragraph 11.2 to the contrary, either party may seek equitable and injunctive relief in any state or federal court in which jurisdiction and venue are proper.

(b) Any dispute not resolved within five (5) days after the meeting shall be resolved by means of alternative dispute resolution, as provided in the New Jersey Alternative Procedure for Dispute Resolution Act, N.J.S.A. 2A:23A-1 et seq. (the "Act"). Other than as set forth herein to the contrary, the parties expressly waive the right to resolve all claims, disputes and issues arising out of or relating to this Agreement by means of traditional litigation, including the right to appeal, except as provided in the Act. Except as otherwise provided in this Agreement, the Act shall govern the procedures and methods for any ADR Proceeding. No punitive damages may be awarded in

- (c) Notice of a demand for resolution of a dispute under the Act (a "Notice of Dispute") given by either party shall be in writing specifying the issue or issues in dispute.
- (d) Within fifteen (15) days after a Notice of Dispute is given, each party shall select two (2) prospective umpires from among (i) any retired judge of the federal courts or state appellate courts of New Jersey or New York; (ii) any retired managing partner of a law firm with no less than twenty-five (25) partners; or (iii) such other person with such qualifications upon which the parties agree. The umpires shall be free from bias and conflict of interest with respect to either party and shall be in a position to immediately hear the dispute and render a prompt resolution, but in no event later than six (6) months from the date of the Notice of

24

Dispute. Within fifteen (15) days after each party has selected its prospective umpires, the parties shall agree to one (1) umpire from among the four (4) prospective umpires to hear the dispute. In the event that the parties do not agree on an umpire, the prospective umpires shall name the umpire.

The proceeding for the alternative resolution of a dispute (the "ADR Proceeding") shall be held at a location with the State of New Jersey or New York as selected by the umpire and shall commence no later than forty (40) days after the Notice of Dispute is given.

The fees payable to the umpire shall be the usual hourly rate of such umpire for consulting or dispute resolution services. All fees and expenses associated with the ADR Proceeding incurred by the parties, including the umpire fees, attorneys' fees and disbursements, shall be paid by the party against whom the decision is rendered.

- 11.3 No Agency or Employment: Neither Block nor Access is to be considered the agent or employee of the other for any purpose, and neither party has the right or authority to enter into any contracts or assume obligations for the other or to give any warranty or make any representation on behalf of the other party except where and to the extent specifically authorized in writing to do so.
- 11.4 Notice: Every notice or other communication required or contemplated by this Agreement by either party shall be in writing.

- (a) Every notice or other communication required or contemplated by this Agreement by either party shall be delivered to the other party by either: personal delivery; or facsimile; or certified or registered mail, postage prepaid, addressed to the party for whom such notice was intended; or by overnight courier.
- (b) Notice delivered in person shall be deemed to have been delivered upon receipt by the party to whom such notice was sent.
- (c) Notice delivered by facsimile shall be deemed to have been delivered at noon on the first business day after the date on which the facsimile was sent.
- (d) Notice by certified mail shall be deemed to have been delivered on the date it is officially recorded as delivered to the intended recipient by return receipt or equivalent, and in the absence of such record of delivery, the effective date shall be presumed to have been the fifth (5th) business day after it was deposited in the mail.
- (e) Notice delivered by overnight courier shall be deemed to have been delivered upon receipt by the party to whom such notice was sent.
- (f) Unless Access receives notice to the contrary, all notices directed to Block shall be sent to the attention of:

Block Drug Corporation 257 Cornelison Avenue Jersey City, New Jersey 07302 Fax (201) 333-3585

(g) Unless Block receives notice to the contrary, all notices directed to Access shall be sent to the attention of:

Kerry P. Gray President and Chief Executive Officer Access Pharmaceuticals, Inc. 2600 Stemmons Freeway, Suite 176 Dallas, Texas 75207 Fax: (214) 905-5101

- 11.5 Severability: Whenever possible, each section, subsection, provision or condition of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any section, subsection, provision or condition of this Agreement should be prohibited or invalid under applicable law, such section, subsection, provision or condition shall be considered separate and severable from this Agreement to the extent of such prohibition or invalidity without invalidating the remaining sections, subsections, provisions and conditions of this Agreement.
- 11.6 Entire Agreement/Merger: This Agreement sets forth the entire agreement between the parties hereto pertaining to the subject matter hereof and supersedes all negotiations,

2.8

preliminary agreements, memoranda or letters of proposal or intent, discussions and understandings of the parties hereto in connection with the subject matter hereof. All discussions between the parties have been merged into this Agreement, and neither party shall be bound by any definition, condition, understanding, representation, warranty, covenant or provision other than as expressly stated in or contemplated by this Agreement or as subsequently shall be set forth in writing and executed by a duly authorized representative of the party to be bound thereby.

- 11.7 Amendment: No amendment, change or modification of any of the terms, provisions or conditions of this Agreement shall be effective unless made in writing and signed on behalf of the parties hereto by their duly authorized representatives.
- 11.8 Counterparts: This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original document, but all such separate counterparts shall constitute only one and the same instrument.
- 11.9 No Waiver of Rights: No waiver of any term, provision, or condition of this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision, or condition of this Agreement.

- 11.10 Force Majeure: Neither party shall be liable hereunder to the other party nor shall be in breach for failure to deliver, provided failure to deliver is no greater than the delay in time caused by circumstances beyond control for either party, including but not limited to acts of God, fires, floods, riots, wars, civil disturbances, sabotage, accidents, labor disputes, shortages, government actions (including but not limited to priorities, requisitions, allocations and price adjustment restrictions) and inability to obtain material, equipment, labor or transportation.
- 11.11 Further Assurances: The parties hereto shall each perform such acts, execute and deliver such instruments and documents and do all such other things as may be reasonably necessary to accomplish the transactions contemplated in this Agreement.
- 11.12 Audit Rights: Each party shall keep books and records in sufficient detail to permit the other to verify items including, but not limited to, Access Revenue, Access Net Sales or Block Net Sales. Each party shall have the right, upon reasonable Notice and during normal business hours, but in no event more frequently than once during any twelve (12) month period or

more than two (2) years after the close of any party's fiscal year, to audit, or have audited by a Certified Public Accountant, the relevant books and accounts to verify the accuracy of the reported Net Sales and Access Revenue. In the event such audit reveals that the audited party has mis-reported information by more than * , that party, in addition to paying or reimbursing any additional amounts due, shall pay the reasonable costs associated with such audit. The parties shall maintain the results of any such audit in

* - Confidential portions have been omitted and are on file separately with the Commission

30

confidence. All records pertaining to any payment shall be maintained for not less than five (5) years after the year of payment hereunder.

- 11.13 Binding Effect: This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective permitted successors and assigns.
- 11.14 No Strict Construction: This Agreement has been prepared jointly and shall not be strictly construed against either party.
- 11.15 Consent Not Unreasonably Withheld or Delayed: Whenever provision is made in this Agreement for either party to secure the consent or approval of the other, such consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions made for one party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.
- 11.16 Bankruptcy: At least thirty (30) days prior to filing a petition in bankruptcy, each party must inform the other of its intention to file the petition or of a third party's written Notice of its intention to file a voluntary or an involuntary petition in bankruptcy.
- 11.17 Assignment: Block may assign this Agreement to any parent, affiliate, subsidiary or entity in common control without the consent of Access. Block may also assign this agreement to a third party, either alone or as part of an agreement to dispose of all or a

31

substantial part of its assets or business. In the event of an assignment, the assignee shall have the identical rights granted to Block hereunder. Block may assign this agreement to a third party as part of an agreement to dispose of a substantial part of its business without the consent of Access. If Block wishes to assign this agreement alone to a third party, however, such assignment shall not take place without Access' written consent. If Access wishes to assign this agreement, such assignment shall not take place without the written consent of Block and Takeda.

- 11.18 Taxes: All taxes levied on account of royalties accruing under this Agreement shall be paid by the receiving party. If laws or regulations require withholding of taxes, the taxes will be deducted by the paying party from remittable royalty payments and will be paid by the paying party to the proper taxing authority. Proof of payment shall be sent to the receiving party within sixty (60) days following payment.
- as required by law and in interviews between professional sales representatives and a potential prescribers of a Product or Improvement, use each other's name in any manner, or issue any public statement disclosing the existence of, or relating to, this Agreement or any of the activities conducted hereunder, without the other party's prior written permission. To the extent this Agreement triggers, in the opinion of counsel, an obligation for a party to file a report with the SEC on Form 8-K, such party shall either (1) not file a copy of this Agreement or (2) request SEC approval for the deletion of certain confidential information identified jointly by parties and

32

then file a redacted version of this Agreement. Access shall not publish, or allow to be published, any manuscript, article, report or other form of oral or written presentation regarding Amlexanox without the express written approval of Block.

- 11.20 Costs of Agreement: The parties hereto shall each bear their own costs and expenses (including attorneys' fees) incurred in connection with the negotiation and preparation of this Agreement and consummation of the transactions contemplated hereby.
- 11.21 Headings For Convenience Only: The titles, headings or captions and paragraphs in this Agreement do not define, limit, extend, explain or describe the scope or extent of this Agreement or any of its terms or conditions and therefore shall not be considered in the interpretation, construction or application of this Agreement.
- 11.22 Independent Contractor: Each party is an independent contractor with respect to the other, and is not an agent, partner, joint venture, or employer of the other. Neither party shall have any responsibility for the hiring, termination, compensation or benefits of the other party's employees. No employees or representatives of either party shall have any authority to bind or obligate the other party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other party without said party's authorized written approval.

33

- 11.23 No Finder's Fee: The parties acknowledge that no "finder" has been involved in bringing the parties together and that no compensation is due to any third party(s) as a result of the execution of this Agreement.
- 11.24 Notification of Infringement: Each party shall promptly Notify the other party of any infringement or misappropriation based upon or arising from any of the intellectual property that is the subject of this agreement.
- 11.25 References: All references herein to articles, sections, paragraphs and attachments shall be to articles, sections, paragraphs and attachments of this Agreement.
- 11.26 Singular and Plural: The use herein of the singular form shall also denote the plural form, and the use herein of the plural form shall denote the singular form as in each case the context may require.
- 11.27 Successors and Assigns: This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns permitted under this Agreement.
- 11.28 Validity and Severability: Whenever possible, each clause, subclause, provision or condition of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any clause, subclause, provision or condition of this Agreement

34

should be prohibited or invalid under applicable law, such clause, subclause, provision or condition shall be considered separate and severable from this Agreement to the extent of such prohibition or invalidity without invalidating the remaining clauses, subclauses, provisions and conditions of this Agreement.

