FORM 10-K405/A

Annual report pursuant to section 13 and 15(d), Regulation S-K Item 405 [amend]

Filing Date: **2001-02-14** | Period of Report: **1999-12-31**
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FILER

MGI PHARMA INC

CIK:**702131**| IRS No.: **411364647** | State of Incorp.:**MN** | Fiscal Year End: **1231**
Type: **10-K405/A** | Act: **NE** | File No.: **000-10736** | Film No.: **1543836**
SIC: **2834** Pharmaceutical preparations

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A-2
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 1999	Commission File No. 0-10736

MGI PHARMA, INC.
(Exact name of Registrant as specified in its charter)

Minnesota	41-1364647
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
6300 West Old Shakopee Road, Suite 110 Bloomington, Minnesota	55438
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 952/346/4700

Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.01 par value

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes X No ___ ___

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

The aggregate market value of voting stock held by non-affiliates of the Registrant as of March 14, 2000 was approximately $591,568,028 (based on the closing price of such stock as reported by The Nasdaq Stock Market on such date).

The number of shares outstanding of each of the Registrant's classes of

common stock, as of March 14, 2000, was: Common Stock, $.01 par value; 15,381,092 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Pursuant to General Instruction G, the responses to Items 5, 6, 7, 7A and 8 of Part II of this report are incorporated herein by reference to certain information contained in the Registrant's Annual Report to Shareholders for the fiscal year ended December 31, 1999 and the responses to Items 10, 11, 12 and 13 of Part III of this report are incorporated herein by reference to certain information contained in the Registrant's definitive Proxy Statement for its 2000 Annual Meeting of Shareholders to be held on May 9, 2000.

AMENDMENT NO. 2 TO FORM 10-K

On March 24, 2000, MGI PHARMA, Inc. (the "Company") filed its Annual Report on Form 10-K for the fiscal year ended December 31, 1999. On March 31, 2000, the Company filed Amendment No. 1 to its Form 10-K to correct the omission on the cover page of the Form 10-K of the aggregate market value of voting stock held by non-affiliates of the Company. The sole purpose of this Amendment No. 2 to the Form 10-K is to file an additional Exhibit 10.26.

Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K

		Section Reference in the Annual Report to Shareholders
(a) 1.	Financial Statements	
	Balance Sheets at December 31, 1999 and 1998	*
	Statements of Operations for the Years Ended December 31, 1997, 1998 and 1999	*
	Statements of Cash Flows for the Years Ended December 31, 1997, 1998 and 1999	*
	Statements of Stockholders' Equity for the Years Ended December 31, 1997, 1998 and 1999	*
	Notes to Financial Statements	*
	Independent Auditors' Report	*

* The financial statements and the Independent Auditors' Report listed above, which are included in the Annual Report to Shareholders, are incorporated by reference in Item 8 hereof.

Except for the financial statements listed above and the items specifically incorporated herein by reference in Items 5, 6, 7, 7A and 8 hereof, the Annual Report to Shareholders is not deemed to be "filed" as part of this Annual Report on Form 10-K.

2.	Financial Statement Schedules	Page in this Annual Report
	Independent Auditors' Report on Financial Statement Schedule	30
	Schedule II - Valuation and Qualifying Accounts	30

All other schedules have been omitted because they are not applicable or not required, or because the required information is included in the financial statements or the notes thereto.

3. Exhibits

Exhibit No.	
3.1	Restated Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-2, File No. 33-40763).
3.2	Restated Bylaws of the Company, as amended to date (Incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998).
4.1	Specimen certificate for shares of Common Stock of the Company (Incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998).
4.2	Rights Agreement, dated as of July 14, 1998, between the Company and Norwest Bank, Minnesota, N.A. (including the form of Rights Certificate attached as Exhibit B thereto) (Incorporated by reference to Exhibit 1 to the Company's Registration Statement on Form 8-A, filed July 15, 1998).
4.3	First Amendment to Rights Agreement, dated March 14, 2000, between the Company and Norwest Bank, Minnesota, N.A. (Incorporated by reference to Exhibit 2 to the Company's Registration Statement on Form 8-A/A-1, filed March 20, 2000).

*10.1 1993 Nonemployee Director Stock Option Plan (Incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 1994).

*10.2 Nonemployee Director Stock Option Plan (Incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K for the year ended December 31, 1994).

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*10.8 Stock Acquisition Assistance Loan Program (Incorporated by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K for the year ended December 31, 1994).

*10.9 1997 Stock Incentive Plan (Incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 1996).

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10.13 Trademark License Agreement, dated as of December 31, 1989, between the Company and Norwich Eaton Pharmaceutical, Inc. (Incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K for the year ended December 31, 1994).

**10.14 Supply and License Agreement, dated March 19, 1992, among E. Merck Fine Chemicals Division, EM Industries and the Company (Incorporated by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the year ended December 31, 1997).

10.15 Development, Marketing and Cooperation Agreement, dated October 23, 1995, between the Company and Dainippon Pharmaceutical Co., Ltd. (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1995).

10.16 Manufacturing Agreement, dated December 12, 1995, between the Company and Global Pharm Inc. (Incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the year ended December 31, 1995).

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*10.19 Termination Agreement, dated as of September 27, 1999, with Leon O. Moulder, Jr. (Incorporated by reference to the Company's Annual Report on Form 10-K previously filed for the year ended December 31, 1999).

10.20 Promotion Agreement, dated April 1, 1999, between the Company and Connetics Corporation, (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 1999).

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*10.22 Separation Agreement, dated April 2, 1999, between the Company and Lori-jean Gille, (Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999).

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* Items that are management contracts or compensatory plans or arrangements required to be filed as an exhibit pursuant to Item 14(c) of this Form 10-K.

** Pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, confidential portions of Exhibits 10.14, 10.17, 10.21, 10.25 and 10.26 have been deleted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

(b) Reports on Form 8-K

The Company filed no reports on Form 8-K during the quarter ended December 31, 1999.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this amendment to its annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 14, 2001

MGI PHARMA, INC.

By /s/ Charles N. Blitzer

Charles N. Blitzer, President, Chief Executive Officer and Director

EXHIBIT INDEX
MGI PHARMA, INC.

Annual Report on Form 10-K
For
Year Ended December 31, 1999

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EXHIBIT 10.26

LICENSE AGREEMENT

THIS AGREEMENT is made as of December 14, 1994, by and between MGI PHARMA, INC. ("MGI"), 300E Opus Center, 9900 Bren Road East, Minneapolis, Minnesota 55343-9667, U.S.A. and KISSEI PHARMACEUTICAL CO., LTD. ("Kissei"), 19-48 Yoshino, Matsumoto, Nagano Prefecture 399, Japan.

Recitals

A. MGI acquires, develops and markets pharmaceuticals that it believes address currently unmet medical needs or significantly improve upon current therapies.

B. Kissei acquires, develops and markets ethical pharmaceutical products in Japan and has established government-approved manufacturing facilities and distribution channels throughout Japan for those purposes.

C. MGI has developed a pharmaceutical product utilizing Pilocarpine Drug Substance (as hereinafter defined) as the active ingredient for certain medical indications, has obtained U.S. Food and Drug Administration approval to market such pharmaceutical product in the United States, and has acquired certain exclusive rights in Japan to the supply of Pilocarpine Drug Substance for non-topical use. MGI distributes a form of Pilocarpine Drug Substance in the United States and elsewhere in the world in tablet form under the trademark Salagen(R).

D. MGI and Kissei have previously entered into that certain Option Agreement dated June 14, 1994 (the "Option Agreement"), under which MGI has granted certain rights to Kissei and Kissei has made certain payments to MGI.

E. MGI desires to have this pharmaceutical product sold, promoted and distributed in Japan, and Kissei desires to obtain rights to sell, promote and distribute this pharmaceutical product in Japan, all upon the terms and conditions set forth in this Agreement.

NOW THEREFORE, in consideration of the premises and the mutual covenants hereinafter set forth, the Parties hereto have agreed as follows:

Article 1.0 INTRODUCTORY PROVISIONS

1.1 Defined Terms. The following terms, when used in capitalized form in this Agreement, shall have the meanings set forth below:

(a) "Adverse Experience Data" shall mean all data concerning any serious or unexpected adverse effects, side-effects and contraindications of any Licensed Product which may come to the attention of either Party or of any permitted sublicensee of either Party and which, in the

reasonable judgment of such Party or a permitted sublicensee of a Party, is of such a nature and magnitude that it is required under the laws of the United States or any country in the Territory to be collected, maintained and reported to a Competent Authority.

