# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

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# FORM 8-K/A
# Amendment No. 2

**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of Report (Date of earliest event reported) December 18, 2003**

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# ALEXION PHARMACEUTICALS, INC.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **0-27756** | **13-3648318** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| **352 Knotter Drive, Cheshire, CT** | **06410** |
|---|---|
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (203) 272-2596**

**Not Applicable**

**(Former Name or Former Address, if Changed Since Last Report)**

**Item 5. Other Events and Regulation FD Disclosure.**

This Amendment No. 2 relates to the Company's Current Report on Form 8-K filed on December 18, 2003 and Amendment No. 1 thereto filed on January 9, 2004. The purpose of this amendment is to update Item 7(c).

On December 18, 2003, the Company announced its entry into a collaborative agreement with XOMA Ltd. (the "Agreement") for the development and commercialization of a rationally designed human c-MPL agonist antibody to treat chemotherapy-induced thrombocytopenia.

On January 9, 2004, the Company filed with the Securities and Exchange Commission an application for confidential treatment of certain portions of the Agreement.

On March 22, 2004, the Company filed a revised application for confidential treatment of certain portions of the Agreement. A copy of the Agreement, with the confidential portions redacted, is filed herewith.

**Item 7. Financial Statements and Exhibits.**

**(c) Exhibits.**

| | |
|---|---|
| 10.28 | Co-Development and Co-Commercialization Agreement between Alexion Pharmaceuticals, Inc. and XOMA (US) LLC, dated as of December 17, 2003 (with certain confidential information omitted, which omitted information is the subject of a revised confidential treatment request and has been filed separately with the Securities and Exchange Commission). |
| 99.1 | Press Release dated December 18, 2003.* |

* Previously filed

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

Date: March 22, 2004

By: /s/ Thomas I. H. Dubin

Name: Thomas I. H. Dubin
Title: Vice President and General Counsel

[*] indicates that a confidential portion of the text of this agreement has been omitted. The non-public information has been filed separately with the Securities and Exchange Commission.

**Execution Copy**

# CO-DEVELOPMENT AND CO-COMMERCIALIZATION AGREEMENT

This Co-Development and Co-Commercialization Agreement, dated as of December 17, 2003 (the "Effective Date"), is between XOMA (US) LLC, a Delaware limited liability company ("XOMA"), located at 2910 Seventh Street, Berkeley, CA 94710, and ALEXION PHARMACEUTICALS, INC., a Delaware corporation ("Alexion"), located at 352 Knotter Drive, Cheshire, CT 06410.

**WITNESSETH:**

WHEREAS, Alexion (together with Alexion Antibody Technologies, Inc., its wholly-owned subsidiary) possesses scientific and technical proprietary technology, know-how, patents and resources relating to the development, manufacture and commercialization of antibody-based products, including Antibody 116, Alexion's novel monoclonal antibody that is currently being developed as a potential treatment in the Field (as defined below);

WHEREAS, XOMA possesses scientific and technical resources relating to the development, manufacture and commercialization of antibody-based products; and

WHEREAS, Alexion and XOMA wish to enter into a collaborative effort to further Develop, Manufacture and Commercialize Product(s) (as such terms are defined below) in the Field to be governed by this Agreement (the "Collaboration");

NOW, THEREFORE, XOMA and Alexion hereby agree as follows:

## 1. DEFINITIONS

**1.1 Definitions**. The following capitalized terms shall have the following meanings for purposes of this Agreement:

"Adverse Drug Reaction" means any untoward medical occurrence in a patient or subject who is administered a Product, whether or not considered related to the Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Product.

"Advertising" has the meaning set forth in Schedule B.

"Affiliate" means any corporation, association or other entity that directly or indirectly controls, is controlled by or is under common control with the Party in question. As used herein with respect to a corporation, association or other entity, the term "control" means control with possession of the power to direct, or cause the direction of, the management and policies of such corporation, association or other entity.

"Agreement" means this document, together with all Schedules hereto.

"Alexion Background Technology" means all Patent Rights, technology, inventions, information, data, know-how, compounds, materials and substances (whether or not patented or patentable) that relate to or are potentially useful for the discovery, screening, design, synthesis, delivery, development, testing, use, manufacture, sale, import or export of any Product in the Field that exist as of the Effective Date and are Controlled by Alexion.

"Alexion Collaboration Technology" means all Patent Rights, technology, inventions, information, data, know-how, compounds, materials and substances (whether or not patented or patentable) that are Controlled by Alexion (alone or together with XOMA) and that: (a) relate to or are potentially useful in connection with the discovery, screening, design, synthesis, delivery, development, testing, use, manufacture, sale, import or export of any Product in the Field, and (b) are conceived or reduced to practice by Alexion or any Third Party on Alexion's behalf in the course of the Collaboration.

"Alexion Development Expenses" means, as to a particular Product, the sum of the [*] percent ([*]%) of Development Expenses incurred in conducting First-Time Pre-Clinical Development Activities for which Alexion is responsible pursuant to Section 3.6(a) and the seventy percent (70%) of Development Expenses incurred in conducting activities under a Development Plan that are not First-Time Pre-Clinical Development Activities for which Alexion is responsible pursuant to Section 3.6(b).

"Alexion Technology" means all Alexion Background Technology and Alexion Collaboration Technology.

"Allocable Overhead" has the meaning set forth in Schedule B.

"Allowable Expenses" has the meaning set forth in Schedule B.

"Antibody 116" means that certain antibody known as "Antibody 116," and any derivatives thereof developed hereunder, including those resulting from changes to the manufacturing process contemplated hereunder, and any other antibody, or modification of any thereof, approved by the JMC as a replacement for such antibody. The current details of Antibody 116 are set forth on Schedule A.

"Arbitrable Dispute" means (a) any dispute relating to, arising out of or based upon matters of contractual construction and interpretation of the provisions of this Agreement, including whether a specific standard articulated in this Agreement has been met in a particular circumstance, (b) any Early Stage Dispute, (c) any dispute described in the fourth sentence of Section 9.2(b), (d) any Section 5.1 Dispute and (e) any disagreement identified as an Arbitrable Dispute in the first sentence of Section 4.9.

"BLA" means a Biologics License Application (as defined in the FDC Act) and any other marketing authorization application or other license, registration or other application seeking approval from a Regulatory Authority to market a Product in the Field in the Territory.

"Breaching Party" has the meaning set forth in Section 13.2(b).

"Budgeted Detail Effort" means for each Party, its percentage of the Budgeted Total Detail Effort for each year.

"Budgeted Total Detail Effort" means for each calendar year the total number of Details for each Party as budgeted by the Development Committee.

"Claim" has the meaning set forth in Section 14.1(a).

"Collaboration" has the meaning set forth in the Recitals.

"Collaboration Technology" means individually or collectively Alexion Collaboration Technology, XOMA Collaboration Technology and Joint Collaboration Technology.

"Combination Product" has the meaning set forth in Schedule B.

"Commercialization" or "Commercialize" means any and all activities associated with marketing, promoting, communicating (including medical communications and publications), distributing, importing, exporting or selling a Product in the Field, including the conduct of Phase III(b)/IV Studies, and activities directed to obtaining pricing and reimbursement approvals, by a Party, its Affiliates or licensees or sublicensees.

"Commercialization Expenses" has the meaning set forth in Schedule B.

"Commercialization Program" means the Commercialization of a Product in the Field in accordance with this Agreement.

"Commercially Reasonable and Diligent Efforts" means those efforts consistent with the exercise of prudent scientific and business judgment, as applied to other pharmaceutical products of similar potential and market size by participants in the biopharmaceutical industry having similar resources to XOMA or Alexion, as the case may be.

"Consumer Promotion" has the meaning set forth in Schedule B.

"Confidential Information" has the meaning set forth in Section 10.1.

"Continuing Party" has the meaning set forth in Section 7.5.

"Control" or "Controlled" means with respect to any material, know-how or other information or intellectual property right, the possession (whether by license, other than solely by virtue of licenses granted in this Agreement, or ownership) by a Party or its Affiliates of the ability to grant to the other Party access or a license as provided herein without violating the terms of any agreement or other arrangement with any Third Party.

"Co-Promotion" or "Co-Promote" has the meaning set forth in Section 4.1.

"Cost of Goods Sold" or "COGS" has the meaning set forth in Schedule B.

"Detail" means a sales presentation by a professional sales representative to a target physician or other person involved in prescribing or influencing usage of a Product in which the primary purpose is to discuss the benefits and features of such Product in order to encourage a sale of such Product.

"Detail Effort" means with respect to a Party, and for any calendar year, the actual number of Details given by its sales force for such calendar year or in the case where the sales force sells other than through Details the selling efforts of the Party performed by its sales force for such calendar year.

"Development" or "Develop" means the conduct of all tests, studies and other activities set forth in, or required to obtain the information set forth in, the Development Plan, including such tests, studies and other activities as may be required or recommended from time to time by the JMC or any Regulatory Authority to obtain Regulatory Approval of a Product in the Field, including test method development, stability testing, toxicology studies, manufacturing processes, formulation, quality assurance/quality control development, statistical analysis and report writing, pre-clinical testing, clinical studies (including studies required to be performed after approval as a condition of approval), packaging and regulatory affairs, product approval and registration activities.

"Development Committee" has the meaning set forth in Section 2.1(b).