- 11.29 Waiver: No waiver of any term, provision, or condition of this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision, or condition of this Agreement.
- 11.30 Takeda Agreement Controlling: This Agreement is subject to the Takeda License Agreement and the Takeda Supply Agreement. To the extent that any term of this Agreement is inconsistent with either the Takeda License Agreement or the Takeda Supply Agreement, such term shall be controlled by and subject to the terms of the Takeda License Agreement and the Takeda Supply Agreement.

ARTICLE 12 TAKEDA CONSENT

12.1 Takeda Approval: This Agreement shall be binding on the parties but not become effective until receipt by Block of written approval from Takeda for Block to enter into this Agreement. If Takeda disapproves this Agreement or fails to approve the Agreement within six (6) months of the Effective Date, then this Agreement shall be void in its entirety.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duty executed as of the day and year first above written.

ACCESS PHARMACEUTICALS, INC. BLOCK DRUG COMPANY, INC.

Name Printed

By: /s/ Arthur J. Looney /s/ Kerry P. Gray By:

Kerry P. Gray Arthur J. Looney Name Printed

President and CEO Vice-President / General Manager

Title Title

May 7, 1998 May 12, 1998

Date Date

36

EXHIBIT A APHTHASOL FORMUALTION AMLEXANOX 5% ORAL PASTE FORMULA

FORMULA #B0960

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> **EXHIBIT B** PATENTS & APPLICATIONS

Amlexanox List

Title(s) Country Patent or Application Number

Methods of Treating Aphthous Ulcers and Other Mucocutaneous Disorders with Amlexanox

> U.S. 5,362,737

Mouth Ulcer Treatment for Muco Cutaneous Disorders By Mediator Release, or 5-Lipogenase Inhibitor Leucotiene or Platelet Activating Factor Antagonist Polymeric Paste Administration

> U.S. App. 682347 Canada 2065496 **EPO** 518798 Japan 5097706

> > EXHIBIT C TAKEDA LICENSE AGREEMENT

LICENSE AGREEMENT

This is an Agreement, effective the 12 day of November, 1987 (the "Effective Date"), by and between TAKEDA CHEMICAL INDUSTRIES, LTD. (hereinafter referred to as "Takeda", a corporation existing under the laws of Japan and having a place of business at 27 Doshomachi 2-Chome, Higashiku, Osaka, Japan, and CHEMEX PHARMACEUTICALS, INC. (hereinafter referred to as "Chemex"), a Wyoming corporation having a place of business at 1401 Seventeenth Street, Suite 850, Denver, Colorado 80202, U.S.A.

WHEREAS, Takeda has developed the Compounds (as hereinafter defined) and is the owner of certain patents related thereto;

WHEREAS, Takeda and Chemex have entered into a Confidential Disclosure Agreement dated March 24, 1987, pursuant to which Takeda has provided certain data and information to Chemex with respect to the Compounds;

WHEREAS, Chemex has advised Takeda of Chemex's interest in developing one or both of the Compounds as Preparations in the Territory (as hereinafter defined respectively); and

WHEREAS, the parties now desire to enter into an agreement under which Chemex will work toward the development of one or both of the Compounds and toward the development of data and information for the governmental authorities in the

Territory, with the object of obtaining their approvals of the marketing in the Territory of one or more Preparations, which shall include one or both of the Compounds.

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants, terms and conditions set forth herein, the sufficiency of which as consideration is hereby acknowledged by each of the parties hereto, and intending to be legally bound. Takeda and Chemex hereby agree as follows:

ARTICLE 1 DEFINITIONS

As used in this Agreement, the following terms shall have the following respective meanings:

- 1.1 "Affiliate" shall mean and include any corporation or business entity controlled by, controlling, or under common control with Takeda or Chemex, respectively. For this purpose "control" shall mean the direct or indirect beneficial ownership of at least 50% of the voting stock, or at least a 50% interest in the income of such corporation or other business entity, or such other relationship as, in fact, constitute actual control.
- 1.2 "Chemex Patents" shall mean any and all United States or foreign patent applications and patents now or hereafter owned or controlled by Chemex in any country of the world relating to the Compounds and/or Preparations, including any and all patents issuing or maturing from such patent applications, or any reissue applications, divisions,

continuations, extensions, improvements and continuations-in-part thereof.

1.3 "Compounds" shall mean and include:

(1)the chemical compound identified as Amlexanox (r-INN) having the chemical name: 2-Amino-7-isopropyl-5-oxo-5H-(1)benzopyrano-(2,3-b)-pyridine-3-carboxylic Acid (Takeda Code No.: AA-673), and

(2)the chemical compound having the chemical name: (RS)-2-Methoxy-3-(Octadecylcarbamoyloxy)propyl 2-(3-thiazolio)ethyl phosphate (Takeda Code No.: CV-3988).

- 1.4 "Dermatological Use" shall mean all uses for treatment of disease and disorders of the integument including, but not limited to, therapeutic, prophylactic and immunological uses. For the purposes of this definition, integument is skin and its appendages, including hair, hair follicles, sebaceous glands, sweat glands, nails, and component and migratory cells of the skin.
- 1.5 "Designee" shall mean a party who Takeda reasonably believes is competent and capable of performing in place of Takeda under this Agreement.
- 1.6 "DMF" shall mean the Drug Master Files, filed with or intended to be filed with the FDA or HPB for the purpose of chemical and physical characterization of the Compounds or Preparations.
 - 1.7 "FDA" shall mean the United States Food and Drug Administration.

- 1.8 "HPB" shall mean the Health Protection Branch, Department of National Health and Welfare of Canada.
- 1.9 "Improvements" shall mean and include all inventions, developments or improvements, whether or not patentable, originated or acquired by Takeda or Chemex, respectively, that relate to the Compounds for topical Dermatological Use and/or the Preparations.
- 1.10 "IND" shall mean and include (1) Notice of Claimed Investigational Exemption for a New Drug filed with or intended to be filed with the FDA for the purpose of initiating clinical trials of the Preparations in the United States, and (2) the corresponding application in Canada, filed with or intended to be filed with the HPB for the purpose of initiating clinical trials of the Preparations in Canada.
- 1.11 "NDA" shall mean a New Drug Application, filed with or intended to be filed with the FDA for the approval of such agency of the marketing of the Preparations in the United States.
- 1.12 "NDS" shall mean a New Drug Submission, filed with or intended to be filed with the HPB for the approval of such agency of the marketing of the Preparations in Canada.
- 1.13 "Net Sales" shall mean gross revenues received by the seller on the sale of one or more of the Preparations less (i) trade discounts actually allowed and (ii) when borne by the seller in connection with the sale, transportation and handling charges; sales, use and excise taxes; import duties, tariffs or

4

other governmental charges; and credits for claims or allowances, retroactive price reductions, refunds, returns, and recalls. There shall not be any imputed gross revenue for samples, free goods or other marketing programs whereby the Preparations are given away to induce sales thereof. For purposes of determining Net Sales, a sale shall be deemed to have occurred when the sale is invoiced or when the product is delivered, whichever occurs first. In the case of the transfer or sale of the Preparations by the seller to an Affiliate or distributor of the seller for sales by such Affiliate or distributor, Net Sales shall be based upon the greater of the total invoice price charged by the seller to such Affiliate or distributor or the total invoice price charged by such Affiliate or distributor to its customers.

- 1.14 "Preparations" shall mean and be limited to topical preparations for the Dermatological Use containing one or both of the Compounds as active ingredients.
- 1.15 "Takeda Patents" shall mean any and all patent applications and patents now or hereafter owned or controlled by Takeda in the Territory relating to the Compounds and/or Preparations, including any and all patents issuing or maturing from such patent applications, or any reissue applications, divisions, continuations, extensions, improvements and continuations-in-part thereof. Such current Takeda Patents and patent applications in the Territory are listed in attached Schedule A to this Agreement.

- 1.16 "Technology and Know-How" shall mean and include (1) any and all information in the possession of either party hereto at any time during the terms of this Agreement which such party has the right to license or sublicense relating to the physical and chemical analysis and stability of the Compounds and Preparations, their clinical effects and indications for use, and their pharmacological, toxicological and pathological study and (2) any and all information in the possession of either party as of the date of execution of this Agreement which such party has the right to license or sublicense relating to method of use, packaging, formulation, method of administration of the Preparations; provided, however, that information relating to Takeda's process of manufacture of the Compounds shall be excluded from the scope of the Technology and Know-How.
- 1.17 "Territory" shall mean Canada and the United States of America, and its territories and possessions, including Puerto Rico.

GRANT OF LICENSE

2.1 Takeda hereby grants to Chemex and Chemex hereby accepts a semiexclusive license (exclusive except for TAP, as hereinafter defined) in the Territory under the Takeda Patents and the Takeda Technology and Know-How to produce, have produced for it, to manufacture, have manufactured for it, to use and/or to sell one or more of the Preparations, either separately or in

6

combination with other products, with the right to grant one sublicense as provided in Section 2.3 ("License"). Nothing in this Section 2.1 shall be construed to permit Chemex to manufacture the Compounds without the prior written approval of Takeda.