(b) "Affiliate" when used with reference to either Party shall mean any corporation controlling, controlled by or under common control with, the said Party. For purposes hereof, "control" shall mean ownership, directly or indirectly, of more than fifty percent (50%) of the securities having the right to vote for the election of directors, in the case of a corporation, and more than fifty percent (50%) of the beneficial interest in the capital, in the case of a business entity other than a corporation.

(c) "Best Efforts" shall mean those efforts that would be made by a reasonably prudent business person acting in good faith and in the exercise of reasonable commercial judgment.

(d) "Competent Authority" shall mean the FDA in the United States, the PAB in Japan, or any other government agency responsible for the issuance of Marketing Authorizations, Pricing Approvals and/or Reimbursement Approvals for pharmaceutical products marketed in any other country in the world.

(e) "Confidential Information" shall mean all proprietary information, including Proprietary Product Information of a Party, including any information on the markets, customers, suppliers, patents or patent applications, inventions, products, procedures, designs, formulas, business plans, financial projections, organizations, employees or consultants or any other similar aspects of a Party's present or future business, the secrecy of which confers a competitive advantage upon that Party.

(f) "Drug Master File" shall mean Type II Drug Master File No. 8453 on file with the FDA, any supplementary or successor drug master file in respect of Pilocarpine Drug Substance that may hereafter be submitted by E. Merck to the FDA, or any corresponding drug master file or similar file in respect of Pilocarpine Drug Substance that may hereafter be submitted by E. Merck to any Competent Authority.

(g) "E. Merck" shall mean E. Merck Fine Chemicals Division, a German corporation, and EM Industries, Incorporated, a New York corporation, together with and representing their "Affiliates" as that term is defined in the E. Merck Agreement, and any and all successors to either of them as parties to the E. Merck Agreement.

(h) "E. Merck Agreement" shall mean that certain Supply and License Agreement dated as of March 19, 1992 between E. Merck and MGI, as the same may be amended from time to time in accordance with Section 14.2.

(i) "Effective Date" shall mean the date first above written.

(j) "FDA" shall mean the United States Food and Drug Administration.

(k) "Good Clinical Practices" shall mean (i) with respect to the United States, those procedures and practices approved by the FDA for the purpose of conducting clinical trials, pursuant to the Code of Federal Regulations, Title 21, and other

administrative interpretations and rulings in connection therewith; (ii) with respect to Japan, those procedures and practices approved by the PAB in Notification No. 874 and other administrative interpretations and rulings in connection therewith; and (iii) with respect to any country in the Territory other than Japan, any analogous or comparable rules and regulations.

(l) "Health Registration Dossier" shall mean all documentation which is now or shall hereafter be on file with the FDA, the PAB or any other Competent Authority in any country other than Japan in the Territory, which comprises the information and data submitted to such agency in support of an application made by either Party, or a permitted sublicensee of either Party, to such Competent Authority for Marketing Authorization for a Licensed Product to treat any Indication.

(m) "Indication" shall mean any medical condition or set of symptoms for the treatment of which a Licensed Product may be determined to be safe and efficacious.

(n) "Know-How" shall mean all information and data, regardless of form, which is necessary or useful to the manufacture of a Licensed Product or to the development or manufacture of dose forms or means of delivery of a Licensed Product, and which is owned, developed, acquired or otherwise licensable by either Party or any permitted sublicensee of either Party during the term of this Agreement.

(o) "Licensed Products" shall mean any pharmaceutical products having as an active ingredient Pilocarpine Drug Substance, either alone or in combination with other substances, whether or not such products are known or in existence on the Effective Date.

(p) "Marketing Authorization" shall mean any governmental approval from a Competent Authority which is legally required under applicable laws, regulations or administrative decisions to put a pharmaceutical product on the market in such country for use in the treatment of any Indication.

(q) "Net Sales Revenue" shall mean, in respect of any period of time, that amount which is the aggregate of the gross sale price of all Licensed

Products sold by Kissei and/or its Affiliates, as well as those sold by all permitted sublicensees of Kissei and/or their Affiliates, to third parties other than their respective Affiliates, as reflected in invoices issued by all such sellers during that period of time, after deduction of (i) credits for returns, including withdrawals and recalls; (ii) sales rebates allowed or paid; (iii) commissions allowed or paid to third-party distributors which are not Affiliates of Kissei; (iv) cash, trade or volume discounts to the extent that the same are not reflected in the invoiced price; (v) sales, value-added and other taxes that are payable by the buyer and are included in the invoiced price; (vi) transportation and insurance costs that are payable by the buyer and related to such sales; and (vii) customs duties.

(r) "PAB" shall mean the Pharmaceutical Affairs Bureau of the Japanese Ministry of Health and Welfare.

(s) "Party" shall mean either of the two parties to this Agreement and, to the extent appropriate when required by context, to any permitted sublicensees of a Party.

(t) "Patents" shall mean any and all patents under the laws of any country or countries which are owned, acquired or otherwise licensable by either Party or its permitted sublicensees during the term of this Agreement and which are necessary or useful (i) to the manufacture of the Licensed Products, (ii) to the development or manufacture of dose forms or means of delivery of the Licensed Products, or (iii) to the use of the Licensed Products in conjunction with other products.

(u) "Pilocarpine Drug Substance" shall mean naturally-occurring pilocarpine (which is derived primarily from the pilocarpus jaborandi and/or the pilocarpus microphyllus species of tropical shrubs), including derivative forms thereof such as, but not limited to, pilocarpine base, pilocarpine hydrochloride and pilocarpine nitrate.

(v) "Pivotal Trial" shall mean a human trial of a Licensed Product, conducted in accordance with a written protocol, which is designed to develop definitive, statistically analyzable, efficacy and safety data for submission to the FDA in the United States, the PAB in Japan and/or to any other Competent Authority in any country other than Japan in the Territory in support of an application for Marketing Authorization for that Licensed Product.

(w) "Pricing Approval" shall mean any governmental approval of the price at which it is intended that a particular pharmaceutical product is to be sold which is or shall hereafter be required under the laws, regulations or administrative decisions in effect in Japan or any other country in the Territory as a condition of the marketing of such

product in that country.

(x) "Product Launch" shall mean the first commercial sale of the Licensed Products for resale or use in Japan or any other country in the Territory.

(y) "Proprietary Product Information" shall mean (i) all information and data now or hereafter contained in any Drug Master File or Health Registration Dossier to which either Party, or any permitted sublicensee of either Party, shall have the right under applicable law, regulations and administrative decisions to refer, to authorize third parties to refer and to prohibit third parties from referring, for purposes of any application for Marketing Authorization for any Licensed Product and (ii) all other information and data now or hereafter in existence which relates to the development, testing, manufacture, marketing or use of any Licensed Product which is incorporated in any Supporting Data and/or Adverse Experience Data and which is not in the public domain.

(z) "Reimbursement Approval" shall mean a decision to include a particular pharmaceutical product on a positive list of pharmaceutical products covered by

the national health insurance system in Japan or any other country in the Territory where such inclusion is a condition to the reimbursement of patients for the cost of such products as a part of the cost of medical treatment.

(aa) "Sjogren's Indication" shall mean the treatment for part or all of the medical condition known as Sjogren's Syndrome.

(bb) "Supporting Data" shall mean all data and information in the possession of either Party or any permitted sublicensee of a Party relating to (i) the pharmacological or toxicological properties of a Licensed Product, (ii) pre-clinical or clinical testing and experience in relation to a Licensed Product which is not included in any Health Registration Dossier and (iii) to the extent reasonably required for purposes of any application for Marketing Authorization, the chemical composition, manufacturing processes and quality control testing of a Licensed Product.

(cc) "Territory" shall mean Japan only, unless otherwise expressly agreed in writing by the Parties.

(dd) "Trademark" shall mean any of the trademarks used to market any Licensed Product in Japan or any other country in the Territory, whether or not such trademark is registered or otherwise protected under the laws of such country.

(ee) "Xerostomia Indication" shall mean the medical condition known as post-radiation xerostomia.

1.2 Other Rules of Interpretation. Unless the context clearly indicates otherwise, the following rules shall govern the interpretation of this Agreement:

(a) The definitions of all terms defined herein shall apply equally to the singular, plural, and possessive forms of such terms;

(b) All references herein to "days" shall mean calendar days; and

(c) All references to "Sections" shall mean the corresponding Sections of this Agreement.