"Development Expenses" means the reasonable internal and external costs set forth in the Development Plans incurred by either Party in the Development of a Product in accordance with each such Development Plan, including:

(a) all out-of-pocket costs and expenses incurred, including payments to investigators, contract research organizations, and consultants, for preclinical studies, pharmacodynamic or pharmacokinetic studies, molecular biology, toxicology studies, data management, statistical design, programming and analysis, clinical studies, clinical trial management, document preparation and review, subject recruitment and reimbursement, insurance, contract negotiation, and BLA (including chemistry and manufacturing controls) preparation;

(b) fees incurred in connection with filings with Regulatory Authorities (including pharmacoeconomic studies, Phase III(b)/IV Studies and any other clinical studies reasonably necessary for Regulatory Approval by relevant Regulatory Authorities to sell such Product in each country);

(c) Manufacturing Development Expenses;

(d) costs incurred under any Third Party licenses entered into prior to the Effective Date or in accordance with Section 3.6(d);

(e) the costs and expenses of clinical supplies, lab supplies, animals and other direct charges for such efforts as set forth in the Development Plan, including: (i) the Cost of Goods Sold of such supplies; (ii) costs and expenses incurred to purchase and/or package comparator or combination drugs or devices; and (iii) costs and expenses of disposal of clinical samples;

(f) the costs of internal scientific, medical, technical, and or managerial personnel engaged in such efforts (to the extent not accounted for in other provisions of this definition, e.g., in Cost of Goods Sold under clause (e)), which costs shall be determined based on the FTE Costs (which amount includes salaries, fringe benefits, overtime and all other costs of employing FTEs), unless another basis is otherwise agreed by the Parties in writing;

(g) actual costs for travel (other than costs relating to committee meetings referred to in Section 2.2); and

(h) any other costs explicitly included in the budgets for the Development Plans.

"Development Plans" has the meaning set forth in Section 3.2.

"Development Program" means the Development of a Product in the Field in accordance with Article 3 hereof.

"Disclosing Party" has the meaning set forth in Section 10.1.

"Distribution Expenses" has the meaning set forth in Schedule B.

"Early Stage Dispute" has the meaning set forth in Section 12.1.

"Education" has the meaning set forth in Schedule B.

"Effective Date" has the meaning set forth in the Preamble.

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

"FDC Act" means the United States Food, Drug and Cosmetic Act (or any successor thereto), as amended, and the rules and regulations promulgated thereunder.

"Field" means chemotherapy-induced thrombocytopenia and any other field of use, application or indication (including any Future Indications) approved by the JMC as an addition thereto.

"First-Time Pre-Clinical Development Activity" has the meaning set forth in Section 3.6(a).

"FTE" means a full time equivalent person year (based on routinely applied practices of the applicable Party) of scientific, technical or managerial work on or directly related to the Development Program or the Commercialization Program.

"FTE Costs" means the amount determined by multiplying (a) the number of FTEs allocated by a Party during the relevant time period, subject to any limitations set forth in the applicable Development Plan or Commercialization Program or otherwise established by the JMC by (b) such Party's FTE Rate.

"FTE Rate" means, for purposes of determining FTE Costs relating to work other than manufacturing (included in COGS), [*], to be adjusted annually (beginning in January 2005) for inflation using the latest available U.S. Producer Price Index for Total Manufacturing Industries, unadjusted (PCUOMFG#) as a simple percentage.

"Future Indication" means any use of a Product for the treatment, prophylaxis or diagnosis of any human or animal illness, sickness, interruption, cessation or disorder of a particular bodily function, system or organ except chemotherapy-induced thrombocytopenia; provided that for purposes of this definition, an individual "Future Indication" shall mean an indication with respect to which no IND has previously been filed by either Party for a Product, and as to which a new IND will be required to be filed, to initiate human clinical trials of a Product therein.

"GCP" means Good Clinical Practices, as set forth in the ICH Harmonized Guidance on Good Clinical Practice (CPMP/ICH/135/95) and 21 C.F.R. Parts 50, 56 and 312 et seq. and any amendments thereto.

"GLP" means Good Laboratory Practices, as set forth in 21 C.F.R. Part 58 et seq., and the rules in force in the EU relating to GLP, including EC Directives 87/18 EEC, 88/320/EEC, and 1999/11/EC, and any amendments thereto.

"GMP" means Good Manufacturing Practices, as set forth in 21 C.F.R. Part 210, et seq., and the Rules Governing Medicinal Products in the European Union volume 4, and any amendments thereto.

"Gross Sales" has the meaning set forth in Schedule B.

"IND" means an application submitted to a Regulatory Authority to initiate human clinical trials of a Product in the Field or a Future Indication, including a United States Investigational New Drug Application (or any successor application) and its foreign equivalents, and all subsequent submissions, supplements and amendments thereto.

"Indemnified Group" has the meaning set forth in Section 14.1(a).

"Initial Development Plan" has the meaning set forth in Section 3.2.

"Joint Collaboration Technology" means Collaboration Technology for which (i) one or more employees, consultants or agents of XOMA or any other persons obligated to assign such Collaboration Technology to XOMA is an inventor under United States patent law; and (ii) one or more employees, consultants or agents of Alexion or any other persons obligated to assign such Collaboration Technology to Alexion is an inventor under United States patent law.

"Joint Management Committee" or "JMC" means a committee comprised of three (3) representatives of each Party responsible for the supervision and coordination of the Collaboration as set forth in Section 2.1.

"Joint Patent Rights" has the meaning set forth in Section 9.2(b).

"Manufacturing" or "Manufacture" means all activities associated with the production, processing, filling, finishing, packaging, labeling, shipping and storage of Products in the Field, including process development, process validation, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, quality assurance and quality control.

"Manufacturing Development Expenses" means, with respect to the Development of a Product, the reasonable internal and external costs of a Party incurred in process development, process validation, process improvement, formulation development, manufacturing scale-up and recovery costs, the development of standard operating procedures, batch records, and quality assurance and quality control methods and procedures, and the production of qualification lots, all costs incurred in obtaining and maintaining approval specifically for the manufacture of such Product for commercial sale, and the costs for preparing, submitting, reviewing or developing data or information for the purpose of a drug master file or for submission to a Regulatory Authority to obtain or retain such approvals. A Party's Manufacturing Development Expenses shall be determined in accordance with generally accepted accounting principles of the United States as consistently applied by such Party in the ordinary course of its business.

"Market and Consumer Research" has the meaning set forth in Schedule B.

"Marketing/Development Partner" has the meaning set forth in Section 4.9.

"Marketing/Development Partner Revenue" has the meaning set forth in Schedule B.

"Marketing Management" has the meaning set forth in Schedule B.

"Non-Breaching Party" has the meaning set forth in Section 13.2(b).

"Non-Exclusive XOMA Ireland License" has the meaning set forth in Section 6.3.

"Operating Profit/Loss" has the meaning set forth in Schedule B.

"Opt Back In" has the meaning set forth in Section 7.1.

"Opted Out Party" has the meaning set forth in Section 7.5.

"Opt Out" has the meaning set forth in Section 7.1.

"Party" means Alexion or XOMA, as the case may be, and "Parties" means Alexion and XOMA.

"Patent Rights" means, with respect to XOMA or Alexion, all United States and foreign patents owned in whole or in part or licensed to XOMA or Alexion, respectively, as to which a sublicense can be granted, at any time during the Term of this Agreement, which would be infringed by the use, development, manufacture, sale, import or export of a Product or which would be infringed by activities to be performed by the Parties in connection with the Development of a Product, including all United States and foreign patents and patent applications (including all reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations, continuations-in-part, and divisions thereof). Patent Rights shall not include the bacterial cell expression patent rights owned or Controlled by XOMA Ireland Limited licensed to Alexion pursuant to the Non-Exclusive XOMA Ireland License, including the Patent Rights (as defined in the Non-Exclusive XOMA Ireland License).

"Phase I Study" means a Phase I clinical trial as prescribed by applicable FDA regulations, or corresponding regulations of any comparable entity.

"Phase II Study" means a Phase II clinical trial as prescribed by applicable FDA regulations, or corresponding regulations of any comparable entity.

"Phase III Study" means a Phase III clinical trial as prescribed by applicable FDA regulations, or corresponding regulations of any comparable entity.

"Phase III(b)/IV Study" means a Phase III(b)/IV clinical trial as prescribed by applicable FDA regulations, or corresponding regulations of any comparable entity.

"Product" means any composition of matter or article of manufacture containing or comprising Antibody 116.

"Product Trademark" means one or more trademarks or logos that are used for the Commercialization of a Product in the Field in the Territory.

"Prosecuting Party" has the meaning set forth in Section 9.2(b).

"Receiving Party" has the meaning set forth in Section 10.1.

"Regulatory Approval" means any and all approvals (including, where applicable, pricing and reimbursement approvals), licenses, registrations or authorizations of any Regulatory Authority, necessary for the testing or sale of a Product in the Field, including INDs and BLAs.

"Regulatory Authority" means any governmental authority in a country or region that regulates the manufacture or sale of pharmaceutical products, including the FDA and the European Agency for the Evaluation of Medicinal Products, and any successors thereto.

"Sales and Marketing Expenses" has the meaning set forth in Schedule B.

"Sales Returns and Allowances" has the meaning set forth in Schedule B.