2.2 Further to the License, Takeda shall be entitled to grant to Takeda-Abbott Research and Development ("R&D(P)"), an Illinois general partnership having a place of business at 1400 Sheridan Road, North Chicago, Illinois 60064, a semi-exclusive license (exclusive except for Chemex or, in Chemex's place, its sublicensee) under the Takeda and Chemex Patents and Technology and Know-How to manufacture, have manufactured for it and/or sell one or more of the Preparations in the Territory. Chemex hereby agrees that R&D(P) shall be entitled to grant an exclusive license under the Takeda and Chemex Patents and Technology and Know-How to market and sell one or more of the Preparations in the Territory to either TAP Pharmaceuticals ("TAP"), an Illinois general partnership having a place of business at 1400 Sheridan Road, North Chicago, Illinois 60064, or TAP Pharmaceuticals, Inc. ("TAP, Inc.") if it succeeds to the business of TAP within the next two years. Takeda shall be entitled to sublicense any one Affiliate of Takeda in place of TAP only with the prior written consent of Chemex, which consent shall not be unreasonably withheld. For the purposes of this Agreement, R&D(P), TAP and TAP, Inc. shall all be referred to collectively as "TAP". As far as the Dermatological Use is concerned, Takeda shall be entitled

7

to supply TAP, or any Affiliate of Takeda in place of TAP, with one or both of the Compounds for use only in the Preparations and/or with one or more of the Preparations under such license.

It is understood that TAP shall be entitled to have Abbott Laboratories, Limited, a Canadian corporation having a place of business at Montreal, Quebec, distribute and sell the Preparations in Canada.

2.3 Chemex shall be entitled to grant to a third party approved by Takeda beforehand one royalty-bearing semi-exclusive sublicense, in place of Chemex, in each country of the Territory (exclusive except for TAP) under the Takeda and Chemex Patents and Technology and Know-How to produce, have produced for it, manufacture, have manufactured for it, to use and/or to sell one or more of the Preparations, either separately or in combination with other products. Takeda shall not withhold such approval unreasonably.

It is understood that Chemex shall be entitled to have one-third party market, distribute and sell the Preparations in Canada.

ARTICLE III FDA FILINGS

3.1 Chemex intends to develop formulations of the Preparations and to file with the FDA and with the HPB, at its own expense, an IND for one or more of the Preparations. If warranted, in Chemex's sole discretion, Chemex intends to carry

8

out the necessary tests and obtain the necessary data with respect to the Preparations for the purpose of filing one or more NDAs and NDSes for the marketing and sale of the Preparations.

3.2 Chemex shall file, at its own expense, an NDA with the FDA in connection with at least one of the Preparations within five (5) years from the Effective Date or at such other time as shall be agreed upon by both parties. Such time period shall not include any period of time in which Chemex is unable to carry on its activities in preparation for filing an NDA due to a force majeure. In the event that Chemex fails to file an NDA within such period, the License shall become nonexclusive.

- 3.3 Chemex will bear final responsibility for any NDA and NDS programs and all related pre-clinical, toxicological, pharmacological, pharmaceutical, biochemical, chemical and clinical studies. Chemex shall also bear final responsibility for all contacts with the FDA and the HPB and other regulatory agencies in the Territory regarding any NDA and NDS programs and related studies.
- 3.4 In the event that Takeda or its Designee manufactures and supplies Chemex with the Compounds and/or the Preparations, Takeda shall file or shall cause such Designee to file with the FDA the DMF therefor, and with the HPB, the corresponding files, and shall allow Chemex to refer to the files in its IND(s), NDA(s) and NDS(es).
- 3.5 In the event that an NDA or an NDS for one or more of the Preparations is approved by the FDA or the HPB, Chemex

Q

shall market each approved Preparation in the United States or Canada, respectively, within six (6) months after the date of the NDA or NDS approval or at a later date as shall be agreed upon by both parties. Such time period shall be extended by an amount of time equal to any delay in timely performance caused by a force majeure.

3.6 If Chemex determines, in its bona fide judgement, that development of one or both Compounds is not technically or commercially feasible or is otherwise impossible because of infringement of third party patents, operation of law or force majeure. Chemex may discontinue the development of such Compound and its corresponding Preparation at any time or stage, in which event Chemex shall promptly so notify Takeda, reporting, in reasonable detail, to Takeda its reasons for such discontinuance. Chemex shall lose as to such Compound and its corresponding Preparation any rights vested in Chemex under this Agreement. Chemex shall return to Takeda any unused sample of such Compound together with all related Takeda Technology and Know-How previously furnished to Chemex by Takeda in writing.

ARTICLE IV DISCLOSURE REQUIREMENTS

4.1 Takeda shall provide Chemex with all the material information that is, in Takeda's reasonable judgment after consultation with Chemex, necessary for the development of the Preparations by Chemex in accordance with the procedures

10

described in this Agreement. Such material information shall include at least the information listed in Appendix A to this Agreement.

- 4.2 Takeda and Chemex shall each select an employee who shall act as its technical correspondent in transmitting technical information and arranging for other assistance necessary to fully exploit the Compounds. Each party shall indicate promptly to the other, in writing, the name of its technical correspondent. The technical correspondent of each party shall cooperatively work out a practical plan to keep each party informed about the other's current and planned activities relating to the use, practice, development, production and sale of the Compounds and Preparations. Chemex and Takeda shall meet at least semi-annually to exchange information on the status and progress of their respective development programs. Takeda shall use its reasonable efforts to provide Chemex on at least an annual basis with summaries of the scientific and medical data relating to the Compounds and/or Preparations generated by any of its licensees of the Compounds. Information pertaining to side effects resulting from any use of the Compounds in all types of applications will be exchanged by both parties hereto on an emergent basis, whether such information was obtained before any approval of an NDA or NDS or thereafter.
- 4.3 The technical correspondent of each party shall be responsible for answering all reasonable technical inquiries received from the technical correspondent of the other party

1

relating to the Compounds and the Preparations and shall provide the other party, to the extent requested, with copies of the pertinent technical information of the providing party, including, to the extent applicable and

necessary, test reports and other technical reports and manuals, lists of ingredients and their proportions in compositions of matter, and quality control procedures.

- 4.4 Takeda agrees to cooperate with Chemex and shall provide to Chemex on a timely basis, at Takeda's expense and to the extent available to Takeda, all descriptions, data, specifications and any other information that may be required by the FDA or the HPB in connection with the Chemex IND(s), NDA(s) and NDS(es), including such material as may be required regarding Takeda's facilities for the manufacture, packaging, storage and shipping into the Territory of any of the Preparations.
- 4.5 Chemex shall provide to Takeda a summary of the data, including the formulation of the Preparations, obtained from the development and tests conducted by Chemex with regard to the Compounds and the Preparations. Chemex shall also provide Takeda with copies of the IND(s), DMF(s), NDA(s), NDS(es) and post-marketing surveillance reports that Chemex files with the FDA or the HPB in connection with the Preparations.
- 4.6 In the event that Chemex files one or more United States or foreign patent applications relating to the utilization of the Compounds for Dermatological Use, including any and all reissue, divisional, continuation, continuation-in-part,

12

extension and improvement applications, Chemex shall provide Takeda with a copy of such application(s) within one (1) month from the filing thereof and, on a timely basis, with any and all subsequent communications relating thereto, to and from the government agencies considering the applications.

4.7 All information exchanged by Takeda and Chemex shall be in English. Furthermore, all such information that is designated as confidential by Takeda shall be maintained in confidence by Chemex. Takeda is entitled to use or cause its licensees of the Compounds to use any such material for its or their own purposes in connection with the development of, and obtaining regulatory approval for, any of the Compounds and Preparations outside the Territory. Studies done in support of marketing and not required under Chemex's NDA(s) or NDS(es), including clinical and preclinical studies and market research, shall not be made available to TAP unless the parties hereto otherwise agree.

ARTICLE V PATENTS

5.1 In the event that an employee, employees or contract worker of Takeda alone or jointly makes an invention or discovery relating to the Compounds and/or Preparations that is assignable or is assigned to Takeda, such invention or discovery of Takeda and the corresponding patent rights throughout the world shall be the property of Takeda. Except for future

13

Improvements, which are provided for in Article VI, if Chemex deems such invention or discovery necessary for its marketing of the Preparations in the Territory or Takeda obtains United States or Canadian patent(s) therefor, Chemex shall have the right to a license thereunder, and Takeda shall grant to Chemex such a license with regard to the Preparations upon reasonable terms to be then negotiated, which terms shall not be significantly different from the terms contained herein and shall otherwise be comparable to the terms offered to any other party for Dermatological Use.

5.2 In the event that an employee, employees or contract worker of Takeda jointly with one or more Chemex employees makes an invention or discovery relating to the Compounds and/or Preparations, such invention or discovery and the corresponding patent rights throughout the world shall be the joint property of Takeda and Chemex, with Takeda and Chemex each possessing an undivided one-half interest in such invention or discovery and in the corresponding patent rights and with Takeda possessing the unrestricted exclusive right (with right to sublicense) to manufacture, to have manufactured for it, to use, to sell and to license any invention covered by any claim or any patent that may issue under the terms of this Section 5.2; provided, however, that Chemex shall, at its option, have a semi-exclusive right (exclusive except for TAP), with a right to sublicense in Takeda's place Takeda's interest, in any such

invention in the Territory upon terms and conditions consistent with this Agreement.

5.3 In the event that an employee, employees or contract worker of Chemex alone or jointly makes an invention or discovery relating to the Compounds and/or Preparations that is assignable or is assigned to Chemex, such invention or discovery of Chemex and the corresponding patent rights shall be the property of Chemex, and Chemex shall offer Takeda a semi-exclusive license thereunder (exclusive except for Chemex) with a right to sublicense TAP, or any one Affiliate of Takeda in its place, subject to the prior approval of Chemex, in the Territory and an exclusive license outside the Territory with the right to sublicense such patent(s).

ARTICLE VI FUTURE IMPROVEMENTS

Until the termination of this Agreement, Takeda and Chemex shall promptly provide each other with information relative to Improvements. Each party hereto hereby grants to the other the option to include within the terms and conditions of this Agreement any such Improvements. Such right may be exercised by the optionee without the payment of any fee by giving written notice to the optionor within ninety (90) days of receipt of notice of existence of such Improvements.