Article 2.0 WARRANTIES AND REPRESENTATIONS; LIMITATIONS

2.1 Limited Warranty. Each Party represents and warrants to the other Party that:

(a) it has the legal right and power to enter into this Agreement;

(b) it has taken all necessary corporate action to authorize and perform this Agreement;

(c) it has not entered into any inconsistent prior obligations that would impair the rights being licensed to the other Party hereunder;

(d) it owns or has the right to license all the rights granted to the other Party herein, including, without limitation, all information and data in any applicable Drug Master Files and/or Health Registration Dossiers which a Party may provide to the other Party under this Agreement; and

(e) it knows of no third party claims that would challenge or impair the license of the rights granted to the other Party herein, including, without limitation, any claims based upon patents, copyrights or trade secret laws in the United States or Japan.

2.2 LIMITATION OF LIABILITY. EXCEPT AS PROVIDED IN SECTION 2.1 ABOVE OR IN THE EVENT OF A MATERIAL BREACH BY EITHER PARTY OF THE LIMITATIONS SET FORTH IN ARTICLE 11.0 BELOW, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY LOSS, EXPENSE OR DAMAGE ARISING OUT OF OR RESULTING FROM THIS AGREEMENT. IN ANY EVENT, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSS OR DAMAGES. IN THE EVENT OF ANY CLAIM FOR SUCH LOSS OR DAMAGES, THE SOLE AND EXCLUSIVE REMEDY FOR ANY LIABILITY UNDER THIS AGREEMENT SHALL BE LIMITED TO A REFUND OF ANY SUMS PAID AND/OR THE TERMINATION OF ANY

RIGHTS GRANTED UNDER THIS AGREEMENT.

Article 3.0 RIGHTS IN INTELLECTUAL PROPERTY

3.1 License to Kissei to Import, Market and Sell. MGI hereby grants to Kissei, and Kissei hereby accepts from MGI, an exclusive, royalty-bearing right and license under all of MGI's Know-How and Proprietary Product Information to apply for Marketing Authorizations for Licensed Products in the Territory and to use, develop (but not make), import, repackage, market, promote and sell Licensed Products in the Territory for any Indications. The right and license granted herein shall be further subject to the following terms and conditions:

(a) In applications for Marketing Authorization for Licensed Products in the Territory, Kissei may refer to documentation incorporating Proprietary Product Information as follows:

(i) Kissei may refer to and/or otherwise use the Drug Master File as well as any MGI Health Registration Dossier, provided, MGI has the lawful right to share such information with a third party and is not precluded from doing so under a confidentiality agreement; and

(ii) Kissei may refer to any Supporting Data from the MGI Pivotal Trials in the United States for the Xerostomia Indication and the Sjogren's Indication.

(b) Kissei may use all Proprietary Product Information required to be provided by MGI pursuant to this Article 3.0 for the purpose of importing, developing (but not making), marketing, promoting and selling Licensed Products.

(c) During the term of this Agreement, MGI shall not market, promote or sell Licensed Products within the Territory or license, supply or otherwise assist any third party to do so.

(d) Kissei may grant sublicenses of the above right and license to non-Affiliates subject to the following conditions but not otherwise:

(i) each proposed sublicensee shall be subject to MGI's prior written approval, which approval shall not be unreasonably withheld;

(ii) each authorized sublicensee may market, sell and promote but may not make or have made the Licensed Products;

(iii) Kissei must have entered into a written sublicense agreement with each such sublicensee in accordance with the obligations of Kissei under this Agreement, including but not limited to Article 7.0, which sublicense agreement shall be in a form acceptable to

MGI;

(iv) No sublicense granted pursuant hereto shall include the right to grant further sublicenses;

(v) An MGI approval of a sublicense shall not relieve Kissei of its obligation to use its own Best Efforts to market, sell and promote the Licensed Products to the extent of its independent capabilities within the Territory or to pay MGI any royalties that would otherwise be due to MGI from Kissei under the provisions of Section 7.2; and

(vi) Kissei hereby guarantees all payments of royalties to MGI due under the provisions of Section 7.2 by any permitted sublicensee of Kissei.

3.2 License of Grant-Back to MGI. Kissei (and any of its permitted sublicensees) hereby grants to MGI, and MGI accepts from Kissei (and any of its permitted sublicensees), an irrevocable, non-exclusive, royalty-free right and license outside the Territory under:

(a) all Proprietary Product Information for any Indication developed by Kissei or its permitted sublicensees during the term of this Agreement; and

(b) all Patents and Know-How conceived and reduced to practice by Kissei or its permitted sublicensees during the term of this Agreement in connection with the use, sale or manufacture of Licensed Products, except for Patents and Know-How developed by Kissei or its permitted sublicensees without use of MGI Confidential Information, as shown by reasonable proof.

3.3 Conditions on Grant-Back License to MGI. The right and license to MGI in Section 3.2 above is granted subject to the following terms and conditions:

(a) Such right and license shall include the right to refer, in any application for Marketing Authorization for the Licensed Products in respect of any country

outside the Territory, to any and all Health Registration Dossiers which Kissei may establish with any Competent Authorities in the Territory;

(b) Such right and license shall also include the right to sublicense MGI's permitted sublicensees outside the Territory; and

(c) Nothing in this Section 3.3 shall impose upon Kissei or its permitted sublicensees any disclosure obligations with respect to Proprietary

Product Information, Patents or Know-How other than those expressly set forth in this Agreement.

3.4 MGI Health Registration Dossiers. MGI shall provide to Kissei, if it has not already done so during the term of the Option Agreement, a copy in English of any documentation contained in or prepared for MGI's Health Registration Dossier for the Xerostomia Indication, within thirty (30) days after the Effective Date. MGI shall also provide a copy in English of any new documentation which is added to the Health Registration Dossier after the Effective Date within thirty (30) days after the date on which MGI submits such documentation to the FDA or other Competent Authority, subject to the provisions of Section 3.6(b). In addition, if any information contained in the Drug Master File is required to be furnished by Kissei to any Competent Authority in the Territory, MGI shall also provide such information (or cause such information to be submitted to such Competent Authority with the appropriate right to reference) to Kissei, subject to the terms and conditions of the E. Merck Agreement.

3.5 Kissei Health Registration Dossiers. Kissei shall provide MGI with a complete copy of the Health Registration Dossier for any Indication, or any amendment or supplement thereto, immediately upon filing of the Health Registration Dossier with the PAB or other Competent Authority in the Territory, in the language it is written in for filing. Within sixty (60) days after such submission (except if an earlier time frame is provided in Section 3.6(b)), Kissei shall provide MGI with a copy in English of (i) a summary of such Health Registration Dossier and (ii) a list of sections of the Health Registration Dossier which are contained within the Health Registration Dossier. MGI shall determine the priority of translation into English of the various sections of such Health Registration Dossier, or amendment or supplement thereto. Kissei shall thereafter have the Health Registration Dossier, or amendment or supplement thereto, translated into English according to the priority established by MGI and shall provide MGI with a copy of such English translation as soon as practicable. If MGI determines at any time that a particular section of such Health Registration Dossier, or amendment or supplement thereto, is needed on an accelerated basis, the Parties shall work together to revise the translation schedule to accommodate MGI's needs as the Parties shall mutually agree.

3.6 Other Information and Data. In accordance with the following provisions, each Party shall provide to the other Party complete and accurate copies of all documentation containing Supporting Data and Adverse Experience Data relating to any Licensed Product which is prepared or acquired by such Party or any of its respective permitted sublicensees during the term of this Agreement:

(a) Copies of Supporting Data in English shall be forwarded by Federal Express or other equivalent courier service as soon as practicable after it has been prepared or acquired, but, in any case, Kissei shall provide a summary in English thereof

no later than sixty (60) days after such preparation or acquisition and the provisions for translation set forth in Section 3.5 shall apply to information provided herein; and

(b) Copies of Adverse Experience Data in English shall be forwarded by facsimile with a duplicate by Federal Express or other equivalent courier service as quickly as may be necessary to permit the recipient to comply with any applicable legal requirements and in no event later than the earlier of (i) fifteen (15) working days after such Adverse Experience Data has been prepared or acquired and translated into English or (ii) the date on which such Adverse Experience Data is provided to any Competent Authority anywhere in the world, but, in any case, no later than thirty (30) days after such preparation or acquisition, or within such other time frame as may be mutually agreed to by the Parties in writing. The Parties shall consult and agree on the form of such reporting of Adverse Experience Data by each Party to the other. The Parties shall cooperate to accelerate the reporting requirements of this provision in the event that the any relevant Competent Authority requires accelerated reporting of such Adverse Experience Data in the future.