"Section 5.1 Dispute" has the meaning set forth in Section 5.1.

"Selling Expenses" has the meaning set forth in Schedule B.

"Term of this Agreement" shall mean the period from the Effective Date until this Agreement expires or is terminated pursuant to its terms.

"Territory" means all the countries in the world.

"Third Party" means any entity other than Alexion or XOMA and their respective Affiliates.

"Trade Promotion" has the meaning set forth in Schedule B.

"Valid Claim" means any claim of an issued and unexpired Patent Right, which claim has not been held unenforceable, unpatentable or invalid by a final decision of a court or governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue, re-examination or express disclaimer.

"XOMA Background Technology" means all Patent Rights, technology, inventions, information, data, know-how, compounds, materials and substances (whether or not patented or patentable) that relate to or are potentially useful for the discovery, screening, design, synthesis, delivery, development, testing, use, manufacture, sale, import or export of any Product in the Field that exist as of the Effective Date and are Controlled by XOMA. XOMA Background Technology shall not include the bacterial cell expression technology owned or Controlled by XOMA Ireland Limited licensed to Alexion pursuant to the Non-Exclusive XOMA Ireland License, including the Licensed Technology (as defined in the Non-Exclusive XOMA Ireland License), and any improvements thereon.

"XOMA Collaboration Technology" means all Patent Rights, technology, inventions, information, data, know-how, compounds, materials and substances (whether or not patented or patentable) that are Controlled by XOMA (alone or together with Alexion) and that: (a) relate to or are potentially useful in connection with the discovery, screening, design, synthesis, delivery, development, testing, use, manufacture, sale, import or export of any Product in the Field, and (b) are conceived or reduced to practice by XOMA or any Third Party on XOMA's behalf in the course of the Collaboration. XOMA Collaboration Technology shall not include the bacterial cell expression technology owned or Controlled by XOMA Ireland Limited licensed to Alexion pursuant to the Non-Exclusive XOMA Ireland License, including the Licensed Technology (as defined in the Non-Exclusive XOMA Ireland License), and any improvements thereon.

"XOMA Development Expenses" means, as to a particular Product, the sum of the [*] percent ([*]%) of Development Expenses incurred in conducting First-Time Pre-Clinical Development Activities for which XOMA is responsible pursuant to Section 3.6(a) and the thirty percent (30%) of Development Expenses incurred in conducting activities under a Development Plan that are not First-Time Pre-Clinical Development Activities for which XOMA is responsible pursuant to Section 3.6(b).

"XOMA Technology" means the XOMA Background Technology and the XOMA Collaboration Technology.

**1.2 Interpretation**. Whenever any provision of this Agreement uses the term "including" (or "includes"), such term shall be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); "herein," "hereby," "hereunder," "hereof" and other equivalent words shall refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used; all definitions set forth herein shall be deemed applicable whether the words defined are used herein in the singular or the plural; wherever used herein, any pronoun or pronouns shall be deemed to include both the singular and plural and to cover all genders; all references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters or calendar years; and any reference to any federal, national, state, local or foreign statute or law shall be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise.

## 2. COLLABORATION GOVERNANCE

**2.1 Joint Management Committee**. (a) Formation and Membership. Promptly after the Effective Date, Alexion and XOMA will each appoint three (3) representatives to the Joint Management Committee. The JMC will meet quarterly or as otherwise mutually agreed. The JMC will assure that agendas and minutes are prepared for each of its meetings. All actions taken and decisions made by the JMC shall be by unanimous agreement. A Party may change any of its appointments to the JMC at any time upon giving written notice to the other Party. The JMC does not itself have the authority to amend this Agreement in any manner that would require the separate approval of authorized officers of the respective Parties.

(b) Development Committee. The Joint Management Committee will establish a development and commercialization committee (the "Development Committee") to oversee the pre-clinical and clinical Development and Commercialization of Products in the Field, and, if XOMA elects to Co-Promote such Product as provided in Section 4.1 below, Co-Promotion of Products in the Field. Decisions of the Development Committee will be by unanimous agreement; provided, however, that subject to the terms of this Agreement it is agreed that (x) Alexion shall have primary responsibility for clinical development; (y) XOMA shall have primary responsibility for the development of clinical and commercial-scale manufacturing processes and shall have primary responsibility for and control the preparation of chemistry and manufacturing controls documentation and/or submission of any drug master file relating to a Product manufactured by XOMA; and (z) Alexion shall have primary responsibility for pre-launch and other Commercialization activities. Should the members of the Development Committee fail to agree on any matter for which unanimous agreement has been sought and Alexion or XOMA requests a resolution, the matter shall be referred to the JMC for resolution in accordance with Article 12.

(c) JMC Responsibilities. The JMC shall be responsible for:

(i) preparing such procedures and mechanisms as may be necessary for the operation of the JMC, the Development Committee, and any other committees the JMC determines to establish to assure efficiency in the Collaboration;

(ii) determining the overall Development, Commercialization and Manufacturing strategy for Products in the Field in the Territory and for all other activities conducted by the Parties hereunder (other than activities where the determination and conduct of strategy and activities are expressly assigned to one Party), with appropriate delegation to the Development Committee and any other committees the JMC determines to establish;

(iii) determining whether to pursue additional indications for Products outside the Field as part of the Collaboration as provided in Article 7;

(iv) reviewing and approving modifications to the Development Plan within thirty (30) days of each submission;

(v) facilitating the transfer through the Development Committee of Technology between the Parties for purposes of the Development Program;

(vi) regularly assessing the progress of the Development Program and Commercialization Program against the proposed timelines;

(vii) monitoring the progress of the Development Committee;

(viii) reviewing and approving the budgets prepared by the Development Committee and any modifications thereto as recommended by such committees within thirty (30) days of each submission; and

(ix) performing such other activities as are contemplated for the JMC under this Agreement.

(d) Development Committee Responsibilities. The Development Committee shall be responsible for:

(i) implementing the Development, Commercialization and Manufacturing strategy for Products in the Field in the Territory as determined by the JMC;

(ii) establishing the Development Plan and the personnel, facilities, expertise and other resources of each Party to be used in the performance of the Collaboration; and

(iii) performing such other activities as are contemplated for the Development Committee under this Agreement.

**2.2 Meetings of the Committees**. The JMC and the Development Committee may meet by telephone, video teleconference or in person at such times as are agreeable to the members of each such committee. Attendance at meetings shall be at the respective expense of the participating Parties. Alexion and XOMA shall alternate the right to determine the location of each meeting. A quorum for the conduct of business at each meeting shall require the attendance of at least one Alexion member and at least one XOMA member.

**2.3 Reports and Administrative Matters**. The Party hosting each meeting shall serve as secretary of that meeting. The secretary of the meeting shall prepare and distribute to all members of the applicable committee minutes of the meeting within thirty (30) days following the meeting to allow adequate review and comment. Such minutes shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the applicable committee. Minutes of each meeting of the JMC and the Development Committee shall be approved or disapproved, and revised as necessary, at the next meeting. Final minutes of each meeting shall be distributed to the members of the applicable committee by the secretary of that meeting.

## 3. DEVELOPMENT PROGRAM

**3.1 Undertaking and Scope**. Each Party agrees to use Commercially Reasonable and Diligent Efforts to perform its activities detailed in the Development Plans in a professional and timely manner.

**3.2 Development Plans**. An initial product development plan for Products in the Field in the Territory (the "Initial Development Plan") is attached hereto as Schedule 3.2. The Initial Development Plan as modified or amended from time to time by the Development Committee and approved by the JMC, as set forth in this Section 3.2, and any subsequent Development Plan as so modified or amended and approved, shall be referred to individually as a "Development Plan" and collectively as the "Development Plans." No later than November 1 of each year, the Development Committee shall review the then current Development Plan and confirm or amend its applicability for the following year, for review and approval by the JMC. Each annual Development Plan shall be in writing and shall set forth with reasonable specificity the research objectives, priorities, applicable development milestones, budgets, and personnel requirements for the period covered by such annual Development Plan to the extent not addressed by this Agreement. The Development Plans shall cover all aspects of development relating to Products, including pre-clinical and clinical development, and shall include, with reasonable specificity, the Development activities to be performed by each Party (including Manufacture of clinical supply by XOMA) and Development activities to be performed by academic collaborators or under contract service agreements. The Development Committee may agree on modifications, and recommend that the JMC approve such modifications, to the provisions of any Development Plan at any time.

**3.3 Personnel and Resources**. Each Party agrees to commit the personnel, facilities, expertise and other resources necessary to perform its obligations under this Agreement in accordance with its terms; *provided, however*, that neither Party warrants that the Collaboration will achieve any of the research or commercial objectives contemplated by the Parties. Each Party agrees to use Commercially Reasonable and Diligent Efforts to assure the complete and prompt exchange, as needed, of Alexion Background Technology and XOMA Background Technology, Collaboration Technology and the results of all activities pursuant to the Development Plans.

**3.4 Development Activities**. (a) General. The Development of Products in the Field will be pursued jointly by the Parties under the direction of the Development Committee in accordance with the Development Plans. The Development Plans shall allocate development tasks between the Parties consistent with their respective capabilities and, to the extent possible, as provided from time to time in the Development Plans.