15 ARTICLE VII PAYMENTS

- 7.1 Chemex agrees to pay to Takeda, as an initial payment for the License, a license fee of (i) \$20,000 on each Compound within thirty (30) day after the Effective Date and (ii) \$20,000 on each Compound within thirty (30) days after each anniversary of the Effective Date. Chemex shall be entitled to deduct from such license fee any United States income tax withheld and remitted to the United States Government by Chemex on account of license fee payments or royalties accruing to Takeda under this Agreement. In the event that Chemex discontinues its development of any Compound and its corresponding Preparation pursuant to Section 3.6, Chemex shall have no further obligation to pay the license fee on such Compound. License fee payment that have been made shall offset future royalties due to Takeda pursuant to Section 7.2 on a Compound-by-Compound basis but shall not be refundable to Chemex for any reason. The amount of any license fee payments that is not used to offset royalties in any year may be carried forward and used to offset royalties in succeeding years until the amount of the license fee payments is fully used.
- 7.2 In consideration for the License granted under this Agreement and in recognition of the expenditure of monies, time and effort by Chemex to develop one or more of the Preparations, including the filing of IND(s), NDA(s) and NDS(es), and the carrying out of the tests and obtaining the data required

16

by the FDA or HPB in order to obtain the approved NDA(s) or NDS(es), the parties hereto agree that Chemex shall pay to Takeda royalties at the times and in the manner hereinafter set forth:

(1)In the event that Takeda does not grant a license to TAP pursuant to Section 2.2 hereof, a royalty of * on Chemex's Net Sales up to * and * on its Net Sales over * .

(2)In the event that Takeda grants a license to TAP pursuant to Section 2.2 hereof, * on Chemex's Net Sales up to * and * on its Net Sales over * . Such payments shall be subject to the provisions of this Agreement, including, but not limited to, Article XII. For the purposes of this Article VII, "Chemex's Net Sales" shall mean and include the Net Sales of either Chemex or its sublicensee and those of its distributors, if any.

7.3 The royalties under Section 7.2 shall be payable on Chemex's Net Sales on a Preparation-by-Preparation and and country-by-country basis until the last to expire of the Takeda Patents with regard to the respective Preparation and/or the Compound contained therein or until the expiration of

ten (10) years from the date of Chemex's first commercial sale of the respective Preparation in the respective country of the Territory, whichever occurs last.

- 7.4 In the event that an unlicensed entity or entities shall market one or both of the Compounds for Dermatological Use
- * Confidential portions have been omitted and are on file separately with the Commission

17

in the Territory and a substantial erosion in Chemex's sales of the Preparations occurs, the parties hereto shall negotiate a reasonable reduction of the royalty rate in good faith.

- 7.5 In the event that Takeda markets or licenses any third party to market in any country of the world other than Japan one or more of the Preparations successfully developed by Chemex, and such marketing is made possible in such country based in whole or in part upon the Chemex Technology and Know-How, including formulation know-how, provided by Chemex to Takeda pursuant to Article IV of this Agreement, then Takeda shall pay to Chemex
- * on Net Sales in such country on a Preparation-by-Preparation basis for the use of such information for a period of ten (10) years from the date of Takeda's or its sublicensees' first commercial sale of such Preparation(s) in such country. No royalties shall be due for the use of such information in Japan.
- 7.6 In the event that pursuant to Section 5.2 or 5.3, Chemex grants Takeda an exclusive license outside the Territory, Takeda shall pay Chemex on a Preparation-by-Preparation and country-by-country basis * on Takeda's Net Sales up to * and * on its Net Sales over * for the life of the valid Chemex Patents covering the respective Preparation in each country. No royalties shall be due for the use of such patents in Japan. Moreover, such license shall be royalty-free to TAP in the Territory.
- * Confidential portions have been omitted and are on file separetely with the Commission

18

7.7 In the event that one or more of the Preparations is sold in a combination package containing other items, Net Sales, for purposes of royalty payments on the combination package, shall be calculated by multiplying the Net Sales of that combination by the fraction A/(A+B) where A is the gross selling price of the Preparation(s) sold separately and B is the gross selling price of the other items sold separately. Royalty payments pursuant to this Agreement shall be made only on that portion of Net Sales attributable to the Preparation(s). In the event that either of the items in such a combination package are not sold separately, the gross sales price of such item for the purposes of determining Net Sales subject to royalty payments shall be mutually agreed upon by the parties acting in good faith.

ARTICLE VIII REPORTS AND RECORDS

8.1 Takeda and Chemex shall keep complete, true and proper records of their sales of the Preparations in sufficient detail to enable royalties payable on Net Sales accurately to be determined. All such records shall be preserved and maintained for a period of five (5) years after the calendar half-year to which the record applies. Payments of earned royalties shall be made no more than sixty (60) days after the end of each calendar half-year for the sale of all Preparations sold during the immediately preceding calendar half-year. Such payments shall be

19

accompanied by a statement showing Net Sales and such other particulars as are necessary or which may be reasonably requested by the recipient for an account of the royalties payable pursuant to this Agreement. Payment of the amount of royalties due shall accompany such statement, which shall be deemed true and correct unless objected to in writing by the recipient no later than thirty (30) days after receipt thereof. All payments shall be in United States dollars.

8.2 Each party shall have the right for a period of two (2) years after receiving any royalty report and giving written notice of objection to appoint an independent certified public accountant, at its expense, who is

acceptable to the other party, and who shall have access to that party's records during reasonable business hours for the purpose of verifying the royalties payable under this Agreement, but this right may not be exercised more than once in any calendar year, and the accountant shall disclose only information relating solely to the accuracy of the royalty report and the royalty payments made in accordance with this Agreement.

ARTICLE IX WARRANTIES, REPRESENTATIONS AND COVENANTS

9.1 Takeda and Chemex each represents and warrants to the other that they have full power and authority to enter into this Agreement and to carry out the transactions contemplated hereby.

20

- 9.2 Takeda represents and warrants to Chemex that Takeda is the owner of and has all right, title and interest to the Takeda Patents that are listed in Schedule A hereto, free and clear of all liens and encumbrances, and that Takeda has the right to license Chemex as intended by the terms of this Agreement. Takeda further represents to Chemex that, to the best of Takeda's knowledge, Takeda has the right to provide to Chemex the material information contained in Appendix A hereto for the purposes contemplated by this Agreement.
- 9.3 During the term of this Agreement, Chemex represents and warrants that it shall use its best efforts to develop, market and promote the sale of one or more Preparations.
- 9.4 Chemex represents and warrants to Takeda that it will not publish or allow to be published any manuscript, article, report or other form of oral or written presentation of the activities of Chemex contemplated by this Agreement, except as provided in Section 16.4. This prohibition may be waived by Takeda after review and approval of the material for publication or other presentation.
- 9.5 At the request of Takeda, Chemex shall introduce to TAP the manufacturer that is making the Preparations to be marketed by Chemex. Chemex shall make all reasonable effort to render or have such manufacturer or Chemex's sublicensee, if any, render TAP the necessary cooperation in obtaining the NDA and/or NDS approval necessary for the marketing of the Preparations so that TAP may legally commence the sale of the Preparations in the

21

Territory simultaneously with Chemex or its sublicensee, and give to the FDA on behalf of TAP a letter of reference to the DMF, NDA and/or NDS for the Preparation filed by Chemex, its manufacturer or sublicensee. Notwithstanding the above expression of intent that Chemex, or its sublicensee, and TAP shall commence the sale of the Preparations simultaneously in the Territory, the parties hereto understand and agree that neither party will be required to unduly or unnecessarily delay any aspect of filing for regulatory approval or market launch in order to accommodate the objective of simultaneous sale.

- 9.6 Takeda and Chemex each represents and warrants that it shall impose upon all is Affiliates, sublicensees, employees and subcontractors that it causes to work on any aspect of the research and development, manufacturing or other activities contemplated by this Agreement substantially the same confidentiality obligations that it assumes hereunder.
- 9.7 Neither Takeda nor Chemex warrants the validity of its Patents or the exclusivity of its Technology and Know-How or that the use by the other party or by such party's sublicensees of such Patents or Technology and Know-How will not infringe any third party patents.
- 9.8 Takeda represents that, as the result of the internal patent search that it has made to date with regard to the countries of the Territory, it has found no issued product patent held by third parties in the Territory which might be infringed with regard to the import and use of the Compounds.

22

Nothing in this Section 9.8 shall be construed to impose on Takeda any liability or responsibility to Chemex with respect to any infringement of patent property owned by third parties.

ARTICLE X INDEMNIFICATION

10.1 Chemex agrees to indemnify, defend and hold harmless Takeda against and in respect of any and all damages (including expectation, incidental and consequential damages), losses (except lost profits), liabilities, judgments, claims and expenses (including, without limitation, court costs and reasonable fees of counsel, regardless of outcome) (collectively, "Losses") resulting or arising from or incurred in connection with:

(a)any misrepresentation, breach of warranty or representation or non-fulfillment or non-performance of any agreement, term or condition on the part of Chemex hereunder or any misrepresentation in or omission from any certificate, agreement or other instrument furnished or to be furnished to Takeda in connection herewith:

(b)any use of the Compounds supplied by Takeda to Chemex or of the Preparations manufactured therefrom and sold directly by Chemex; provided that, Chemex shall have no obligation hereunder and Takeda shall indemnify Chemex for Losses arising out of adulteration (as defined in the United States Food, Drug and Cosmetic Act, as amended) of the

23

Compounds and Preparations manufactured therefrom, caused solely as a result of Takeda's negligence in the course of manufacture of the Compounds;

(c)any actions, suits, proceedings, claim, demands, assessments, judgments, liabilities, costs or expenses incident to any of the foregoing.

10.2 Notwithstanding anything to the contrary in this Article X, neither party shall be entitled to assert any claim or right of action against any shareholder, director or officer of the other party for costs, damages or losses incurred as a result of the other party's improper activities as set forth in Section 10.1. Nothing in this Section 10.2 shall prevent such an action in the event such a claim or right of action arises from the unauthorized and improper activities of any such shareholder, director or officer.

ARTICLE XI TERM AND TERMINATION

11.1 Unless sooner terminated as provided herein, this Agreement shall remain in effect on a Preparation-by-Preparation and country-by-country basis for a term commencing on the Effective Date and terminating upon the expiration of the last to expire of the Takeda Patents in the Territory with regard to the respective Preparation and/or the Compound contained therein or upon the expiration of ten (10) years from the date of the first

24

commercial sale of the respective Preparation in the respective country of the Territory, whichever occurs last ("Term").