3.7 Other MGI Products. MGI hereby grants to Kissei, and Kissei hereby accepts from MGI, a right of first offer to make, promote, sell and distribute in the Territory any other pharmaceutical products developed by or for MGI, whether made from Pilocarpine Drug Substance or not, which are intended for any of the same Indications as the Licensed Products. Any such additional grant of rights shall be subject to the negotiation of mutually acceptable terms and conditions, including, without limitation, the payment of additional upfront fees to MGI. MGI shall notify Kissei in writing about any such proposed pharmaceutical product and its availability to Kissei hereunder. If MGI and Kissei have not reached substantial agreement on mutually acceptable terms and conditions within thirty (30) days of receipt of such notice, MGI shall then be free to offer such product to any other party in the Territory.

Article 4.0 TRADEMARK

4.1 Salagen(R) and other MGI Marks. The Parties hereby acknowledge that the mark "Salagen" is not available in Japan and is therefore not licensed by MGI to Kissei under this Agreement for purposes of marketing any Licensed Product in the Territory. Kissei acknowledges that nothing in this Agreement shall constitute a grant of any license or right in or to any trademarks, trade names or logotypes owned by MGI other than the Trademarks.

4.2 Trademark Selection and Registration. The Parties shall promptly meet and confer to select one or more suitable Trademarks to be used by Kissei under this Agreement for purposes of marketing any Licensed Product in the Territory. Prior to such meeting, Kissei shall use its best efforts to identify a trademark or trademarks that it wishes to use in connection with the marketing of Licensed Products in the Territory, which Kissei shall have determined to be, to the best of Kissei's knowledge after reasonable inquiry, free of conflict with any other

trademark of a third party in the Territory. MGI shall be the sole and exclusive owner of any such Trademarks and shall control any such registration in any jurisdictions in the Territory where there are no conflicting trademarks, provided:

(a) MGI shall be responsible for all reasonable expenses, including attorney's fees, in registering or otherwise protecting such Trademarks in the Territory;

(b) MGI may request Kissei's reasonable assistance in making any registration of a Trademark in Japan;

(c) In the event a conflicting mark is discovered in a jurisdiction within the Territory, the Parties shall consult with each other in regard to an appropriate resolution. Kissei shall cooperate with MGI in resolving such conflict, including reasonable attorney's fees, provided, that, MGI shall have the sole and unfettered ability to abandon a trademark application if MGI's determines that the cost of resolving such conflict is unreasonable;

(d) MGI shall notify Kissei at least thirty (30) days prior to abandoning a trademark application to allow Kissei to pursue such registration if it so chooses, subject to such special arrangements as the Parties may agree; and

(e) If MGI considers it desirable, for defensive reasons, to effect any filing or obtain any governmental approval or sanction for the use of a Trademark in any jurisdiction of the Territory, the Parties shall consult with each other in regard thereto.

4.3 Trademark License Grant. MGI hereby grants to Kissei, and Kissei hereby accepts from MGI, an exclusive, royalty-free right and license, during the term of this Agreement, to reproduce and use any Trademark in connection with the marketing, promotion, advertising and sale or other distribution of the Licensed Products within the Territory and for no other purpose. Kissei may sublicense such right and license to use any Trademark to any permitted sublicensee if such sublicensee agrees in writing to be bound the terms and conditions of this Article 4.0. Immediately upon termination of this Agreement, Kissei shall cease and desist from use of any Trademark in any manner, other than to liquidate its then-existing inventory of Licensed Products within ninety (90) days of such termination. Kissei hereby grants to MGI, in the event of such termination, full power of attorney, with the right of substitution, to cancel, revoke or withdraw any governmental registration or authorization permitting Kissei to use any Trademark in the Territory, and Kissei shall provide such further documentation and assistance as MGI may reasonably request in connection therewith.

4.4 Quality Standards. Any Trademark shall be used only on or in connection with the sale of Licensed Products manufactured and sold in accordance with this

Agreement. Any Licensed Product sold under a Trademark by Kissei or a permitted sublicensee shall be subject to the following restrictions:

(a) The marking or packaging of any Licensed Product shall comply with all applicable laws, regulations and governmental requirements of the jurisdictions in which such Licensed Product is manufactured and sold;

(b) Whenever and wherever legally permissible in the Territory, all packages in which a Licensed Product is to be sold to consumers shall bear a prominent legend in a form approved by MGI and in Japanese or other official languages in

the Territory as are appropriate, stating that such Licensed Product is "Sold by [Kissei or permitted sublicensee] under license from MGI PHARMA, INC., Minneapolis, Minnesota, USA";

(c) To the extent consistent with the foregoing paragraph (a), MGI may establish reasonable standards, after consultation with Kissei and consistent with the rules and regulations of the PAB, for the marking and packaging of Licensed Products and use of a Trademark, which standards shall be provided to Kissei in writing as soon as feasible and in any event prior to the filing by Kissei of the first application for Marketing Authorization of such Licensed Product in the Territory. MGI may also make reasonable changes, consistent with the rules and regulations of the PAB, to such standards, provided that MGI shall give at least thirty (30) days notice to Kissei prior to the implementation of such changes. MGI and Kissei will mutually discuss any proposed changes in MGI's quality standards under this Section 4.4(c), and MGI will agree to such reasonable modifications to such proposed changes, as Kissei may suggest as being necessary in connection with the marketing of a Licensed Product in the Territory;

(d) Upon request by MGI, Kissei shall provide MGI with samples of any brochures, professional literature, packaging and consumer instructions which are created or intended for use by Kissei or any of its Affiliates in the advertising, promotion, marketing or sale of a Licensed Product bearing a Trademark to verify compliance with MGI's trademark standards. If such materials are in any language other than English, Kissei shall also supply a true and accurate translation thereof in the English language to facilitate MGI's review thereof, provided, however, Kissei shall be solely and exclusively responsible for any errors or omissions in such non-English materials, notwithstanding any such review by MGI. Kissei shall also permit MGI, upon reasonable notice and at times reasonably acceptable to Kissei, to examine any stocks of Licensed Products held by Kissei or any permitted sublicensees to verify compliance with MGI's trademark standards;

(e) If MGI notifies Kissei in writing of any non-conformity with MGI's standards in the use of a Trademark, Kissei shall promptly take all reasonable steps or measures, at Kissei's sole cost and expense, necessary to ensure that such use complies with MGI's standards; and

(f) Neither Kissei nor its permitted sublicensees may use a Trademark in combination with any other trademark or trade name.

4.5 Reservation of Rights. Kissei acknowledges MGI's proprietary rights in and to any Trademark, subject to the license and right granted in Section 4.3. Kissei shall not adopt, use or register any words, phrases or symbols which are identical to or confusingly similar to any Trademark and shall not use any Trademark as part of its corporate or trade name or permit any third party to do so.

4.6 Infringements. Kissei shall promptly notify MGI of any use in the Territory by any third party of any Trademark or of any similar mark which may constitute an infringement or passing off of a Trademark. MGI shall have the exclusive right, at its option, to institute proceedings against third-party infringers in respect of infringements occurring in the Territory. If MGI elects not to institute such proceedings within a period of thirty (30) days after notification of the alleged infringement, Kissei shall have the option to do so, and MGI shall thereafter refrain from doing so. MGI shall have the exclusive right in its sole discretion to institute proceedings against third-party infringers in respect of infringements occurring outside the Territory. Each Party shall cooperate fully with the other Party in connection with any such proceedings against third-party infringers of the Trademarks in the Territory provided that all expenses of such proceedings shall be borne by the Party instituting same and all damages which may be awarded or agreed upon in settlement of such action shall accrue to such Party.

Article 5.0 PRODUCT REGULATORY APPROVALS

5.1 Regulatory Approvals. Kissei shall submit all applications and Supporting Data and information to obtain Marketing Authorizations, Pricing Approvals and Reimbursement Approvals required for the marketing, promotion and sale of any Licensed Product in the Territory and shall use its Best Efforts, in consultation with MGI, promptly to obtain such Marketing Authorizations, Pricing Approvals and Reimbursement Approvals. Such responsibility shall include the conduct and documentation of such testing and clinical trials as are required in connection with the submission of applications for Marketing Authorization within the Territory.

5.2 Kissei's Regulatory Responsibilities. In Kissei's performance of its duties under Section 5.1 above, the following terms and conditions shall apply:

(a) Kissei shall use its Best Efforts to ensure that the first Health Registration Dossier for a Licensed Product is submitted to the PAB in

Japan not later than January 31, 2000. Notwithstanding Kissei's Best Efforts, if the submission of such Health Registration Dossier in Japan is delayed beyond such date, the Parties shall consult with one another on modification of such date. In the event that the submission of such Health Registration Dossier in Japan is delayed more than twelve (12) months beyond such date, and for so long thereafter as such delay shall continue, MGI may elect to terminate this Agreement pursuant to Section 12.2, regardless of whether the delay is due to Kissei's fault or not.