(b) General Allocation of Responsibilities. The Parties anticipate that (i) Alexion will be primarily responsible for pre-clinical animal modeling and associated experiments, and in vitro luciferase and CD34 assays, as well as clinical laboratory and regulatory support, and (ii) XOMA will be primarily responsible for toxicology and certain other pre-clinical work pursuant to the Development Plan, fermentation development, master cell bank preparation, purification development, quality assurance, quality control, pre-IND Manufacturing, and GMP Manufacture of clinical supplies of Products. Subject to the approval of the JMC, each Party shall be permitted to engage academic, research, or other non-commercial institutions or contract service organizations to conduct Development activities on Products.

(c) Availability of Employees. Each Party shall make available its employees engaged in the Development Program upon reasonable notice during normal business hours and at their respective places of employment to consult with employees of the other Party on the progress of the Development Program and to exchange Collaboration Technology.

**3.5 Regulatory Matters**. (a) Regulatory Responsibility. The preparation, filing, prosecution and maintenance of INDs, BLAs and other regulatory filings required to be filed with any Regulatory Authority with regard to each Product will be in the name of and the responsibility of Alexion. Alexion shall own the Regulatory Approvals. The costs incurred by the Parties in the preparation, filing and submission of such regulatory filings will be deemed Development Expenses and subject to the terms of Section 3.6. Except as otherwise provided in an applicable Development Plan, Alexion shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions, including filings and submissions of supplements and amendments thereto, to Regulatory Authorities with respect to each Product and shall give XOMA a reasonable opportunity for prior review of all such material communications, filings and submissions.

(b) Regulatory Meetings and Correspondence. Except as otherwise provided in the Development Plans, Alexion shall be responsible for interfacing, corresponding and meeting with Regulatory Authorities with respect to the Product, and XOMA will promptly refer any contacts or questions from Regulatory Authorities to the party so designated. Both Parties will be entitled to attend all meetings and, if reasonably practicable, telephone conferences with Regulatory Authorities. The regulatory groups of the Parties shall agree on the types of telephone conferences with Regulatory Authorities that the Parties will be required to notify the other Party of and permit the other Party to participate in.

(c) Reporting Adverse Drug Reactions. Alexion and XOMA will develop and agree upon safety data exchange procedures governing the collection, investigation, reporting, and exchange of information concerning Adverse Drug Reactions, product quality and product complaints involving Adverse Drug Reactions, sufficient to permit each Party to comply with its legal obligations, including to the extent applicable, those obligations contained in ICH guidelines

E2A, E2B and E2C and the FDC Act. The safety data exchange procedures will be promptly updated if required by changes in legal requirements or by agreement between the Parties. Alexion will be responsible for reporting all Adverse Drug Reactions to the appropriate Regulatory Authorities in the Territory in accordance with applicable laws and regulations.

(d) Future Indications. Notwithstanding anything herein to the contrary, (i) neither Party shall have the rights or responsibilities set forth in Sections 3.1, 3.2, 3.3, 3.4, 3.5 and 3.6 with respect to any Product in a particular Future Indication as to which such Party has Opted Out and not Opted Back In, and (ii) in the case of any Product in a particular Future Indication as to which Alexion has Opted Out and not Opted Back In, XOMA shall have the rights and responsibilities ascribed to Alexion in this Section 3.5; *provided*, that, with respect to both clause (i) and clause (ii), both Parties shall in any event retain their obligations pursuant to the first two sentences of Section 3.5(c), Section 4.14 and the first sentence of Section 4.16, regardless of any such Opt Out.

**3.6 Funding of the Development Program**. (a) First-Time Pre-Clinical Development Activities. Alexion shall bear [*] percent ([*]%), and XOMA shall bear [*] percent ([*]%), of all Development Expenses incurred in conducting each activity set forth in the Initial Development Plan for the first Product to undergo such activity (collectively, the "First-Time Pre-Clinical Development Activities").

(b) Other Development Expenses. Alexion shall bear seventy percent (70%), and XOMA shall bear thirty percent (30%), of all Development Expenses incurred in conducting each activity under a Development Plan that is not a First-Time Pre-Clinical Development Activity.

(c) Certain Manufacturing Costs. Notwithstanding the terms of Section 3.6(b), all Manufacturing Costs necessary to produce Product in sufficient volumes and quality necessary for conduct of the first Phase I Study of the first Product in the Field will be borne [*] percent ([*]%) by Alexion and [*] percent ([*]%) by XOMA.

(d) Third Party Licenses. The costs associated with obtaining, as well as those payable under, any licenses from Third Parties that the Development Committee determines are necessary for the Development of a Product shall be borne by the Parties in accordance with Section 3.6(b). Either Party may propose that the Development Committee determine whether a Third Party license is necessary for the Development of a Product in the Field. In the event the Development Committee determines that such Third Party license is necessary, the Development Committee shall determine which Party shall be responsible for obtaining such license. The Party so selected by the Development Committee shall control the negotiation and execution of such Third Party license but the final commercial and other material terms thereof shall be as consented to by the other Party (which consent shall not be unreasonably withheld). In making any such determination provided for in this Section 3.6(d) as to the need for any such Third Party license, due consideration shall be given to the advisability of seeking an opinion of counsel and the efforts required to design around the patents at issue.

(e) Reconciliation. Development Expenses shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in this Section 3.6(e). Each Party

shall report their Development Expenses to the Development Committee within thirty (30) days after the end of each calendar quarter. The Party that incurs more than its share of the total actual Development Expenses for a Product shall be paid by the other Party an amount of cash sufficient to reconcile to its agreed percentage of actual Development Expenses in each quarter. Such payment shall be made within ten (10) days after receipt and approval of such report by the Development Committee.

## 4. CO-PROMOTION OF PRODUCTS

**4.1 Co-Promotion Election**. (a) Within thirty (30) days of the filing of a BLA for a Product (other than a Product as to which XOMA has Opted Out and not Opted Back In), XOMA may elect by written notice to Alexion to participate in the co-promotion of such Product in the Field in accordance with the terms of this Agreement ("Co-Promotion" or "Co-Promote"). XOMA may elect to Co-Promote on a Product-by-Product and country-by-country basis. XOMA may also elect to co-promote on an indication-by-indication basis, *provided* that for purposes of this provision, an individual "indication" shall mean a broad grouping of related diseases or conditions (e.g., oncology, transplantation or autoimmune diseases would each be a single "indication").

(b) In the event that (i) Gross Sales for a Product in each of three (3) consecutive years are lower than Gross Sales of such Product in each immediately preceding year for a non-External Reason (as defined below) or (ii) Gross Sales for a Product in each of six (6) consecutive quarters are lower than Gross Sales of such Product in each immediately preceding quarter for a non-External Reason, then XOMA shall again have the right to elect to Co-Promote such Product as provided in this Section 4.1, notwithstanding any previous failure to elect to do so or waiver thereof by XOMA, by delivery of written notice to Alexion. As used herein, "External Reason" means a cause outside of Alexion's reasonable control that would be expected negatively to impact sales volumes, such as an adverse labeling change or other adverse regulatory action, expiration of significant patents or marketing exclusivity, introduction of a significant competing product or material new claims or data for a competing product, negative change in relevant third party reimbursement terms, significant supply constraints or general changes in medical practice significantly disfavoring the Product. Failure of XOMA to elect to Co-Promote as described in this Section 4.1 within thirty (30) days following receipt by XOMA of the final Gross Sales figures for such Product in such three (3) year or six (6) quarter period, as the case may be, shall act as a waiver of XOMA's rights under this Section 4.1(b) as to such three (3) year or six (6) quarter period; *provided* that in the event of any such waiver, XOMA shall not be permitted to exercise its right to elect to Co-Promote as provided in this Section 4.1(b) following any of the succeeding three (3) quarters (including the quarter in which the waiver occurred) but may do so, in the event of lower Gross Sales as set forth in the first sentence hereof, following the fourth succeeding quarter and thereafter.

**4.2 Marketing and Marketing Plans**. If XOMA elects to Co-Promote a Product in the Field in a particular country and indication as provided in Section 4.1, the Development Committee shall coordinate and implement the joint marketing and detailing strategies and tactics, joint sales force training program, sales forecasts and post-approval clinical studies for such Product for each calendar year in each country and indication where the Parties will Co-Promote such Product. If XOMA does not elect to Co-Promote a Product in the Field in a particular

country and indication as provided in Section 4.1, Alexion may Commercialize the Product (including without limitation the activities described in the previous sentence) in such country and indication in its discretion.

**4.3 Labeling and Promotion**. Each Product will be marketed in each country with one label and will bear one or more Product Trademarks. All advertising and promotional material in respect of each Product in each country (including any Product labeling or packaging inserts to the extent permitted by law or required by any Regulatory Authority and approved by the Development Committee) will include XOMA's name and address to indicate its role as manufacturer and/or co-promoter, the size and placement of which will be determined by the Development Committee. The Development Committee will be responsible for developing and approving marketing plans and the advertising and other promotional materials to be used in Co-Promoting each Product. In respect of each Co-Promotion country and indication, the Development Committee will determine the Parties' respective responsibilities for seeking acceptance of the relevant Product on formularies, if applicable, and for all other negotiations with managed care organizations and other institutional purchasers.