- 11.2 Either Takeda or Chemex may terminate this Agreement immediately in the event that:
- (a)The other party fails in any material respect to perform any of its obligations hereunder and fails to remedy such default or breach within one hundred and twenty (120) days after receiving written notice thereof from the first party; provided, however, that if the defaulting or breaching party cures such default or breach within the one hundred and twenty (120) day period referred to, this Agreement shall continue in full force and effect the same as if such default or breach had not occurred; or
- (b)The other party files a petition in bankruptcy or makes a general assignment for the benefit of creditors or otherwise acknowledges insolvency or is adjudged bankrupt, goes into or is placed into a process of complete liquidation other than as part of a merger or reorganization, or has a receiver appointed for its business and such receiver is not discharged within one hundred and twenty (120) days after appointment; provided, however, that if the legal action that constituted the breach is dismissed, the termination or reversion shall be void as of the date of dismissal and of no further force and effect. The parties shall thereafter have the same rights

2:

and obligations as they had immediately prior to such breach.

11.3 In the event that this Agreement is terminated by Takeda pursuant to Section 11.2 or Chemex discontinues the development of any Preparation pursuant to Section 3.6 or for any reason, Takeda shall be entitled to use, free of charge, any and all data and information collected by Chemex in its

development of the Preparation(s), and if Chemex has filed INDs, NDAs and/or NDSes on the Preparation(s), Takeda or its Designee shall be entitled to take over the INDs, NDAs and/or NDSes free of charge and shall have the cooperation of Chemex in that endeavor. Takeda shall be entitled to the use of any Chemex Patents

- 11.4 In the event that this Agreement is terminated by Chemex pursuant to Section 11.2, the License shall vest in Chemex, and Chemex shall receive a fully paid-up, royalty-free, semi-exclusive License (exclusive except for TAP and Takeda). Takeda shall also cooperate with Chemex or its sublicensee, in its place, and provide such technical assistance as is necessary in setting up a manufacturing process that will operate at a commercially viable production rate. The parties hereto shall negotiate in good faith the terms for such cooperation and technical assistance when such necessity arises.
- 11.5 The right of either party to terminate this Agreement as provided in this Article XI shall not be affected in any way by its waiver of or failure to take action with respect to any previous breach or default.

26

- 11.6 In the event of termination of this Agreement for any reason whatsoever, all rights and obligations under it shall terminate except as specifically provided herein and except the obligation to make reports, to pay all sums accrued under this Agreement and to maintain confidentiality pursuant to Article XIV.
- 11.7 Upon the termination of this Agreement and any license granted under it for any reason other than Chemex's failure to cure a material breach of this Agreement, Chemex shall have the right for one (1) year to dispose of the Compounds and Preparations then on hand by sale, processing such Compounds into one or more Preparations and completing all orders for such Preparations, or otherwise. Royalties shall be paid to Takeda with respect to such orders as though this Agreement had not been terminated.
- 11.8 The provisions of Section 9.4. Section 9.6 and Article XIV shall survive the termination or expiration of this Agreement and shall remain in full force and effect for ten (10) years thereafter. The remaining provisions of Article IX and the provisions of Articles X and XV shall survive such termination or expiration and shall remain in full force and effect for an indefinite period.
- 11.9 The License granted to Chemex pursuant to Section 2.1 and any licenses granted by either party to the other during the Term pursuant to the provisions of Article V and Sections 7.5 and 7.6 shall survive the Term and, after the expiration of the

27

respective periods for royalty payments as set forth herein, such licenses shall be available to Chemex and Takeda on a paid-up, royalty-free nonexclusive basis.

- 11.10 Takeda's right to use information previously furnished by Chemex pursuant to the provisions of Article IV shall survive the Term.
- 11.11 In the event that this Agreement is terminated by either party pursuant to Section 11.2, such termination shall be deemed to be a material breach terminating that certain Supply Agreement between the parties hereto of even date herewith, pursuant to Section 11.3 thereof.

ARTICLE XII PATENTS INFRINGEMENT

12.1 Takeda and Chemex shall each give immediate written notice to the other of any infringement or threatened infringement of the Takeda or Chemex Patents by third parties as may come to its knowledge. In the event of any infringement or in the event of any application being made for revocation of any of such Patents, the owner of such Patents may at its determination take all actions or proceedings that may be necessary, at its own costs, to restrain the infringement or defend the revocation, as the case may be, and shall have the reasonable cooperation of the other party in that endeavor. If the owner of such Patents does not want to take any such action or start any such proceedings within thirty (30) days of being so notified, both parties shall

consult on how to cope with such situation, with the intention of taking all reasonable steps to protect their Patents.

- 12.2 If, in exercising its rights under this Agreement, Chemex is accused of infringing a product patent owned by a third party with regard to any of the Compounds, Takeda shall use its best efforts to obtain rights for Chemex under the third party patent. If in obtaining such rights from such third party Takeda is required to make any payment, the amount of such payment to the date of infringement settlement shall be shared between Chemex and the party holding a semi-exclusive license from Takeda pursuant to Section 2.2 on a pro rata basis, according to the cumulative Net Sales of each from the date of the respective party's first commercial sale to the date of such payment. Any additional royalty payments to such third party thereafter shall be shared equally by increasing the royalty rates payable by Chemex and the party holding a semi-exclusive license from Takeda pursuant to Section 2.2 by an equal percentage rate.
- 12.3 If, in exercising its rights under this Agreement, Takeda is accused of infringing a product patent owned by a third party with regard to any of the Preparations, Chemex shall use its best efforts to obtain rights for Takeda under the third party patent. If in obtaining such rights from such third party Chemex is required to make any payment, the amount of such payment to the date of infringement settlement shall be shared between Chemex and the party holding a semi-exclusive license

29

from Takeda pursuant to Section 2.2 on a pro-rata basis, according to the cumulative Net Sales of each from the date of the respective party's first commercial sale to the date of such payment. Any additional royalty payments to such third party thereafter shall be shared equally by increasing the royalty rates payable by Chemex and the party holding a semi-exclusive license from Takeda pursuant to Section 2.2 by an equal percentage rate.

12.4 If the costs imposed on either party pursuant to Sections 12.2 and 12.3 are excessive in that party's judgment, such party may terminate this Agreement forthwith.

ARTICLE XIII PRODUCT MANUFACTURING

Chemex shall purchase from Takeda or its Designee Chemex's entire requirements in the Territory for the Compounds for use in the manufacture of the Preparations, and Takeda agrees to supply or have its Designee supply the Compounds to Chemex in accordance with Chemex's commercial orders for the term of this Agreement under the terms and conditions of that certain Supply Agreement of even date herewith

ARTICLE XIV CONFIDENTIALTY

14.1 Chemex shall keep in confidence and shall not disclose to any third party the Takeda Technology and Know-How.

- 14.2 Chemex shall use the Takeda Technology and Know-How only for the purposes contemplated in this Agreement.
- 14.3 Takeda shall keep in confidence the Chemex Patent specifications disclosed by Chemex to Takeda pursuant to Section 4.6 and the formulation know-how of the Preparations disclosed by Chemex to Takeda pursuant to Articles IV and VI and shall use the same only for the purposes contemplated in this Agreement.
- 14.4 The foregoing restrictions shall not apply to any portion of the Takeda and Chemex Technology and Know-How:
- (a) which is now or hereafter becomes disclosed in published papers, literature or patents;
- (b) which the receiving party can prove was in its possession prior to disclosure by the transmitting party; or
 - (c) which is hereafter disclosed to the receiving party by a third party

having no obligation of confidentiality to the transmitting party.

14.5 Notwithstanding anything to the contrary in Section 14.1, either party shall be permitted to disclose confidential information, as reasonably necessary, to regulatory and other government agencies in support of applications to market and distribute the Preparations, and to its sublicensees, employees and subcontractors in the manufacture, use, marketing, distribution and sale of the Preparation, so long as it imposes

3

upon them substantially the same confidentiality obligations that it assumes under this Agreement.

ARTICLE XV ARBITRATION

Any dispute or differences of interpretation concerning this Agreement that cannot be settled by mutual accord between the parties shall be settled by arbitration in Denver, if initiated by Takeda, or in Osaka, if initiated by Chemex, in accordance with the rules then obtaining of the International Chamber of Commerce, except as otherwise provided herein. The dispute or differences shall be referred to a single arbitrator, if the parties agree upon one, or otherwise to three arbitrator, one to be appointed by each party and a third arbitrator to be appointed by the first named arbitrators in writing; and if either party shall refuse or neglect to appoint an arbitrator within thirty (30) days after the other party shall have appointed an arbitrator and shall have served a written notice upon the first mentioned party requiring such party to make such appointment, then the arbitrator first appointed shall, at the request of the party appointing him, proceed to hear and determine the matters in difference as if he were a single arbitrator appointed by both parties for the purposes, and the award or determination that shall be made by the arbitrator shall be final and binding upon the parties hereto. The decision of a majority of the arbitrators will be final and binding upon the

32

parties hereto. The arbitrator or the arbitrators shall make their award in accordance with and based upon all the provisions of this Agreement and judgment upon the award rendered may be entered in any court having jurisdiction. The expense of the arbitration shall be shared equally between the parties.

ARTICLE XVI MISCELLANEOUS PROVISIONS

- 16.1 Force Majeure. Neither party shall be liable for failure to perform or delay in performing with respect to any provision of this Agreement to the extent performance in the customary manner shall be prevented, hindered or delayed in whole or in part by transportation conditions, strikes, riots, earthquakes, floods, or other acts of God, compliance with an act or request of a governmental authority or persons purporting to act with governmental authority (including but not limited to, orders or actions in response to shortages of fuel or other energy sources, or of raw materials), labor difficulty (whether or not involving its own employees) or any other event that is not reasonably within such party's control.
- 16.2 Assignability. Without the prior written approval of the other party hereto, neither party may assign this Agreement or transfer its interest or any party thereof to any of its Affiliates or to any third party.
- 16.3 Independent Contractor. This Agreement shall not create an agency, partnership, joint venture or employer/employee

33

relationship. Takeda and Chemex each hereby agrees not to represent itself in any of such capacities in any manner whatsoever. The sole relationship established by this Agreement is that of an independent contractor, and nothing hereunder shall be construed to give either party the power or authority to act for, represent, bind, or commit the other party or any of its Affiliates.