(b) Because MGI's ability to assure exclusive rights to Pilocarpine Drug Substance for Kissei in Japan during the term of this Agreement is dependent on obtaining Marketing Authorization in the Territory by the end of August, 2002, pursuant to the terms of the E. Merck Agreement, Kissei shall use its Best Efforts to obtain Marketing Authorization for a Licensed Product in Japan at the earliest date possible, based on the following development schedule:

Conduct of Early Phase II trials	October 1995 to October 1996
Conduct of Late Phase II trials	April 1997 to March 1998
Conduct of Phase III trials	June 1998 to June 1999

Long-term experience	April 1997 to June 1999
Filing of Health Registration Dossier	December 1999 to January 2000

At the conclusion of the Early Phase II trials, the Parties shall meet to review the development schedule and to determine whether the schedule, as set forth above, can be accelerated to achieve an earlier date for filing of the Health Registration Dossier with the PAB or if the time frame for review of the Health Registration Dossier by the PAB is different from the 32 month time-period anticipated at the time of signing of this Agreement. If the Parties determine that the development schedule cannot be accelerated and that the review period for the Health Registration Dossier by the PAB is not likely to be significantly shorter than the period set forth in this subsection, then the Parties will cooperate and use their Best Efforts to approach E. Merck regarding extension of the exclusive supply provisions of the E. Merck Agreement as such provisions apply to the Territory.

(c) Kissei shall use its Best Efforts to achieve the Product Launch of a Licensed Product in Japan within six (6) months after Kissei's receipt of Marketing Authorization and any required Pricing Approval and/or Reimbursement Authorization. Notwithstanding Kissei's Best Efforts, if Kissei fails to achieve the Product Launch by that date, MGI may elect to terminate this Agreement pursuant to Section 12.2, provided, however, the foregoing shall not apply if such delay is solely due to MGI's failure to supply Licensed Product to Kissei under the Supply Agreement, of even date herewith, between the Parties (the "Supply

Agreement").

(d) In the event that the Territory is expanded to include countries in addition to Japan as provided in Section 1.1(cc) of this Agreement, Kissei shall use its Best Efforts to ensure that Marketing Authorization for a Licensed Product is granted in each country in the expanded Territory within the time frames negotiated in good faith by both Parties at the time of expansion of the Territory and that a Product Launch in each such country in the Territory other than Japan occurs within six (6) months after receipt of Marketing Authorization and of any required Pricing Approval and/or Reimbursement Approval in, such country. Notwithstanding Kissei's Best Efforts, if Kissei fails to receive Marketing Authorization or achieve the Product Launch within the time frames specified in this Section 5.2(d) or agreed to hereunder, MGI may elect to terminate this Agreement as to that country only pursuant to Section 12.2, provided, however, the foregoing shall not apply if such delay is solely due to MGI's failure to supply Licensed Product to Kissei under the Supply Agreement.

(e) Except as provided in Section 5.3 below, Kissei shall bear all its own costs and expenses to register, market and promote Licensed Products in accordance with the provisions herein.

5.3 Mutual Assistance. Each Party shall use its Best Efforts to provide such assistance as the other Party shall reasonably request for purposes of obtaining Marketing Authorizations, Pricing

Approvals and Reimbursement Approvals for the Licensed Products, in accordance with the following provisions:

(a) Each Party shall use its Best Efforts to make its personnel available, either in person or by telephone, for reasonable periods of time and subject to the availability of such personnel, to advise the other Party in connection with its applications for Marketing Authorization for the Licensed Products. Where such assistance will require travel of the Party requested to provide such assistance, the requesting Party shall notify the other Party of such need at least thirty (30) days in advance of the day on which it desires such personnel, unless unusual or emergency circumstances arise that make such notice unfeasible;

(b) Each Party shall collaborate with and assist the other Party in interpretation of any Health Registration Dossier or other Supporting Data provided by either Party to the other, (ii) review of regulatory documentation and submissions prepared by the other Party and (iii) obtaining of cooperation from third parties as needed in connection with the foregoing;

(c) Each Party shall promptly notify and share with the other Part any Adverse Experience Data as provided in Section 3.6(b); and

(d) Each Party shall bear the cost and expenses of its own personnel engaged in the foregoing cooperative efforts. However, it is the intent of the Parties that the scope and duration of such efforts shall not be such as to require the hiring of additional personnel or as to conflict with the efficient operation of either Party's other business or to be borne unevenly (given the anticipated relative contributions of the Parties). In the event that more extensive cooperation may be required than can be achieved in a manner consistent with these criteria, the Parties will jointly consider possible cost-sharing or other mutually-beneficial solutions.

5.4 Inspections. Kissei shall cooperate with any inspection by MGI of Kissei's distribution or storage facilities for the Licensed Products in the Territory and, at no cost to MGI, shall furnish (and shall cause Kissei's permitted sublicensees to furnish) adequate and representative samples of such Licensed Products from time to time to enable MGI to verify that the Licensed Products are being sold in accordance with MGI's quality standards (consistent with the requirements of the PAB) for such products. In addition, Kissei shall furnish copies of any internal quality assurance or other related documentation that are reasonably requested by MGI for such purposes.

Article 6.0 PROMOTION AND MARKETING

6.1 General Best Efforts Obligation. Kissei shall commit adequate funding and use its Best Efforts, comparable to those that it devotes to other products with similar potential, to fund and support Product Launch and ongoing promotion, marketing and sale of Licensed Products. Representatives of Kissei and MGI shall meet from time to time, at least on an annual basis, at such place as the Parties shall mutually agree, to discuss Kissei's and MGI's respective

promotional and marketing efforts relating to the Licensed Products in the Territory and in the United States.

6.2 Compliance with Law. Kissei shall market, promote and sell the Licensed Products in compliance with the conditions and requirements of all applicable Marketing Authorizations, Pricing Approvals and Reimbursement Approvals and with all other applicable legal and regulatory requirements in the Territory.

6.3 Trade Shows, Product Fairs, Etc. Kissei shall attend any medical or pharmaceutical conventions, trade shows, product fairs or other comparable events in the Territory, to the extent that Kissei judges them to be suitable and rewarding for purposes of promoting Licensed Products and where it would be normal and customary to display and promote ethical pharmaceuticals of the type and nature of a Licensed Product, and shall feature the Licensed Products at such events in such manner as it devotes to other Kissei products with similar

potential.

6.4 Advertising. In compliance with applicable laws or regulations, Kissei shall advertise the Licensed Products in such medical or pharmaceutical journals and similar publications where it would be normal and customary to display and promote ethical pharmaceuticals of the type and nature of a Licensed Product, and shall feature the Licensed Products in such publications in such manner as it devotes to other Kissei products with similar potential.

Article 7.0 LICENSE ISSUE FEE AND ROYALTIES

7.1 License Issue Fee. Kissei shall pay a total of Two Million Five Hundred Thousand Dollars (US $2,500,000) to MGI as a license issue fee ("License Issue Fee"), which payment shall be made in three (3) installments ("Milestone Payments") as follows:

(a) The first Milestone Payment of Eight Hundred and Forty Thousand Dollars (US $840,000) shall be due and payable upon execution of this Agreement by the Parties, subject to a credit of One Hundred Twenty-Five Thousand Dollars (US $125,000) for Kissei's payments to MGI under the Option Agreement;

(b) the second Milestone Payment of Eight Hundred and Thirty Thousand Dollars (US $830,000) shall be due and payable upon the earlier of (i) the date of Kissei's commencement of the first Pivotal Trial for a Licensed Product for any Indication in Japan or (ii) within ten (10) days of the date on which Kissei determines no such Pivotal Trials are required in Japan due to the sufficiency of information in MGI's Health Registration Dossier or Supporting Data or otherwise; and

(c) the third Milestone Payment of Eight Hundred and Thirty Thousand Dollars (US $830,000) shall be due and payable upon the date of Kissei's submission of the initial Health Registration Dossier for a Licensed Product to the PAB in Japan.

7.2 Royalties. In addition to the License Issue Fee under Section 7.1 above, Kissei shall pay to MGI the following:

(a) Royalties equal to *** of Net Sales Revenue on all Licensed Products sold by Kissei and/or its permitted sublicensees to third parties but exclusive of sales or other transfers made by Kissei to its Affiliates or permitted sublicensees ("Product Royalties").