**4.4 XOMA Detail Effort**. If XOMA makes the written election referred to in Section 4.1, XOMA shall be required, subject to the remainder of this Section 4.4, to provide [*] of the number of Details called for by the Commercialization Program in respect of the Product, country and indication so elected. For each calendar year, within thirty (30) days after establishment of the Budgeted Total Detail Effort for the calendar year, XOMA by written notice and within its sole discretion, may elect a Budgeted Detail Effort for such calendar year that is less than [*] of the Budgeted Total Detail Effort (but not less than [*]), in which case the Budgeted Detail Effort of XOMA for such calendar year shall be decreased in accordance with such election with, at Alexion's option (i) an increase in the Budgeted Detail Effort of Alexion up to the amount necessary to maintain the Budgeted Total Detail Effort, (ii) a corresponding decrease in the Budgeted Total Detail Effort, or (iii) a combination of (i) and (ii). XOMA shall not be entitled to provide in a subsequent calendar year a greater percentage of Budgeted Total Detail Effort than it selected for the then current calendar year (even pursuant to Section 4.1(b)), except to the extent of growth in the Budgeted Total Detail Effort for the upcoming calendar year from the current calendar year or to the extent of net attrition from Alexion's sales force (or Alexion's permitted delegates under Section 4.8) during the current calendar year. In connection with an election by XOMA under Section 4.1(b), Alexion will use commercially reasonable efforts to reassign its sales representatives to allow XOMA to provide up to its maximum [*] entitlement of Budgeted Total Detail Effort. Alexion shall notify XOMA in writing of any such growth or attrition and of the number of Details relating thereto to be added to the Budgeted Total Detail Effort for the next year no later than September 1 of each year, and XOMA shall notify Alexion in writing no later than October 1 of such year of the number of such additional Details to be included in its Budgeted Detail Effort for the following year, it being understood that XOMA shall be entitled to elect to undertake as many of such Details as will allow it to provide up to [*] of the Budgeted Total Detail Effort for such year, by Product, country and indication (in accordance with Section 4.1). XOMA shall report its Selling Expense incurred in connection with performing its Budgeted Detail Effort to Alexion on a quarterly basis within thirty-five (35) days after the end of each calendar quarter. Alexion shall reimburse XOMA one hundred percent (100%) of such XOMA Selling Expense within forty-five (45) days after the end of such calendar quarter, and shall include such reimbursement as a selling Cost incurred by it in calculating such

quarter's Sales and Marketing Expenses. The Party's reimbursable Selling Expense in respect of each Detail shall not exceed the amount thereof approved by the JMC. XOMA's reimbursable Selling Expense in respect of each Detail shall not exceed the costs incurred by Alexion for providing a similar Detail, provided by an individual of comparable seniority conducting similar activities in the same or comparable geographic area.

**4.5 Sales Training**. Alexion shall develop the training program for the respective sales forces. In the event that XOMA is Co-Promoting a Product, XOMA agrees to utilize such training program to assure a consistent, focused promotional strategy and message.

**4.6 Samples**. In the event a decision is made by the Development Committee to provide samples of a Product, each of the Parties will keep accurate records as to the distribution of samples, and comply with all applicable laws, rules and regulations dealing with the distribution of samples.

**4.7 Promotional Materials**. In respect of Co-Promotion countries and indications, each of Alexion and XOMA may disseminate only those promotional and advertising materials for the relevant Product that have been provided or approved for use by the Development Committee. Alexion shall supply XOMA quantities of promotional materials needed by XOMA to exercise its Co-Promotion rights under this Agreement. In respect of Co-Promotion countries and indications, neither Alexion nor XOMA shall, and each shall cause its employees, representatives and agents not, to make any claims or representations in respect of Products that have not been approved by the Development Committee.

**4.8 Delegation**. Subject to Section 4.9, each of Alexion and XOMA may use its respective employees or the employees of one or more of its respective Affiliates, or Third Party contract service organizations or distributors in the course of Co-Promoting Products under this Agreement; *provided, however*, that, in the event either Party chooses to delegate services or functions in accordance with the foregoing to a Third Party or Third Parties, that Party shall first offer the provision of such services or function to the other Party, who shall have fifteen (15) business days to agree to accept such offer. If the other Party elects not to accept such offer or fails to do so within such fifteen (15) day period, the Party making the offer shall be free to delegate such services or function to a Third Party or Third Parties selected by the delegating Party and, where the delegating Party is XOMA, reasonably acceptable to Alexion.

**4.9 Marketing/Development Partners**. As to any Product in the Field (as in effect on the Effective Date) or in a Future Indication as to which Alexion has not Opted Out or has Opted Out and Opted Back In or Opted Out while retaining a right to Opt Back In, (i) in respect of any country or countries (other than the United States) in which XOMA retains or has exercised any Co-Promotion rights hereunder, following consent by the Joint Management Committee, Alexion may, and (ii) in respect of all other countries (other than the United States) and Products, Alexion may in its discretion, license or sublicense any Alexion Background Technology, XOMA Background Technology or Collaboration Technology to one or more Third Parties (each, a "Marketing/Development Partner") to use, develop, make, have made, sell, have sold, offer for sale, import or export Products in the Field, subject to all applicable provisions of this Agreement; *provided*, that, notwithstanding the foregoing, the consent of XOMA (which consent shall not be unreasonably withheld) to such license or sublicense shall be required in the event

the proposed license or sublicense relates to a particular Product in a particular country where XOMA has exercised its Co-Promotion right with respect to the same Product in a different indication; and, *provided, further,* that, notwithstanding the foregoing, if the determination to license or sublicense a potential Marketing/Development Partner is being considered for execution before completion of a Phase I Study in or for the United States regarding such Product, then either both Parties shall agree on such license or sublicense to such potential Marketing/Development Partner or any disagreement between the Parties relating to such license or sublicense or Marketing/Development Partner shall be an Arbitrable Dispute and the provisions of Sections 12.1 and 12.2 shall apply. In the event a license or sublicense is granted to a Marketing/Development Partner in accordance with this Section 4.9, in those countries where XOMA retains or has exercised its Co-Promotion rights, its right to provide Details hereunder shall be based on [*] of the Details not provided by or on behalf of the Marketing/Development Partner. As to any Product in a Future Indication as to which Alexion has Opted Out without a remaining right to Opt Back In, XOMA may, in its discretion, license or sublicense any Alexion Background Technology, XOMA Background Technology or Collaboration Technology to one or more Marketing/Development Partners to use, develop, make, have made, sell, have sold, offer for sale, import or export such Product in the Field, subject to all applicable provisions of this Agreement; *provided*, that, notwithstanding the foregoing, the consent of Alexion (which consent shall not be unreasonably withheld) to such license or sublicense shall be required in the event the proposed license or sublicense relates to a particular Product in a particular country where Alexion has not Opted Out or has Opted Out and Opted Back In or Opted Out while retaining a right to Opt Back In, with respect to the same Product in a different indication. Nothing in this Section 4.9 shall affect XOMA's manufacturing rights and obligations hereunder, it being understood that matters otherwise arising in the context of this Section 4.9 that relate to manufacturing shall be subject to and governed by Section 5.1 hereof and related provisions.

**4.10 Returns**. Alexion shall be responsible for handling all Product returns (other than a Product in a Future Indication as to which Alexion has Opted Out and not Opted Back In). Any Product returned to XOMA shall be shipped by XOMA to the address designated by Alexion with shipping costs authorized by Alexion to be paid by Alexion.

**4.11 Orders**. All customer orders for Product (other than a Product in a Future Indication as to which Alexion has Opted Out and not Opted Back In) shall be received and executed in each country by Alexion. XOMA shall transmit any such orders that it receives to Alexion.

**4.12 Completion of Sales**. All sales of Product (other than a Product in a Future Indication as to which Alexion has Opted Out and not Opted Back In) will be completed, distributed, accounted for, billed and booked by Alexion at prices established by Alexion.

**4.13 Exchange of Marketing Information**. From time-to-time Alexion will develop call lists, schedules and other appropriate information for the purpose of determining the physicians and other persons involved in the drug purchase decision-making process to whom XOMA and Alexion will Detail each Product in Co-Promotion countries. The Parties agree to cooperate in finding an inexpensive and expeditious way to provide a call list and other information indicating the identity of those physicians and other persons involved in the decision-making process regarding the purchase of pharmaceuticals. The Parties will establish a method of confirming when Details have been made in Co-Promotion countries so that, among other things, XOMA's and Alexion's Detail Effort can be calculated.

**4.14 Notice of Adverse Reactions**. Each Party shall advise the other as promptly as reasonably practical by telefax or overnight delivery service addressed to the attention of its Vice President, Regulatory Affairs (or equivalent), of any Adverse Drug Reaction that has been brought to that Party's attention at any place and that is alleged to be related to administration of any Product.

**4.15 Regulatory and Other Inquiries**. Upon being contacted by any Regulatory Authority for any regulatory purpose pertaining to this Agreement or to a Product, XOMA and Alexion shall promptly notify and consult with one another, and the owner (or proposed owner) of the relevant Regulatory Approval (or proposed Regulatory Approval), determined in accordance with Section 3.5, shall provide a response as it deems appropriate, and such Party shall have sole right and responsibility for responding to all inquiries to Alexion or XOMA, as the case may be, regarding the benefits, side effects and other characteristics of a Product.