16.4 Publicity. Either party may publicize the existence of this Agreement, but neither party may disclose the terms of this Agreement without the prior written approval of the other party hereto. Chemex

understands that Takeda may find it necessary to disclose the terms of this Agreement to TAP, Abbott Laboratories, or other Takeda licensees of the Compounds; Chemex agrees to permit such disclosure. Chemex shall not use the name of Takeda or of any scientists affiliated with Takeda, in any manner without its prior written approval, except that either party may make such disclosures without written approval if required to do so by local, state or federal law or regulation. An opinion of an independent legal counsel that such disclosure is required shall constitute adequate basis for such disclosure. A party relying upon an opinion of counsel shall provide the other party with prompt notice of its intention to do so.

16.5 Notice. Any notice expressly provided for under this Agreement shall be in writing, sent by first class airmail, overnight mail, Telex or telecopy, addressed as set forth below:

34

For notice to Takeda:

Takeda Chemical Industries, Ltd. 27 Doshomachi 2 Chome Higashiku, Osaka

Telecopy: 011-81-6-204-2244

Telex: J63404

Attention: Manager, Planning Department,

New Product Planning and Development Division

For notice to Chemex:

Chemex Pharmaceuticals, Inc. 1401 Seventeenth Street, Suite 850 Denver, Colorado 80202 Telecopy: (303) 298-0332

Telex: 53005 Attention: President

- 16.6 Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provisions shall be replaced with a provision that accomplishes, to the extent possible, the original business purpose of such part or provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the parties hereto.
- 16.7 Captions. The captions of this Agreement are solely for convenience of reference and shall not affect its interpretation.
- 16.8 Entire Agreement. This Agreement and the Exhibits hereto represent the entire Agreement between the parties and as such supersedes all previous negotiations, agreements, representations, understandings and commitments with

35

respect to the subject matter hereof. No release, discharge, change or modification of this Agreement shall be effective unless made in writing and executed by authorized representatives of each of the parties hereto.

- 16.9 Waiver. The failure of Takeda or Chemex to exercise or enforce any right granted in this Agreement or obligation arising thereunder shall not be deemed to be a waiver of such right or obligation or operate to bar the exercise or enforcement thereof at any time thereafter.
- 16.10 Governing Law. The rights and obligations of the parties under this Agreement shall be governed by and construed in accordance with the laws of the State of New York, United States of America.

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

"Chemex" "Takeda"

CHEMEX PHARMACEUTICALS, INC. TAKEDA CHEMICAL INDUSTRIES, LTD.

By: /s/ E. Neiss By: /s/ Masao Uchibayashi

Dr. Edward S. Neiss Dr. Masao Uchibayashi

President and Chief Operating Managing Director and

Officer General Manager International Division

By: /s/ Y. Takahashi

Yoshinao Takahashi, M.D.

Director and General

Manager,

New Product Planning &

Development Division

37 SCHEDULE A TAKEDA PATENTS

1. AA-673

Countr		No. Patent No. (Issue Date)	
U.S.A.	881237 (Feb. 27, 1987)	4143042 (Mar. 6, 1799)	Mar. 6, 1996
U.S.A.		4255576 (Mar. 10, 1981)	Mar. 10, 1998
U.S.A.	177550 (Aug. 13, 1980)	4299963 (Nov. 10, 1981)	Nov. 10, 1998
Canada	297785 (Feb. 27, 1978)	1087188 (Oct. 7, 1980)	Oct. 7, 1997

2. CV-3988

(1) Takeda's Case 1000 (Compound)

Country	Application	No. Patent No.	Expiration
	(Filing Date)	(Issue Date)	Date
U.S.A.	237970 (Oct	4408052 (. 4, 1983)	Oct. 4, 2000
U.S.A.	513617 (Jan	4565865 . 21, 1986)	Jan. 21, 2003
Canada	371856 (Aug	1152068 g. 16, 1983)	Aug. 16, 2000

Application No. Patent No. Country Expiration (Filing Date) (Issue Date) Date 45282824 U.S.A. PCT/JP83/00289 (Apr.15, 2003) 614024 (Apr. 15, 1986) Canada 461429 (Aug. 21, 1984) MEMORANDUM OF AMENDMENT (LICENSE AGREEMENT)

In connection with the License Agreement ("License Agreement") on AA-673 and CV-3988 as of November 12, 1987, as amended, between Takeda Chemical Industries, Ltd. ("Takeda") and Chemex Pharmaceuticals, Inc. who has assigned the License Agreement to Block/Chemex, G.P. ("Block/Chemex"), Takeda and Block/Chemex hereby agree as follows:

- 1. Section 1.17 of the License Agreement shall be amended to read as follows:
- 1.7 "Territory" shall mean Canada, United States of America and its territories and possessions, including Puerto Rico, Australia, New Zealand, Republic of South Africa, Russian Federation, West European countries and South American countries, the exact names of the latter two of which will be confirmed by separate letter.
- 2. In accordance with the amendment of the definition of the Territory set forth in above Item 1, references to the United States and Canada in the License Agreement shall be deemed to include other countries in the Territory. For instance, "IND" shall be deemed to include applications in the Territory filed governmental agencies for the purpose of initiating clinical trials of the Preparation and "NDA" and/or "NDS" shall be deemed to include applications for approval of governmental authorities prior to the marketing of the preparation in the Territory.
- 3. Schedule A attached to the License Agreement shall be replaced by Schedule A attached to this Memorandum.
- 4. Takeda hereby waives its rights to grant to TAP a semi-exclusive license and to sublicense its Affiliates in place of TAP set forth in Section 2.2 of the License Agreement.
- 5. Section 2.1 of the License Agreement shall be amended to read as follows:
- 2.1 Takeda hereby grants to Chemex and Chemex hereby accepts an exclusive license in the Territory under the Takeda Patents and the Takeda Technology and Know-How to produce, have produced for it, to manufacture, have manufactured for it, to use and/or to sell one or more of the Preparations, either separately or in combination with other products, with the right to grant sublicense as provided in Section 2.3 ("License"). Nothing in this Section 2.1 shall be construed to permit Chemex to manufacture the Compounds without the prior written approval of Takeda.
- 6. Section 2.3 of the License Agreement shall be amended to read as follows:
- 2.3 Chemex shall be entitled to grant to a third party approved by Takeda beforehand royalty-bearing sublicense in the Territory under the Takeda and Chemex Patents and Technology and Know-How to produce, have produced for it, manufacture, have manufactured for it, to use and/or to sell one or more of the Preparations, either separately or in combination with other products. Takeda shall not withhold such approval unreasonably.
- 7. This Memorandum shall be effective as of August 1, 1994.

Takeda and Block/Chemex have caused this Memorandum to be signed in duplicate by their duly authorized officers.

TAKEDA CHEMICAL INDUSTRIES, LTD.

/s/ K. Murakami

_ _____

Name:Kenkichi Murakami Title:Member of the Board General Manager International Division Pharmaceutical Group Date: October 14, 1994

BLOCK/CHEMEX, G.P.

/s/ H. McDade, Jr.

- -----

Name:Herbert H. McDade, Jr. Title:President & CEO of Chemex

Date:October 25, 1994

BLOCK DRUG COMPANY, INC.

/s/ J. Peters

- -----

Name:John E. Peters Title:Senior Vice President-General Counsel & Secretary

Date:October 26, 1994

EXHIBIT D TAKEDA SUBLICENSED PATENTS

SCHEDULE A

TAKEDA PATENTS

AA-673

Country	Application 1 (Filing Date)	No. Patent No (issue Date)	
U.S.A.	881237 (Feb. 27, 1978)	4143042 (Mar. 06, 1979)	
U.S.A.	970105 (Dec. 18, 1978)	4255576 (Mar. 10, 1981)	
U.S.A.	177580 (Aug. 13, 1980)	4299963 (Nov. 10, 1981	
Canada	297785 (Feb. 27, 1978)		Oct. 07, 1997
Austria	A1499-78 (Mar. 02, 1978)	360535 (Nov. 28, 1980)	
Belgium	0-185734 (Mar. 07, 1978)	864647 (Sep. 07, 1978)	
Switzerla	nd 2486-78 (Mar. 07, 1978)	634322 (Jan. 16, 1983)	· ·
Germany	P2809720. (Mar. 07, 1978)		Mar. 07, 1998
Denmark	924-78 (Mar. 01, 1978)	156661 (Feb. 05, 1990)	Mar. 01, 1998
Spain	468.042	468042	Oct. 20, 1998

(Mar. 08, 1978) (Oct. 20, 1978)

France	7806538 (Mar. 07, 1978)	7806538 (Oct. 06, 1980)	Mar. 07, 1998
U.K.	8518-78 (Mar. 03, 1978)		Mar. 02, 1998
U.K.	7930850 (Sep. 05, 1979)		Mar. 02, 1998
Italy	20957A-78 (Mar. 07, 1978)		Mar. 07, 1998
Netherlar	nds 7802526 (Mar. 08, 1978)		Mar. 08, 1998
Country	y Application (Filing Date)	No. Patent No. (issue date)	
Norway	780777	149737	Mar. 07, 1998

Exhibit E Supply Agreement

SUPPLY AGREEMENT

This is an Agreement, effective the 12 day of November, 1987 (the "Effective Date"), by and between TAKEDA CHEMICAL INDUSTRIES, LTD., (hereinafter referred to as "Takeda"), a corporation existing under the laws of Japan and having a place of business at 27 Doshomachi 2-Chome, Higashiku, Osaka, Japan and CHEMEX PHARMACEUTICALS, INC. (hereafter referred to as "Chemex"), a Wyoming corporation having a place of business at 1401 Seventeenth Street, Suite 850, Denver, Colorado 80202, U.S.A.