(b) As a condition of maintaining the license granted under this Agreement, Kissei shall be required to pay to MGI Annual Minimum Royalties in amounts not less than shown below for the following periods:

Year	Annual Minimum Royalty
Year 1	***
Year 2	***
Year 3	***
Year 4 and thereafter	***

(c) At the conclusion of the Early Phase II trials, as set forth in Section 5.2(b) of this Agreement, the Parties shall meet to review the Annual Minimum Royalties set forth in Section 7.2(b) and to evaluate whether the Annual Minimum Royalties should be adjusted either upward or downward. In evaluating the marketing model, the Parties shall consider assumptions relating to pricing of Licensed Products in the Territory, patient population and market penetration. Following receipt of Marketing Authorization, Kissei may request a meeting with MGI to further evaluate the appropriateness of the Annual Minimum Royalties, as in effect at such time, if the marketing model referred to in this Section 7.2(c) is different from the model on which the Annual Minimum Royalties were based. In addition, the Parties agree to evaluate the appropriateness of the Annual Minimum Royalties if at any time following launch of a Licensed Product in the Territory, the PAB takes action to and does reduce the price that Kissei may charge for a Licensed Product.

(d) "Year" for purposes of Section 7.2 shall mean the calendar year in which Kissei's first sale of a Licensed Product occurs in the Territory and each succeeding calendar year during the term of this Agreement.

(e) The Annual Minimum Royalties shall be payable until a generic product directly competing with the Licensed Product(s) is introduced for sale in the Territory. The Annual Minimum Royalty for Year 1 shall be prorated based on the number of months remaining in the calendar year following the first sale of a Licensed Product. The Annual Minimum Royalty shall be payable no later than February 15 of the year following the year for which the Annual Minimum Royalty is due; any Product Royalties actually paid to MGI under the provisions of Section 7.2(a) shall be used to offset the Annual Minimum Royalty due under Section 7.2(b).

(f) The Annual Minimum Royalty payable under the terms of Section 7.2(b) shall be payable for any year in which a sale of a Licensed Product occurs in the Territory despite the fact that this Agreement may be terminated by either Party prior to the due date for payment of the Annual Minimum Royalty under the provisions of

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

Section 7.2(d). The amount of the Annual Minimum Royalty due for such year shall be prorated based on the number of months of the year that the Agreement is in effect before termination.

7.3 Payments and Reports. Kissei shall pay the Product Royalties to MGI by wire transfer on a quarterly basis on or before forty-fifth (45th) day after the end of each calendar quarter during the term of this Agreement and shall simultaneously provide to MGI a report which shows the Net Sales Revenue and the calculation of the Product Royalties payable for such quarter by Licensed Product and by country in the Territory. Kissei shall bear all wire transfer or other applicable bank charges for such payments.

7.4 Exchange Rates. All royalties due under the provisions of Section 7.2(a) shall be paid to MGI in U.S. Dollars or Japanese Yen. If paid in U.S. Dollars, the currency rate conversions from Japanese yen to U.S. Dollars shall be based on the average (arithmetic mean) of the exchange rates published for Japanese yen and U.S. Dollars in the Wall Street Journal on the Monday and the Friday of the week preceding the payment due date or, if any such Monday or Friday is not a day on which the Wall Street journal is published, on the next regular publication day thereof following such day. The Annual Minimum Royalties payable under the provisions of Section 7.2(b) shall be paid to MGI in U.S. Dollars. For purposes of the payment of the Annual Minimum Royalties under Section 7.2(b) only the currency rate conversion of Yen to Dollars is to be deemed to be 100 Yen for $1.00 at the time of execution of this Agreement. In the event that, at the time of payment of the Annual Minimum Royalties in any year, the currency rate conversion of Yen to Dollars has varied more than ten percent (10%) either up or down, then Kissei shall be entitled to the benefit of ninety percent (90%) of the currency rate conversion differential in excess of the ten percent (10%) change in determining the Annual Minimum Royalties due to MGI in such year. Determination of the exchange rates for purposes of the Annual Minimum Royalties shall be based on the average (arithmetic mean) of the exchange rates published for Japanese yen and U.S. Dollars in the Wall Street Journal on the Monday and the Friday of the week preceding the payment due date for the Annual Minimum Royalties or, if any such Monday or Friday is not a day on which the Wall Street Journal is published, on the next regular publication day thereof following such day.

7.5 Books and Records. Kissei shall keep adequate and complete books and records showing all Licensed Products sold by Kissei and its permitted sublicensees with respect to which Product Royalties are due MGI hereunder. Such books and records shall include all information necessary to verify the total amount and computation of the Product Royalties hereunder, and shall be open to inspection, audit and copying by MGI or its agents during reasonable business hours and upon reasonable notice to the extent necessary to verify the amount of such Product Royalties. Such inspection, audit and copying may be conducted at the expense of MGI by an independent Certified Public Accountant or other agent appointed by MGI and reasonably acceptable to Kissei, provided, however, Kissei shall reimburse MGI its reasonable expenses incurred in such inspection and audit if they reveal any underpayment of Product Royalties owed to MGI of more than Ten Thousand Dollars (US $10,000) or five percent (5%), whichever is greater, for

any quarter covered by such inspection and audit. MGI shall cause such independent Certified Public Accountant or other agent appointed by MGI to maintain as confidential any information it has gained during the auditing of Kissei's books and records and shall not disclose or use such information for any purpose except as provided in this Section 7.5.

7.6 Withholding. With respect to any income taxes in the Territory applicable to the License Issue Fee or the royalties payable to MGI under the provisions of Section 7.2, including, without limitation, Japanese income taxes under the U.S.-Japan Income Tax Treaty,

(a) MGI shall pay such income taxes and hereby authorizes Kissei to withhold such taxes from the applicable payments due to MGI under this Agreement and to pay such withheld amounts to the relevant tax authorities within the Territory; and

(b) whenever Kissei withholds and pays such income taxes from any payments due to MGI under this Agreement, it shall furnish MGI with a certificate of the relevant tax authorities within the Territory, in a form issued by such tax authorities and reasonably acceptable to the U.S. Internal Revenue Service, documenting payment of such taxes.

7.7 Net Payments. Except as expressly provided in Section 7.6 above, all payments by Kissei to MGI under this Agreement represent the net amounts that MGI is entitled to receive and shall not be subject to any other withholding or deduction for any reason whatsoever.

7.8 Interest. If any payment owed to MGI under this Agreement is overdue, in whole or in part, interest shall accrue on such overdue amount at the rate of eighteen percent (18%) per annum or the legal rate of interest, whichever is lower.

7.9 Currency Controls. If Kissei is precluded at any time from paying any Milestone Payment or royalties due to MGI under the provisions of Section 7.2 because Kissei has failed, notwithstanding its Best Efforts, to obtain any governmental approvals that may be required under the laws and regulations of any jurisdiction in the Territory for such transfers of funds, then Kissei shall:

(a) deposit, or cause its agent to deposit, such sums to the account of MGI at a bank within such jurisdiction designated by MGI;

(b) provide, or cause its agent to provide, to MGI documentary evidence of such deposits; and

(c) remit such deposits to MGI immediately upon the subsequent receipt of any required governmental approvals for such transfers.

Article 8.0 INDEMNIFICATION

8.1 Product Liability Claims. Each of the Parties shall indemnify and hold harmless the other Party and its Affiliates from and against all liabilities, damages, losses, costs and expenses (including reasonable attorneys' fees) arising out of claims, suits or proceedings brought by third parties wherein it is alleged that personal injury or death has resulted from use of the Bulk Finished Product marketed by Kissei in the Territory, as follows:

(a) MGI shall indemnify and hold harmless Kissei, its Affiliates, if and to the extent that any such claim, suit or proceeding is based upon (i) negligence, gross negligence or willful misconduct of or attributable to MGI in connection with the

conduct of pre-clinical or clinical testing of any Bulk Finished Product; (ii) negligence, gross negligence or willful misconduct of or attributable to MGI, E. Merck, or any contractor of MGI in the manufacture of any Bulk Finished Product supplied by MGI to Kissei; (iii) failure of any Bulk Finished Product supplied by MGI to Kissei to conform to the Product Release Specifications for such Bulk Finished Product or to comply with the warranties as set forth in this Agreement or the Supply Agreement or with applicable laws, regulations or administrative decisions; or (iv) failure of MGI to comply with any provision of this Agreement or of the Supply Agreement or with any applicable laws, regulations and/or administrative decisions relating to the Bulk Finished Product; or otherwise arises from the sale or provision of any Bulk Finished Product by MGI to any third party, except to the extent subject to indemnification by Kissei pursuant to Section 8.1(b).