**4.16 Product Recall**. In the event that either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or other removal of any Product, or any lot or lots thereof, from the market in any country, it shall advise and consult with the other Party with respect thereto. Alexion shall make the final determination to recall or otherwise remove the Product or any lot or lots thereof from the market, except as to a recall related only to a Product in a Future Indication as to which Alexion has Opted Out and not Opted Back In, in which case XOMA shall be entitled to make any such determination. The costs and expenses of such recall or removal in each country, including expenses and other costs or obligations to Third Parties, the cost and expense of notifying customers and costs and expenses associated with shipment of the recalled Product from a customer to either Alexion or XOMA shall be included in Commercialization Expenses; except as to any Product in a Future Indication as to which one Party has Opted Out and not Opted Back In, in which case the other Party shall bear such costs.

## 5. MANUFACTURE AND SUPPLY OF PRODUCTS

**5.1 Designation of XOMA as Manufacturing Party**. (a) Capacity. XOMA shall Manufacture and supply Alexion quantities of Product necessary to satisfy commercial demand, provided that such quantities can be manufactured in [*]. If [*] determines that [*] as the Parties shall reasonably agree, at competitive COGS in accordance with agreed specifications and GMP, for pre-clinical, clinical and commercial purposes, then, subject to the last sentence of Section 5.3(a), [*] shall identify a Third Party to undertake such Manufacturing responsibilities (in whole or in part), and [*] shall oversee Manufacturing of Product with such Third Party manufacturers as it may designate. Any dispute concerning whether XOMA possesses the capacity referred to in the immediately preceding sentence shall be a "Section 5.1 Dispute" and shall be subject to the dispute resolution procedures of Sections 12.1 and 12.2. In the event that the JMC cannot agree on a Third Party manufacturer, the provisions of Article 12 shall apply. Alexion and XOMA each agree to license their respective Background Technology and Collaboration Technology to such Third Party as reasonably necessary for such Third Party to manufacture the Product; and XOMA will procure for such Third Party manufacturer a license to use the bacterial

cell expression technology owned or Controlled by XOMA Ireland Limited to manufacture the Product, on the same terms as Alexion's license thereto (without any milestone obligations and with the royalty obligations subject to the same net terms as in Section 6.3 hereof).

(b) Technology Transfer. XOMA will provide or cause to be provided all reasonably necessary technology transfer to additional manufacturers designated by the JMC, and Alexion will reimburse XOMA seventy percent (70%) of its actual costs in connection therewith. Alexion or its Affiliate may be the Third Party manufacturer referred to in clause (a) above.

**5.2 Supply Price**. All Product Manufactured by XOMA (or by Alexion, its Affiliate or a Third Party under Section 5.1) shall be supplied at a price equal to its COGS, as reviewed by the JMC and subject to verification as provided in Section 6.5. COGS for Product to be used prior to Regulatory Approval shall be included in Development Expenses and treated as such (including pursuant to Section 3.6). COGS for Product to be used following Regulatory Approval shall be included in Allowable Expenses and shall be payable by Alexion upon delivery of vialed Product to or on behalf of Alexion pursuant to firm orders under Section 5.3(b) or as otherwise requested for delivery by Alexion and agreed to by XOMA. All other Manufacturing cost shall be payable by Alexion (and included in Development Expenses or Commercialization Expenses, as applicable) when incurred.

**5.3 Supply**. (a) Product Supply. XOMA shall supply exclusively (subject to Section 5.1) all of Alexion's requirements of Product in accordance with this Section 5.3. XOMA's supply obligations shall be limited to the reasonable capacity (one shift/day) of [*]. When [*] indicate that demand will exceed capacity of [*], the Parties will use commercially reasonable efforts to determine an appropriate means of expanding capacity.

(b) Orders; Forecasts. Within sixty (60) days following the completion of the first Phase III Study relating to a particular Product, Alexion and XOMA shall agree upon (i) a firm order for the amount of such Product to be delivered during the calendar quarter immediately following the quarter in which such agreement is reached and (ii) a quarter-by-quarter demand forecast for the following three (3) quarters. No later than ninety (90) days prior to the beginning of each subsequent quarter, Alexion shall provide XOMA with Alexion 's firm order for the amount of Product to be delivered during such quarter and its revised quarter-by-quarter forecast for the amount of Product it will desire for delivery in each of the three (3) quarters immediately thereafter; *provided*, that (i) if the total of Alexion's firm orders for delivery in any quarter is less than [*] of its most recent quarterly estimate for such quarter, Alexion shall be required to purchase at least [*] of the estimate for such quarter, (ii) if the total of Alexion's firm order for delivery in any quarter exceeds [*] of its most recent quarterly estimate for such quarter, XOMA shall use commercially reasonable efforts, but shall have no obligation, to deliver quantities in excess of [*] of the estimate for such quarter, and (iii) in any such revised forecast, the estimate therein for the first and second quarters immediately following the quarter for which a firm order is then provided shall not vary by more than [*], respectively, from the most recent estimate for such quarter; *provided, further*, that in no event shall XOMA be required to deliver in excess of [*] of the quarterly manufacturing capacity of [*] in any quarter. XOMA shall ship Product in unlabeled vials to a facility or facilities designated by Alexion within each such quarter after the receipt of such purchase order from Alexion. Title to the Product shall pass to Alexion upon receipt by Alexion at such facility. XOMA shall use commercially reasonable efforts to build inventory in anticipation of purchase orders, consistent with Alexion's forecast.

## 6. FINANCIAL PROVISIONS

**6.1 Access Fee**. As partial consideration for the rights granted hereunder and the obligations undertaken herein, XOMA shall pay Alexion One Million Five Hundred Thousand Dollars ($1,500,000) on the Effective Date. Such payment shall be made in cash by wire transfer to the bank account designated by Alexion in writing.

**6.2 Milestone Payment by XOMA**. XOMA shall pay Alexion One Million One Hundred Thousand Dollars ($1,100,000) upon submission of the first IND.

**6.3 Non-Exclusive XOMA Ireland License**. With reference to the Non-Exclusive License Agreement, dated as of January 31, 2001, by and between XOMA Ireland Limited and Alexion (the "Non-Exclusive XOMA Ireland License"), XOMA hereby agrees [*] of the Non-Exclusive XOMA License [*]; and [*] of the Non-Exclusive XOMA License [*]. Nothing herein shall serve to amend, or extend or modify the scope of, the Non-Exclusive XOMA Ireland License.

**6.4 Operating Profit/Loss for Products**. Beginning with the Effective Date and throughout the Term of this Agreement, all Operating Profits/Losses shall be shared by the Parties as follows: (a) seventy percent (70%) for Alexion; and (b) thirty percent (30%) for XOMA as provided in Schedule B, except as provided in Section 3.6(a). For the avoidance of doubt, payments by XOMA under Section 6.1, 6.2 or 6.3 shall not be included in XOMA's Development Expenses or Commercialization Expenses, or otherwise enter the calculation of Operating Profits/Losses.

**6.5 Records**. Alexion and XOMA shall each keep accurate books and accounts of record in connection with the Manufacture, Development and Commercialization of Product in sufficient detail to permit accurate determination of all figures necessary for verification of compensation hereunder. Alexion and XOMA shall maintain such records for a period of three (3) years after the end of the year in which they were generated. At such Party's expense, a Party, through a certified public accountant, shall have the right to access the books and records of the other Party for the sole purpose of verifying such statements; such access shall be conducted after reasonable prior written notice to the Party, during ordinary business hours and not more frequently than once during each calendar year. In the event that there has been an underreporting or overreporting of items reviewed by such accountants of five percent (5%) or greater over the full period reviewed by such accountants, then the cost of such accountants shall be borne by the Party who was economically advantaged by such underreporting or overreporting. Any underpaid or overpaid amounts shall be paid within thirty (30) days after notice of the underreporting or overreporting.

**6.6 Currency of Payment**. All payments to be made under this Agreement shall be made in United States dollars in the United States to a bank account designated by the Party to be paid. Any determination(s) hereunder requiring the conversion of currency shall be made by the Party responsible for such determination(s) in the same manner as made by such Party in connection with the preparation of its externally-published financial statements (or those of its parent company), consistent with U.S. generally accepted accounting principles.

**6.7 Taxes Withheld**. Any income or other tax that either Party is required to withhold and pay on behalf of the other Party, its Affiliates, licensees or sublicensees with respect to the Development, Manufacturing, Commercialization or Co-Promotion of a Product or other amounts payable under this Agreement shall be deducted from and offset against amounts owed to the other Party hereunder prior to remittance; *provided, however*, that in regard to any tax so deducted, each Party shall give or cause to be given to the other Party such assistance as may reasonably be necessary to enable such other Party to claim any available withholding exemptions or rate reductions and/or credits in respect of any withholding, and in each case shall furnish such other Party proper evidence of the taxes paid on its behalf.