RECITALS

WHEREAS, Takeda and Chemex have entered into that certain License Agreement of even date herewith (the "License Agreement"), pursuant to which Takeda granted to Chemex a semi-exclusive license (the "License") to manufacture, use and/or sell the Preparations (as hereinafter defined):

WHEREAS, Chemex desires to purchase from Takeda its entire requirements of the Compounds (as hereinafter defined) for use in the manufacture of the Preparations; and

WHEREAS, Takeda is willing to supply the Compounds to Chemex upon the terms and conditions contained herein;

NOW, THEREFORE, in consideration of the foregoing premises and of the mutual covenants, terms and conditions set forth herein, the sufficiency of which as consideration is hereby

acknowledged by each of the partners hereto, and intending to be legally bound. Takeda and Chemex hereby agree as follows:

ARTICLE I DEFINITIONS

As used in this Agreement, the following terms shall have the following respective meanings:

1.1 "Affiliate" shall mean and include any corporation or business entity controlled by, controlling, or under common control with

Takeda or Chemex, respectively. For this purpose "control" shall mean the direct or indirect beneficial ownership of at least 50% of the voting stock, or at least a 50% interest in the income of such corporation or other business entity, or such other relationship as, in fact, constitutes actual control.

- 1.2 "Compounds" shall mean and include:
- (1) the chemical compound identified as Amlexanox (r-INN) having the chemical name: 2-Amino-7-isopropyl-5-oxo-5H-[1]benzopyrano-[2,3-b]-pyridine-3-carboxylic Acid (Takeda Code No.: AA-673), and
- (2) the chemical compound having the chemical name: (RS)-2-Methoxy-3-(Octadecylcarbamoyloxy)propyl 2-(3-thiazolio)ethyl phosphate (Takeda Code No.: CV-3988).
- 1.3 "Dermatological Use" shall mean all uses for treatment of diseases and disorders of the integument including, but not limited to, therapeutic, prophylactic and immunological uses. For the purposes of this definition, integument is skin

2

and its appendages, including hair, hair follicles, sebaceous glands, sweat glands, nails, and component and migratory cells of the skin.

- 1.4 "Designee" shall mean a party who Takeda reasonably believes is competent and capable of performing in place of Takeda under this Agreement.
- 1.5 "FDA" shall mean the United States Food and Drug Administration.
- 1.6 "Preparations" shall mean and be limited to topical preparations for the Dermatological Use containing one or both of the Compounds as active ingredients.
- 1.7 "Territory" shall mean Canada and the United States of America and its territories and possessions, including Puerto Rico.

ARTICLE II PURCHASE AND SUPPLY

2.1 Chemex shall purchase from Takeda or its Designee Chemex's entire requirements in the Territory for the Compounds for the use in the manufacture of the Preparations, or the Preparations if Takeda manufactures them for any third party in the Territory. Takeda agrees to supply or have its Designee supply the Compounds in accordance with Chemex's commercial orders as far as Takeda manufactures or to have its Designee manufacture the Compounds in accordance with all applicable current FDA approved Good Manufacturing Practices standards.

3

- 2.2 Chemex shall not, directly or indirectly, export the Compounds or the Preparation outside the Territory.
- 2.3 With the exception of either Takeda-Abbott Research and Development or TAP Pharmaceuticals (or TAP Pharmaceuticals, Inc. if it succeeds to the business of TAP Pharmaceuticals within two years from the Effective Date) (hereinafter collectively referred to as "TAP"), both Illinois general partnerships having a place of business at 1400 Sheridan Road, North Chicago, Illinois 60064. Takeda shall not supply any third party with one or both of the Compounds for Dermatological Use of Preparations in the Territory so long as the License is semi-exclusive with regard to such Compound or Preparation in the Territory.
- 2.4 In the event that Chemex discontinues the development of any Compound, such Compound and its corresponding Preparation shall be excluded from the scope of this Agreement and Takeda shall be released from its obligation under Section 2.3 as far as such Compound and its corresponding Preparation are concerned.

ARTICLE III ESTIMATE AND ORDER

3.1 During the term of this Agreement, at least one hundred and eighty (180) days prior to the start of each calendar quarter, Chemex shall provide Takeda with a written estimate of the amount of the Compounds that Chemex will require during such

quarter and during each of the next three (3) quarters. No such estimate shall constitute a firm purchase order by Chemex.

- 3.2 Chemex shall enter its firm order with Takeda for purchase of the Compounds at least ninety (90) days in advance of the requested delivery date.
- 3.3 Chemex shall purchase from Takeda in any calendar year not less than sixty percent (60%) of the sum of the estimates, as revised in each succeeding estimate, for the four (4) quarters comprising such calendar year. Takeda shall supply Chemex with up to, but shall not be required to supply more than, one hundred and fifty percent (150%) of the sum of such revised quarterly estimates.

ARTICLE IV PRICE AND PAYMENT

- 4.1 The price for each of the Compounds to be purchased under this Agreement shall be separately agreed upon in good faith between the parties hereto.
- 4.2 Takeda shall use its best efforts to supply Chemex with the Compounds and/or the Preparations, if TAP is so supplied, at a reasonable price. If Takeda cannot supply Chemex with the Compounds at such price, both parties shall negotiate in good faith an alternative method of procuring the Compounds, including allowing Chemex or its sublicensee, in its place, to manufacture the Compounds in the Territory for its use. In such case, Takeda shall cooperate with Chemex or its sublicensee, in

5

its place, and provide such technical assistance as is necessary in setting up a manufacturing process that will operate at a commercially viable production rate. The parties hereto shall negotiate in good faith the terms for such cooperation and technical assistance when such necessity arises.

- 4.3 If Takeda gives TAP more favorable pricing terms with respect to the Compounds or Preparations for Dermatological Use, Chemex shall be entitled to elect such more favorable terms.
- 4.4 Takeda will invoice Chemex upon delivery of the Compounds. Payments for the supplies of the Compounds to be delivered by Takeda shall be made by Chemex to Takeda in Japanese yen or any other currency that may be agreed upon between the parties, prior to each shipment by check or any other mode of remittance upon which the parties may agree.
- 4.5 Takeda shall provide Chemex with samples of the Compounds in reasonable quantities and at Takeda's expense for use during the development of the corresponding Preparation.

ARTICLE V TITLE AND RISK OF LOSS

Unless otherwise agreed upon, title and risk of loss to the Compounds and/or Preparations supplied hereunder shall pass to Chemex upon delivery to the carrier designated by Chemex at an international airport in Osaka or Narita or such other place as the parties may agree upon.

6 ARTICLE VI SHIPMENT AND TESTING

- 6.1 Takeda shall ship the Compounds and/or the Preparations ordered by Chemex in accordance with its directions. The Compounds and/or the Preparations normally will be delivered to the carrier designated by Chemex at an international airport in Osaka or Narita or such other place as the parties may agree upon together with a certificate of analysis, the form of which shall be separately agreed upon between the parties hereto. Takeda shall number each lot of Compounds and/or Preparations shipped for future production reference and quality control protocols, including analysis results.
- 6.2 Takeda agrees to exercise all reasonable and necessary efforts to satisfy the delivery requirements of Chemex and to insure timely delivery of the Compounds.
- 6.3 Chemex shall perform all analytical testing within sixty (60) days after the delivery of the Compounds under Section 6.1. Such testing shall be in accordance with the method of assay to be separately agreed upon between the parties in good faith at the earliest possible date. If the Compounds supplied by Takeda under this Agreement are found not to

conform to the specifications thereof, Chemex shall notify Takeda of such nonconformity no later than ninety (90) days after receipt thereof and Takeda shall, at its option, either replace such Compounds with new Compounds at no additional charge or cost to Chemex, delivered at Chemex's premises, or credit Chemex for the

7

purchase and delivery of the Compounds at Chemex's premises. Chemex shall bear the duties to be imposed upon the import of the new Compounds to be exchanged with the original Compounds not conforming to the specifications in case the duties imposed upon the import of the original Compounds are legally redeemable.

ARTICLE VII WARRANTIES AND REPRESENTATIONS

- 7.1 Takeda and Chemex each represents and warrants to the other that they have full power and authority to enter into this Agreement and to carry out the transactions contemplated hereby.
- 7.2 Takeda represents and warrants that the Compounds supplied by Takeda hereunder shall conform to specifications to be separately agreed upon between the parties in good faith at the earliest possible date.
- 7.3 Except for the warranties undertaken by Takeda under this Article VII, Takeda makes no other warranty of any kind, express or implied, arising by law or otherwise, including, but not limited to, the implied warranty of merchantability, any implied warranty arising from course of performance, course of dealing or usage or trade, and any implied warranty of fitness for particular purpose, safety or effectiveness of the Compounds, or adequacy of warning as to risks.

8 ARTICLE VIII RESPONSIBILITY AND INDEMNIFICATION

- 8.1 Chemex shall be responsible for:
- (a) the labeling utilized on and in connection with the Preparations sold by Chemex;
- (b) the proper storage and handling of the Compounds after delivery by Takeda hereunder; and
- (c) the proper manufacture and marketing of the Preparations in due compliance with all applicable laws and regulations in the Territory.
- 8.2 Chemex agrees to indemnify, defend and hold harmless Takeda against and in respect of any and all damage (including expectation, incidental and consequential damages), losses (except lost profits), liabilities, judgments, claims and expenses (including, without limitation, court costs and reasonable fees of counsel, regardless of outcome) (collectively, "Losses") resulting or arising from or incurred in connection with any use of the Compounds supplied by Takeda to Chemex or of the Preparations manufactured therefrom and sold directly by Chemex; provided that, Chemex shall have no obligation hereunder and Takeda shall indemnify Chemex for Losses arising out of adulteration (as defined in the United States Food, Drug and Cosmetic Act, as amended) of the Compounds and Preparations manufactured therefrom, caused solely as a result of Takeda's negligence in the course of manufacture of the Compounds or of the Preparations manufactured from such adulterated Compounds.

- 8.3 Notwithstanding anything to the contrary in this Article VIII, neither party shall be entitled to assert any claim or right of action against any shareholder, director or officer of the other party for costs, damages or losses incurred as a result of the other party's improper activities as set forth in this Article VIII. Nothing in this Section 8.3 shall prevent such an action in the event that such a claim or right of action arises from the unauthorized and improper activities of any such shareholder, director or officer
- 8.4 In the event that any portion of this hold harmless and indemnity provision becomes or is held invalid, it is agreed that the remaining portions of this hold harmless and indemnity provision shall remain valid and binding and continue in full legal force and effect.