(b) Kissei shall indemnify and hold harmless MGI and its Affiliates, if and to the extent that any such claim, suit or proceeding is based upon negligence, gross negligence or willful misconduct of or attributable to Kissei in the promotion, marketing, packaging, labeling or sale of any Bulk Finished Product, whether or not supplied by MGI, or failure of Kissei to comply with any provision of this Agreement or of the Supply Agreement or with any applicable laws, regulations and/or administrative decisions relating to the Bulk Finished Product; or otherwise arises from the sale or provision of any Bulk Finished Product by Kissei to any third party, except to the extent subject to indemnification by MGI pursuant to Section 8.1(a).

(c) Whenever either Party shall become aware of a claim, suit or proceeding in respect of which such Party and its Affiliates shall be entitled to indemnification under the provisions of this Agreement, such Party shall give notice in writing to the other Party, shall permit the other Party to assume exclusive control of the defense or settlement of the matter, and shall provide, at the expense of the

other Party, all authority, information and assistance which the other Party shall reasonably request for purposes of such defense. If a single law firm engaged by the indemnified Party would be subject to any material conflict of interest in representing one or more of such Parties, the indemnified Party shall not be required to waive such conflict and may, instead, request separate representation by an independent law firm at the expense of the indemnifying Party. An indemnified Party may engage its own counsel, at its own expense, to monitor the defense of any such matter.

(d) The following definitions shall apply to this Section 8.1:

"Bulk Finished Product" shall mean Licensed Products in the form of finished tablets not packaged or labeled for distribution or resale.

"Product Release Specification" shall mean the analytical (chemical/physical) product quality specification for the Bulk Finished Product as established by mutual agreement of the Parties from time to time.

8.2 Further Indemnification. Notwithstanding any other provision hereof, each Party hereby indemnifies and holds harmless the other Party from and against any loss, liability, damage or expense (including reasonable attorney's fees) which the other Party may suffer or sustain as a direct and proximate result of:

(a) any gross negligence or willful misconduct on the part of employees or agents of the indemnifying Party or its Affiliates,

(b) any breach of any covenant or agreement of the indemnifying Party contained in this Agreement, or

(c) any misrepresentation by the indemnifying Party in or in connection with this Agreement.

8.3 Subrogation. If a Party has indemnified the other Party under Section 8.1 or Section 8.2 above, the indemnifying Party shall be subrogated to the rights of the indemnified Party against any third party, and such indemnified Party hereby assigns to the indemnifying Party all claims, causes of action and other rights which the indemnified Party may then have against any third party. Conversely, and without in any way limiting the obligation of either Party to indemnify the other Party as herein provided, to the extent that an indemnifying Party fails to perform its indemnification obligations under Section 8.1 or Section 8.2 above, the indemnifying Party hereby assigns to the indemnified Party all claims, cause of action and other rights which the indemnifying Party may then have against any third party with respect to the claim, suit or proceeding.

Article 9.0 LOYALTY

During the term of this Agreement, Kissei shall not make, market, promote or sell within any country in the Territory any pharmaceutical product which is directly competitive with the Licensed Products.

Article 10.0 FORCE MAJEURE

10.1 Definition and Notice. "Force Majeure" shall mean any event, not existing as of the Effective Date and not reasonably within the control of the Parties as of such date, which, in whole or in material part, prevents or makes commercially unreasonable one Party's performance of its obligations under this Agreement. Force Majeure shall include, without limitation: fire, storm, earthquake, flood, acts of State or other governmental action, war or civil unrest, strikes, and prolonged shortage of energy or any other supplies. A Party affected by an event of Force Majeure shall promptly provide the other Party with written notice describing the event, its cause and foreseeable duration, and its possible consequences upon performance under this Agreement.

10.2 Suspension of Performance. After an affected Party has given notice under Section 10.1, that Party shall be relieved of any liability under this Agreement, except for the obligation to pay amounts due and owing, but only to the extent and only for so long as the Force Majeure prevents performance. The other Party may likewise suspend the performance of all or part of its

obligations, except for the obligation to pay any amounts due and owing, to the extent that such suspension is commercially reasonable.

10.3 Termination. If the period of Force Majeure continues for more than one (1) year, either Party may terminate this Agreement upon giving notice to the other Party without incurring liability other than the obligation to make payments due to such date.

Article 11.0 CONFIDENTIALITY

11.1 Non-Use and Non-Disclosure. Each Party acknowledges and agrees that all the other Party's Confidential Information is confidential and proprietary to the disclosing Party. Each Party shall not use or disclose to any third party the other Party's Confidential Information for any purpose other than as permitted or required hereunder. Each Party shall take the same reasonable measures necessary to prevent any disclosure by its employees, agents, contractors, permitted sublicensees, or consultants of the other Party's Confidential Information as it applies to the protection of its own Confidential Information.

11.2 Marking. To be entitled to protection as Confidential Information, all MGI or Kissei documents containing that Party's Confidential Information shall be appropriately and clearly marked as "Proprietary," "Secret," "Confidential," or other words to similar effect. If a disclosure of Confidential Information is made orally, as in a meeting, the disclosing Party shall indicate the nature of that information at the time of its disclosure and shall confirm such

designation in writing within ten (10) days of the date of such disclosure to the receiving Party.

11.3 Exclusions. Information shall not be considered Confidential Information hereunder if it:

(a) was already in the possession of the receiving Party prior to its receipt from the disclosing Party, as shown by the receiving Party's books and records;

(b) is, or becomes, part of the public knowledge or literature through no fault, act or omission of the receiving Party, provided, Proprietary Product Information shall not be deemed to have entered the public domain by reason of its having been filed with any Competent Authority;

(c) is, or becomes, available to the receiving Party from a source other than the disclosing Party, which source has rightfully obtained the same information and has no obligation of confidentiality to the disclosing Party with respect to it;

(d) is made available on an unrestricted basis by the disclosing Party to a third party unaffiliated with the disclosing Party; or

(e) is required to be revealed pursuant to law, provided, however, the receiving Party which is under any such requirement of law shall give reasonable notice to the disclosing Party of such requirement and shall cooperate with the disclosing Party in reasonable legal efforts to limit or mitigate any such revelation so as to preserve the proprietary nature of any Confidential Information contained therein.

11.4 Duration; Surviving Obligation. Each Party's obligations of non-use and non-disclosure of the other Party's Confidential Information shall apply during the term of this Agreement and shall also survive for a period of five (5) years after its termination for any reason.

11.5 Option Agreement. The non-disclosure and non-use provisions of this Agreement hereby supersede the provisions of Article 4.0 of the Option Agreement, provided, however, this Article 11.0 shall be deemed retroactive to the effective date of the Option Agreement.

Article 12.0 TERM AND TERMINATION

12.1 Term. Unless earlier terminated in accordance with Section 12.2 or 12.3 below, this Agreement shall be in effect for a period of ten (10) years after the first launch of a Licensed Product in the Territory (the "Initial Term"). This Agreement shall automatically renew for successive one (1) year periods thereafter ("Renewal Term"), unless either Party notifies the other Party in

writing of its intention to terminate this Agreement at least one hundred and twenty (120) days prior to the expiration of the Initial Term or any Renewal Term.

12.2 Termination for Cause. Either Party may terminate this Agreement at any time by giving notice in writing to the other Party, which shall be effective sixty (60) days after its date, in accordance with the following provisions:

(a) if the other Party files a petition of any type as to its bankruptcy, is declared bankrupt, becomes insolvent, makes an assignment for the benefit of creditors, goes into liquidation or receivership, or otherwise loses legal control of its business;

(b) if the other Party is in material breach of this Agreement and has failed to cure such breach within sixty (60) days of the receipt of written notice of breach from the non-breaching Party; or

(c) if an event of Force Majeure continues for more than one (1) year as provided in Section 10.3.

12.3 Termination by Mutual Agreement. The Parties may agree in writing to terminate this Agreement for their mutual convenience at any time and for any reason, subject to such terms and conditions as they may adopt.