## 7. FUTURE INDICATIONS

**7.1 Proposals**. Any Party may propose to the Development Committee that a particular Product be developed in a particular Future Indication. If the Development Committee agrees to further evaluate the proposal, the Development Committee will develop a detailed proposal, which will include a Development Plan and commercial analysis. The JMC shall review and evaluate such proposals and make a recommendation as to whether or not to pursue such Product in such Future Indication as proposed. The recommendations made by the JMC shall not be binding unless and until Alexion's President approves of the proposed Future Indication in writing. Each Party shall review and evaluate proposals for Future Indications in good faith; however, either Party may decline to participate in ("Opt Out" of) the Development of a particular Product in a particular Future Indication in its sole discretion. Subject to Section 7.2, in the event the Development Committee or the JMC cannot reach consensus regarding a proposed Future Indication, the Party whose representatives oppose such proposal shall be deemed to have Opted Out of such Future Indication. Pursuant to Section 7.4, the Parties may also elect to again participate in ("Opt Back In" to) the Development and Commercialization of a particular Product in a particular Future Indication after having Opted Out pursuant to this Section 7.1. The exercise of any such rights to Opt Back In shall be subject to the other provisions of this Agreement, including the obligation to share Operating Profits/Losses, Development Expenses and Commercialization Expenses, and such exercise shall not entitle a Party to any rights greater than those they would have had if they had initially agreed to develop a Future Indication in accordance with this Section 7.1. For so long as and whenever both Parties are participating in the Development or Commercialization of a particular Product in a particular Future Indication as provided herein, the definition of Field shall include such Future Indication as it relates to such Product.

**7.2 Alexion's Sole Right to Prohibit Development**. Subject to payment of a prohibition fee if required by Section 7.6, and notwithstanding anything to the contrary herein, for each Future Indication, Alexion shall have the right in its sole discretion to prohibit XOMA from investigating and/or developing or assisting others in investigating or developing such Future Indication as follows ("Right of Prohibition"):

(i) Exercise upon JMC's Recommendation to Develop. Alexion may exercise its Right of Prohibition initially upon Alexion's review of the

JMC's recommendation concerning a proposed Future Indication. If Alexion exercises its Right of Prohibition at this stage no prohibition fee as described in Section 7.6 shall be owed.

(ii) Exercise after Phase II Study. In the alternative, Alexion may permit XOMA to conduct a Phase II Study for a proposed Future Indication at XOMA's sole cost and risk but Alexion shall have the right, in its sole discretion, to exercise its Right of Prohibition after completion of each such Phase II Study. Following completion of each such Phase II Study, XOMA shall provide Alexion with written notice of such completion and enclose a copy of a summary analysis performed in accordance with the pre-specified statistical analysis plan filed with the FDA. Upon receipt of the notice and report, Alexion shall have sixty (60) days to exercise its Right of Prohibition. During this sixty (60) day period, XOMA shall provide Alexion with all updates to the report, and all additional material information, data and reports. In addition, XOMA shall make its personnel, agents and/or contractors available to respond to reasonable inquiries by Alexion.

**7.3 Study Objectives and Success Criteria**. Alexion will have final approval of all study objectives, primary study endpoints and success criteria for all studies relating to any Future Indication. Said approval shall be made prior to enrollment in a study and shall be made by means of a written document executed by Alexion's President or his/her designee.

**7.4 Exercise of Rights to Opt Back In**. (a) Alexion. For each Product in a particular Future Indication which Alexion has Opted Out of pursuant to Section 7.1, Alexion shall have the right to Opt Back In to such Product in such Future Indication upon completion of a successful Phase II Study for such Product in such Future Indication under the following terms and conditions:

(i) Notice, Delivery of Reports and Time to Exercise. Following completion of each successful Phase II Study for such Product in such Future Indication, XOMA shall provide Alexion with written notice of such completion and enclose a copy of a summary analysis performed in accordance with the pre-specified statistical analysis plan filed with the FDA. Upon receipt of the notice and report, Alexion shall have ninety (90) days to exercise its right to Opt Back In by providing written notice to XOMA of such intent. During this ninety (90) day period, XOMA shall provide Alexion with all updates to the report and all additional material information, data and reports. In addition, upon request XOMA shall make the raw data as well as its personnel, agents and/or contractors available in response to reasonable inquiries by Alexion.

(ii) Fee. For each Product in each Future Indication which Alexion Opts Back In to pursuant to Section 7.4(a)(i), Alexion shall owe XOMA an amount equal to four hundred and fifty percent (450%) of the Alexion

Development Expenses incurred by XOMA solely for that particular Product in that particular Future Indication through completion of the Phase II Study. Fees owed pursuant to this Section 7.4(a) shall be payable within thirty (30) days of exercise of the right to Opt Back In.

(iii) Waiver. Alexion will waive its right to Opt Back In under this Section 7.4(a) with respect to a particular Product in a particular Future Indication if it fails to timely provide the written notice of such intent or timely tender the fee for such Future Indication, each as provided herein.

(b) XOMA. For each Product in a particular Future Indication which XOMA has Opted Out of pursuant to Section 7.1, XOMA shall have the right to Opt Back In to such Product in such Future Indication upon completion of a successful Phase II Study for such Product in such Future Indication under the following terms and conditions:

(i) Notice, Delivery of Reports and Time to Exercise. Following completion of each successful Phase II Study for such Product in such Future Indication, Alexion shall provide XOMA with written notice of such completion and enclose a copy of a summary analysis performed in accordance with the pre-specified statistical analysis plan filed with the FDA. Upon receipt of the notice and report, XOMA shall have ninety (90) days to exercise its right to Opt Back In by providing written notice to Alexion of such intent. During this ninety (90) day period, Alexion shall provide XOMA with all updates to the report and all additional material information, data and reports. In addition, upon request Alexion shall make the raw data as well as its personnel, agents and/or contractors available in response to reasonable inquiries by XOMA.

(ii) Fee. For each Product in each Future Indication which XOMA Opts Back In to pursuant to Section 7.4(b)(i), XOMA shall owe Alexion an amount equal to four hundred and fifty percent (450%) of the XOMA Development Expenses incurred by Alexion solely for that particular Product in that particular Future Indication through completion of the Phase II Study. Fees owed pursuant to this Section 7.4(b) shall be payable within thirty (30) days of exercise of the right to Opt Back In.

(iii) Waiver. XOMA will waive its right to Opt Back In under this Section 7.4(b) with respect to a particular Product in a particular Future Indication if it fails to timely provide the written notice of such intent or timely tender the fee for such Future Indication, each as provided herein.

**7.5** Certain Effects of Opting Out. (a) Royalty. In the event either Party Opts Out of a particular Product in a particular Future Indication and does not Opt Back In as provided herein (the "Opted Out Party"), the other Party (the "Continuing Party") shall pay the Opted Out Party a

royalty of (i) if Alexion is the Opted Out Party, [*] of Gross Sales in the Territory of such Product in such Future Indication and (ii) if XOMA is the Opted Out Party, [*] of Gross Sales in the Territory of such Product in such Future Indication. Appropriate provision shall be made so that the Continuing Party shall have the benefit of, but also all responsibility for (including without limitation with respect to the payment of royalties and other amounts due under), any third party licenses relating to such Product in such Future Indication. The Continuing Party shall make quarterly reports to the Opted Out Party, and shall maintain records and grant access thereto, regarding the payments required hereunder in the same manner as provided in Section 3.1 of Schedule B hereto and Section 6.5 hereof, respectively. Payments of the amounts required hereby shall be made concurrently with the reports referred to above, and the provisions of Section 6.6 shall apply thereto. The Continuing Party's royalty obligation hereunder shall continue for the Term of this Agreement.

(b) Good Faith as to Other Indications. In the event either Party Opts Out of a Product in a particular Future Indication and does not Opt Back In as provided herein, the other Party shall act in good faith and exercise reasonable judgment in the Development and Commercialization of Products in such Future Indication so as not to jeopardize the Development or Commercialization of Products in the other indications in which Products are being Developed and/or Commercialized hereunder.

(c) XOMA Manufacturing Obligation. Subject to the other provisions of this Agreement regarding expiration and termination, in the event XOMA Opts Out as to a Product in a particular Future Indication, the manufacture and supply provisions of Article 5 shall nonetheless apply to all Products in such Future Indication, except that the Parties agree to negotiate in good faith a reasonable profit for XOMA from such manufacturing and supply based on market conditions and other relevant factors at that time.

**7.6 Prohibition Fee**. In the event that Alexion permits XOMA to develop a proposed Future Indication at XOMA's sole cost and then pursuant to Section 7.2 following completion of a Phase II Study elects to prohibit such development after XOMA has incurred XOMA Development Expenses for such proposed Future Indication, then:

(a) If XOMA has met the criteria for success of such Phase II Study as pre-defined pursuant to Section 7.3, then Alexion shall owe XOMA three hundred and fifty percent (350%) of the XOMA Development Expenses which are solely related to such Future Indication and which are incurred prior to receipt by XOMA of Alexion's notice to terminate.

(b) If the studies sponsored by XOMA have failed to meet the criteria for success defined by Alexion pursuant to Section 7.3 or neither Party wishes to continue further development for the particular Future Indication, then Alexion shall have no payment obligations to XOMA.

**7.7 No Opt-In**. In the event that either Party does not Opt-In to a Future Indication, such Party's sole compensation with respect to royalties for such Future Indication is set forth in Section 7.5(a).

**7.8 Compliance with Privacy Laws**. As of the Effective Date, the Parties shall use Commercially Reasonable and Diligent Efforts to obtain all necessary consents required for

disclosure of the data and reports which they are required to provide pursuant to this Article 7. For purposes of this Article 7, Commercially Reasonable and Diligent Efforts shall include seeking contractual obligations from clinical research sites obligating the sites to seek subjects' consent to disclosure of private data to the Parties, their licensees and collaborators. In the event that any such consent cannot be obtained, the Party having the right to Opt Back In shall be provided with data and documentation which is redacted to make disclosure lawful. With respect to any particular Product in a particular Future Indication, the Continuing Party will reimburse all of the Opted Out Party's reasonable costs associated with compliance with this Section 7.8.