Chemex shall, by means of circulars provided and enclosed with the Preparations or otherwise delivered, provide warning and advice for use of the Preparations, including Product Description, Clinical Pharmacology, Indication and Usage, Contra-indications, Warnings, Precautions, Adverse Reactions, and How Supplied, as required by the governmental authorities in the Territory. Chemex shall exercise due diligence in revising the circulars as appropriate.

10 ARTICLE X CONFIDENTIALITY

- 10.1 All information disclosed by Takeda to Chemex under this Agreement shall be kept by Chemex in confidence. Such restrictions shall not apply to any such information (i) which is, or subsequently may become, within the knowledge of the general public by means of published papers, literature or patents, without the fault of Chemex, (ii) which may already be known to Chemex at the time of the receipt thereof from Takeda as shown by documents, (iii) which may be proved to have been developed by Chemex independently and wholly without resort to the proprietary information of Takeda as shown by documents, (iv) which may subsequently be rightfully obtained from sources other than Takeda that have no obligation of confidentiality to Takeda, or (v) in any case, more than ten years after the expiration of the term or earlier termination of this Agreement.
- 10.2 Notwithstanding anything to the contrary in Section 10.1, Chemex shall be permitted to disclose confidential information, as reasonably necessary, to regulatory and other government agencies in support of applications to market and distribute the Preparations, and to its sublicensees, employees and subcontractors in the manufacture, use, marketing, distribution and sale of the Preparations, so long as it imposes upon them substantially the same confidentiality obligations that it assumes under this Agreement.

11 ARTICLE XI TERM AND TERMINATION

- 11.1 Unless sooner terminated or extended as provided herein, this Agreement shall come into force on the Effective Date and shall remain in effect on a Compound-by-Compound and country-by-country basis for ten (10) years from the date of the first commercial sale of the respective Compound's corresponding Preparation in the respective country of the Territory. This Agreement shall be renewed thereafter for a period of five (5) years at Chemex's option to be exercised no later than six (6) months prior to the expiration date of the original period. The option period shall be automatically extended thereafter for additional period of one year unless either party hereto notifies the other party, not later than six (6) months prior to the expiration date of the option period or of any additional renewal period, of its intention to terminate this Agreement on the expiration date.
- 11.2 Upon the termination of this Agreement by Chemex pursuant to Section 11.3, Takeda shall cooperate with Chemex or its sublicensee, in its place, and provide such technical assistance as is necessary in setting up a manufacturing process that will operate at a commercially viable production rate. The parties hereto shall negotiate in good faith the terms for such cooperation and technical assistance when such necessity arises.
- 11.3 Either Takeda or Chemex may terminate this Agreement immediately in the event that:

- (a) The other party fails in any material respect to perform any of its obligations hereunder and fails to remedy such default or breach within one hundred and twenty (120) days after receiving written notice thereof from the first party; provided, however, that if the defaulting or breaching party cures such default or breach within the one hundred and twenty (120) day period referred to, this Agreement shall continue in full force and effect the same as if such default or breach had not occurred; or
- (b) The other party files a petition in bankruptcy or makes a general assignment for the benefit of creditors or otherwise acknowledges insolvency or is adjudged bankrupt, goes into or is placed into a process of complete liquidation other than as part of a merger or reorganization, or has a receiver appointed for its business and such receiver is not discharged within one hundred and twenty (120) days after appointment; provided, however, that if the legal action that constituted the breach is

dismissed, the termination or reversion shall be void as of the date of the dismissal and of no further force and effect. The parties shall thereafter have the same rights and obligations as they had immediately prior to such breach.

11.4 In the event that this Agreement is terminated by either party pursuant to Section 11.3, such party may elect to treat such termination as a material breach terminating that

13

certain License Agreement between the parties hereto of even data herewith, pursuant to Section 11.2 thereof.

- 11.5 The right of either party to terminate this Agreement as provided in this Article XI shall not be affected in any way by its waiver of or failure to take action with respect to any previous breach or default.
- 11.6 In the event of termination of this Agreement for any reason whatsoever, all rights and obligations under it shall terminate except as specifically provided herein.

ARTICLE XII ARBITRATION

Any dispute or differences of interpretation concerning this Agreement that cannot be settled by mutual accord between the parties shall be settled by arbitration in Denver, if initiated by Takeda, or in Osaka, if initiated by Chemex, in accordance with the rules then obtaining of the International Chamber of Commerce, except as otherwise provided herein. The dispute or differences shall be referred to a single arbitrator if the parties agree upon one, or otherwise to three arbitrators, one to be appointed by each party and a third arbitrator to be appointed by the first named arbitrators in writing; and if either party shall refuse or neglect to appoint an arbitrator within thirty (30) days after the other party shall have appointed an arbitrator and shall have served a written notice upon the first mentioned party requiring such party to make such

14

appointment, then the arbitrator first appointed shall, at the request of the party appointing him, proceed to hear and determine the matters in difference as if he were a single arbitrator appointed by both parties for the purposes, and the award or determination that shall be made by the arbitrator shall be final and binding upon the parties hereto. The decision of a majority of the arbitrators will be final and binding upon the parties hereto. The arbitrator or the arbitrators shall make their award in accordance with and based upon all the provisions of this Agreement and judgement upon the award rendered may be entered in any court having jurisdiction. The expense of the arbitration shall be shared equally between the parties.

ARTICLE XIII MISCELLANEOUS PROVISIONS

13.1 Force Majeure. Neither party shall be liable for the failure to perform or delay in performing with respect to any provision of this Agreement to the extent performance in the customary manner shall be prevented, hindered, or delayed in whole or in part by transportation conditions, strikes, riots, earthquakes, floods, or other acts of God, compliance with an act or request of a governmental authority or persons purporting to act with governmental authority (including but not limited to, orders or actions in response to shortages of fuel or other energy sources, or of raw materials), labor difficulty (whether or not involving its own employees) or any other event that is not reasonably within such party's control.

- 13.2 Assignability. Without the prior written approval of the other party hereto, neither party may assign this Agreement or transfer its interest or any part thereof to any of its Affiliates or to any third party.
- 13.3 Survival. The provisions of Article X shall survive the termination or expiration of this Agreement and shall remain in full force and effect for ten (10) years thereafter. The provisions of Articles VII, VIII and XII shall survive such termination or expiration and shall remain in full force and effect for an indefinite period.
- 13.4 Independent Contractor. This Agreement shall not create an agency, partnership, joint venture or employer/employee relationship. Takeda and Chemex each hereby agree not to represent itself in any of such capacities in any manner whatsoever. The sole relationship established by this

Agreement is that of an independent contractor, and nothing hereunder shall be construed to give either party the power or authority to act for, represent, bind, or commit the other party or any of its Affiliates.

13.5 Publicity. Either party may publicize the existence of this Agreement, but neither party may disclose the terms of this Agreement without the prior written approval of the other party hereto. Chemex understands that Takeda may find it necessary to disclose the terms of this Agreement to TAP, Abbott Laboratories, or other Takeda licensees of the Compounds; Chemex agrees to permit such disclosure. Chemex shall not use the name

of Takeda or any scientist affiliated with Takeda, in any manner without its prior written approval, except that either party may take such disclosures without written approval if required to do so by local, state or federal law or regulation. An opinion of an independent legal counsel that such disclosure is required shall constitute an adequate basis for such disclosure. A party relying upon an opinion of counsel shall provide the other party with prompt notice of its intention to do so.

13.6 Notice. Any notice expressly provided for under this Agreement shall be in writing, sent by first class airmail, overnight mail, telex or telecopy, addressed as set forth below. For notice to Takeda:

> Takeda Chemical Industries, Ltd. 27 Doshomachi 2-Chome Higashiku, Osaka Telecopy: 011-81-6-204-2244

Telex: J63404

Attention: General Manager International Division

For notice to Chemex:

Chemex Pharmaceuticals, Inc. 1401 Seventeenth Street, Suite 850 Denver, Colorado 80202 Telecopy: (303) 298-0332 Telex: 53005

Attention: President

13.7 Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with the applicable laws or regulations of any jurisdiction, the invalid or unenforceable part or provisions shall be replaced with a provision that accomplishes, to the extent possible, the original

17

business purpose of such part or provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the parties

- 13.8 Captions. The captions of this Agreement are solely for convenience of reference and shall not affect its interpretation.
- 13.9 Entire Agreement. This Agreement represents the entire Agreement between the parties with regard to the supply of the Compounds and as such supersedes all previous negotiations, agreements, representations, understandings and commitments with respect thereto. No release, discharge, change or modification of this Agreement shall be effective unless made in writing and executed by authorized representatives of each of the parties hereto.
- 13.10 Waiver. The failure of Takeda or Chemex to exercise or enforce any right granted in this Agreement or obligation arising thereunder shall not be deemed to be a waiver of such right or obligation or operate to bar the exercise or enforcement thereof at any time thereafter.
- 13.11 Governing Law. The rights and obligations of the parties under this Agreement shall be governed by and construed in accordance with the laws of the State of New York, Untied States of America.

18

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duty authorized offices as of the day and year first above written.

TAKEDA CHEMICAL INDUSTRIES, LTD.

By: /s/ Masao Uchibayashi

Dr .Masao Uchibayashi Managing Director and General Manager International Division

"Chemex" CHEMEX PHARMACEUTICALS, INC.

By: /s/ E. Neiss

Dr. Edward S. Neiss

President and Chief

Operating Officer

19 SUPPLY AGREEMENT

INDEX

	Page		
		-	
Article I	-Definitions	2	
Article II	-Purchase and Supply	3	
Article III	-Estimate and Order	4	
Article IV	-Price and Payment	5	
Article V	-Title and Risk of Loss	6	
Article VI	-Shipment and Testing	7	
Article VII	-Warranties and Representa	ations 8	
Article VIII	-Responsibility and Indemr	nification 9	
Article IX	-Obligation of Chemex to V	Varn Physicians 10	
Article X	-Confidentiality	11	
Article XI	-Term and Termination	12	
Article XII	-Arbitration	14	
Article XIII	-Miscellaneous Provisions	15	