12.4 Rights and Obligations on Termination. If this Agreement is terminated for any reason, the Parties shall have the following rights and obligations:

(a) Termination of this Agreement shall not release either Party from the obligation to make payment of all amounts then or thereafter due and payable;

(b) Each Party's respective obligations of non-use and non-disclosure under Article 11.0 shall survive as provided in Section 11.4;

(c) Each Party's respective obligations of indemnification under Article 8.0 and to settle all disputes, controversies or claims under Article 13.0 shall survive such termination of this Agreement;

(d) The license granted under Section 3.2 and the provisions of Section 3.3 shall survive termination of this Agreement and such license shall extend to the whole world, including the Territory;

(e) Kissei (and any permitted sublicensees) shall, within ninety (90) days of the date of the termination of this Agreement, return any documentation and all copies of documentation (in any media) in its possession, custody or control that contain the MGI's Confidential Information, including, without limitation, any Health Registration Dossiers, the Drug Master File, and the Supporting Data, and shall

certify in writing that it has done so after a reasonable examination of all its files where such documentation has been maintained; and

(f) If Kissei or any permitted sublicensee has any remaining inventory of Licensed Products, there will be a sell-off period of ninety (90) days after the effective date of termination in which such residual inventory may be sold, provided Product Royalties shall be due and owing on any such sales. After that date, and at the option of MGI, Kissei or its permitted sublicensees may sell and MGI may buy any unsold remaining inventory at a price to be negotiated between the Parties.

12.5 No Compensation. The Parties agree that, subject to the above provisions of Section 12.4, and without prejudice to any other remedies at law or in equity that either Party may have in respect of any breach of this Agreement, neither Party shall be entitled to or claim that it is entitled to any compensation or like payment as a result of or arising out of any termination in accordance with this Article 12.0, whether claimed as loss of good will, foregone profits, lost investments, or otherwise.

Article 13.0 DISPUTE RESOLUTION

13.1 Negotiation. The Parties agree to consult and negotiate in good faith to try to resolve any dispute, controversy or claim that arises out of or relates to this Agreement. Except as provided in Section 13.2, no formal dispute resolution shall be used by either Party unless and until the chief executive officers of each Party shall have attempted to meet in person to achieve such an amicable resolution.

13.2 Reservation for Litigation. Notwithstanding Section 13.3 below, each Party expressly reserves the right to seek judicial relief from a court of competent jurisdiction if the other Party is or appears to be in violation of such other Party's obligations of non-use and non-disclosure under Article 11.0 above, including, without limitation, any injunction or other preliminary relief.

13.3 Arbitration. Subject to the reservation of the Parties under Section 13.2 above, all disputes, claims or controversies arising out of or in connection with the present Agreement shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The place of

arbitration shall be Honolulu, Hawaii, United States of America. The arbitration shall be conducted in the English language.

13.4 Survival. The duty of the Parties to arbitrate any dispute, controversy or claim under this Article 13.0 shall survive the termination of this Agreement for any reason.

Article 14.0 ADDITIONAL COVENANTS OF MGI

14.1 E. Merck Agreement. During the term of this Agreement, MGI shall comply with its obligations under the E. Merck Agreement to the extent necessary to preserve its exclusive rights in the Territory thereunder and to preserve its rights to a regular supply of Pilocarpine Drug Substance for production of Licensed Products.

14.2 Amendment or Termination of E. Merck Agreement. MGI shall not terminate the E. Merck Agreement, or agree to any amendment to or modification of the E. Merck Agreement which may materially adversely affect any rights of Kissei under this Agreement or the ability of MGI to perform its obligations hereunder this Agreement, without the prior written consent of Kissei, which consent shall not unreasonably be withheld.

14.3 Sjogren's Syndrome Trials. MGI acknowledges that Kissei believes a major Indication for the Licensed Products is the Sjogren's Indication. Accordingly, MGI will use Best Efforts to accelerate its Sjogren's program in the United States for the Sjogren's Indication, consistent with Good Clinical Practices and statistical considerations regarding individual site enrollment, substantially in accordance with the following targets:

(a) completion of patient enrollment for Sjogren's Indication Pivotal Trial, with a target date of December 31, 1995, provided the FDA permits MGI to modify its research protocol design for such trials to substantially reduce the eye portion thereof and thus to have reduced the number of patients required therein, thereby allowing study enrollment to be reached earlier than would otherwise be the case; and

(b) as soon as is practical after completion of appropriate studies and/or data analyses for the Sjogren's Indication, submission to the FDA by MGI of a file for the alteration of labeling for the Licensed Product in the United States to acknowledge its utility in the treatment of Sjogren's Syndrome, provided, however, MGI's technical and regulatory consultants agree that such a submission to the FDA is warranted by the data accumulated during the Pivotal Trial (as modified in accordance with paragraph (a) above) and provided, further, that FDA does not require additional clinical or pre-clinical studies over those presently contemplated. The Parties agree that the requirements of this Section 14.3 shall cease to apply at such time as the FDA agrees to inclusion of language covering a Sjogren's Indication in the labeling for Salagen(R) Tablets in the United States.

14.4 Access to E. Merck Drums Master File. MGI shall obtain for Kissei the written permission of E. Merck to allow Kissei exclusive right to reference to the non-topical Drug Master File to be established in Japan by E. Merck.

Article 15.0 GENERAL PROVISIONS

15.1 Entire Agreement. This Agreement, along with the Supply Agreement, constitute the entire agreement of the Parties with respect to the subject matter hereof and thereof and supersede all the Parties' previous correspondence, term sheets, understandings, agreements and representations, oral or written, including any prior Non-Disclosure Agreements or the Option Agreement between the Parties.

15.2 Assignment. Neither Party shall assign or otherwise transfer its rights or obligations under this Agreement except with the prior written consent of the other Party; provided that no such consent for a transfer to an entity shall be required and all rights and obligations arising hereunder shall inure to the benefit of that entity if it is (a) an Affiliate of either Party, (b) the successor in interest of one Party by reason of sale, merger or operation of law, or (c) has acquired all or substantially all of the assets and business of a Party.

15.3 Amendment. This Agreement may not be modified or amended, in whole or in part, except by a written agreement signed by both Parties.

15.4 Severability. If one or more of the provisions of this Agreement is subsequently declared invalid or unenforceable, this Agreement shall be treated as though that provision were not in this Agreement, and this shall not affect the validity or enforceability of the remaining provisions of this Agreement (unless those provisions that are invalidated or unenforceable are clearly material and inseparable from the other provisions). The Agreement as modified shall be applied and construed to reflect substantially the good faith intent of the Parties and to achieve the economic effects originally intended by the terms hereof.

15.5 Notices; Language. Except as may be otherwise provided in this Agreement, any notice, demand or request given, made or required to be made shall be in writing and shall be effective, unless otherwise provided herein, when received after delivery by (a) registered air mail, postage prepaid; (b) facsimile with electronic confirmation of receipt; or (c) a reputable international courier such as Federal Express or DHL at the addresses set forth on the first page of this Agreement or to any other address that a Party specifies in writing. All reports, notices and communications required or permitted hereunder shall be in the English language.

15.6 Waiver. Either Party's failure or delay in exercising any remedy for default shall not be deemed a waiver of that or any subsequent default of that provision or of any other provision hereof.

15.7 Counterparts. This Agreement shall be executed in two (2) or more counterparts in the English language, each of which shall be deemed an original. In the event of any difference with the translation of this Agreement into any other language, the original English version shall prevail.

15.8 Governing Law. Except as to patents, this Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of

Minnesota, excluding (a) its choice of law rules and (b) the United Nations Convention on the International Sale of Goods and provided however that the operation of the arbitration agreement contained in Section 13.3

hereof, and the enforcement of any award rendered pursuant thereto, shall be governed by United States federal law to the exclusion of any state law.

15.9 Relationship. The Parties are independent contractors and have only a licensor-licensee relationship hereunder and shall not be deemed to have formed any partnership, joint venture or other relationship. Neither Party shall make, or represent to any other person that it has the power or authority to make, any financial or other commitment on behalf of the other Party.

15.10 Governmental Approvals. If any governmental approval is required for this Agreement to become effective, Kissei shall undertake to obtain such approval from any relevant agency of the Government of Japan, and MGI shall undertake to obtain any such approval from any relevant agency of the Government of the United States. Each Party shall use its Best Efforts to obtain such approvals as rapidly as possible and shall keep the other Party reasonably informed about any such applications for approval. Each Party shall furnish the other Party with a copy of any such approval within ten (10) days of its receipt.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the date first above written.

MGI PHARMA, INC.	KISSEI PHARMACEUTICAL CO., LTD.
By /s/ Kenneth F. Tempero	By /s/ Mutsuo Kanzawa
Kenneth F. Tempero	Mutsuo Kanzawa
Chairman and Chief Executive Officer	President and Chief Executive Officer