## 8. LICENSES.

**8.1 Grant**. (a) XOMA Grant. XOMA hereby grants to Alexion a fully-paid, exclusive (except as to XOMA and any Third Party manufacturer designated in accordance with Section 5.1) license to utilize the XOMA Background Technology and the XOMA Collaboration Technology (i) to Develop, Manufacture and Commercialize Products in the Field in the Territory under the terms and subject to the conditions set forth in this Agreement and pursuant to the Development Plan and (ii) to discover, use, develop, make, have made, sell, offer for sale, import or export a Product in a Future Indication as to which XOMA has Opted Out and not Opted Back In. Except as expressly provided herein, such licenses to XOMA Background Technology shall terminate upon expiration or termination of this Agreement and to XOMA Collaboration Technology shall survive expiration or termination of this Agreement forever without regard to the restriction as to Field or the requirement of a Development Plan.

(b) Alexion Grant. Alexion hereby grants to XOMA a fully-paid, exclusive (except as to Alexion and any Third Party manufacturer designated in accordance with Section 5.1) license to utilize the Alexion Background Technology and the Alexion Collaboration Technology (i) to Develop, Manufacture and Co-Promote Products in the Field in the Territory under the terms and subject to the conditions set forth in this Agreement and pursuant to the Development Plan and (ii) to discover, use, develop, make, have made, sell, offer for sale, import or export a Product in a Future Indication as to which Alexion has Opted Out and not Opted Back In. Except as expressly provided herein, such licenses to Alexion Background Technology shall terminate upon expiration or termination of this Agreement and to Alexion Collaboration Technology shall survive expiration or termination of this Agreement forever without regard to the restriction as to Field or the requirement of a Development Plan.

**8.2 Sublicenses**. Neither Party may sublicense the rights granted in Section 8.1 without the prior written consent of the other; *provided* that each of Alexion and XOMA may sublicense their respective rights to XOMA Technology or Alexion Technology, as the case may be, to a Marketing/Development Partner granted a license or sublicense in accordance with Section 4.9 in connection with the Commercialization of a Product.

## 9. INTELLECTUAL PROPERTY

**9.1 Ownership of Technology**. Subject to the terms hereof, including the licenses and other rights granted hereunder, all Technology shall be owned as follows:

(a) Background Technology. All Alexion Background Technology shall continue to be owned or Controlled by Alexion, and all XOMA Background Technology shall continue to be owned or Controlled by XOMA.

(b) Collaboration Technology. XOMA shall own the entire right, title and interest in and to all XOMA Collaboration Technology (including all Patent Rights and other intellectual property rights thereto), and Alexion shall own the entire right, title and interest in and to all Alexion Collaboration Technology (including all Patent Rights and other intellectual property rights thereto). The Parties shall jointly own all Joint Collaboration Technology and, subject to the rights granted each Party under this Agreement, each Party may make, use, sell, keep or license its interest in Joint Collaboration Technology, and otherwise undertake all activities a sole owner might undertake with respect to such Joint Collaboration Technology, without the further consent of and without accounting to the other Party, throughout the world. Notwithstanding the foregoing, data generated by any clinical trials of Product shall be owned by Alexion; provided that XOMA shall be granted access rights to, and a license for such uses as may be reasonably necessary for the Development and Commercialization of any Product in a Future Indication as to which Alexion has Opted Out and not Opted Back In with respect to, such data, without any additional payment by XOMA.

(c) Notice. Subject to appropriate confidentiality undertakings and the filing of any provisional or other patent applications, and also subject to the obtaining of any export or foreign filing licenses, each Party shall notify the other Party promptly and in any event within thirty (30) days after the priority and foreign filings in respect of Collaboration Technology. In case of Joint Collaboration Technology, each Party shall notify the other Party promptly after completion of any invention disclosure statement.

(d) Rights in Collaboration Technology. Each Party and its Affiliates may use and practice its own Collaboration Technology in any application not prohibited by the terms of this Agreement without the consent of the other and without an obligation to notify the other Party of such intended use or to pay royalties or other compensation to the other by reason of such use during the Term of this Agreement and thereafter.

**9.2 Prosecution of Patents**. (a) Sole Collaboration Technology. Subject to the provisions of Section 9.2(b) below, each Party shall have the sole right with respect to Collaboration Technology owned by it to: (i) decide whether patent applications should be filed on such Collaboration Technology, (ii) decide when and in which countries such patent application should be filed or maintained, (iii) control the prosecution and procurement of any such patent application and patents resulting from such patent applications, including their issuance, reissuance, reexamination and their defense in any interference, revocation and/or opposition proceedings, and (iv) select any counsel or other party necessary to prepare, file, prosecute and maintain such patent applications and such patents and advise or represent it in connection with such patent applications and such patents. Each Party shall pay all costs and expenses incurred by it under this Section 9.2(a) with respect to Collaboration Technology owned by it. A Party that decides not to file any patent applications, or not to prosecute or maintain any patents, referred to in this Section 9.2(a) shall notify the other Party with sufficient time for such other Party to do the same, in which case any such patent applications or patents will be assigned to such other party without further consideration.

(b) Joint Collaboration Technology. The JMC shall determine which Party shall be responsible for filing patent applications and such other activities described in Section 9.2(a) in respect of Joint Collaboration Technology, using counsel selected by it with the consent of the other Party (which consent shall not be unreasonably withheld). With respect to the prosecution of such patent applications for Joint Collaboration Technology, the Party prosecuting such Joint Collaboration Technology (the "Prosecuting Party"), shall have the further right to take such actions as are necessary or appropriate to procure and maintain patents with respect thereto; provided, that all such patent applications and patents shall be owned jointly ("Joint Patent Rights"). The Prosecuting Party's costs in preparing, filing, prosecuting and maintaining Joint Patent Rights that are determined by the JMC to have commercial value primarily in connection with a Product shall be shared 70 (Alexion)/30 (XOMA) between the Parties (unless such Joint Patent Rights relate only to a particular Product in a particular Future Indication as to which one Party has Opted Out and not Opted Back In, in which case all such costs shall be borne by the other Party); such costs with respect to Joint Patent Rights that are determined by the JMC to have commercial value primarily in connection with something other than a Product shall be borne by the Prosecuting Party. In the event the JMC cannot make the determination called for by the immediately preceding sentence, the question of whether certain Joint Patent Rights have commercial value primarily in connection with a Product shall be submitted to the dispute resolution procedures of Sections 12.1(a) (except for the fourth sentence thereof) and 12.2 and shall be an Arbitrable Dispute. The non-Prosecuting Party shall be consulted, and due consideration given to any concerns it may raise, with respect to all significant prosecution matters involving the Joint Patent Rights. If the Prosecuting Party for a Joint Patent Right decides to abandon prosecution or maintenance of such Joint Patent Right, it shall so notify the other Party and the other Party shall have the right to take over the prosecution and maintenance of such Joint Patent Right at its own expense and discretion, in which case the original Prosecuting Party shall assign all of its rights and interest therein to the other Party. Either Party may avoid sharing the costs associated with any Joint Collaboration Technology by assigning all of its rights and interests therein to the other Party without further consideration. Costs incurred prior to such assignment shall be shared as set forth above.

**9.3 Enforcement of Patent Rights**. (a) Mutual Notification. If at any time during the Term of this Agreement, XOMA or Alexion becomes aware of any product that it believes (i) is being sold in the Territory for treatment of the same indications or potential indications as any Product or potential Product, and (ii) infringes a Patent Right owned by XOMA and/or Alexion which Patent Right is believed also to protect the use, development, manufacture, sale, import or export of such Product (or potential Product), the Party having such knowledge shall promptly inform the other Party of such infringement. Alexion and XOMA shall thereafter consult and attempt to determine a course of action to terminate any such infringement.

(b) Enforcement of XOMA Patent Rights. Subject to Section 9.3(d) below, XOMA shall have the sole right, at its own expense and in its sole discretion, to initiate, prosecute and control the enforcement of the XOMA Patent Rights against such infringement, or the defense of any declaratory judgment action for non-infringement relating thereto in any Territory and to defend any XOMA Patent Right.

(c) Enforcement of Alexion Patent Rights. Subject to Section 9.3(d) below, Alexion shall have the sole right, at its own expense and in its sole discretion, to initiate, prosecute and control the enforcement of the Alexion Patent Rights against such infringement, or the defense of any declaratory judgment action for non-infringement relating thereto in any Territory and to defend any Alexion Patent Right.

(d) Enforcement in Certain Circumstances. Notwithstanding Sections 9.3(b) and (c) above, in the event either Party in the exercise of its discretion elects not to enforce or defend its Patent Rights in a particular circumstance, the other Party may request that the JMC determine whether such Patent Rights should be enforced or defended in such circumstance. In the event the JMC determines that such Patent Rights should be so enforced, the JMC shall determine which Party shall be responsible for the enforcement or defense thereof in such circumstance. The Party so selected by the JMC shall control such enforcement or defense, using counsel selected by it with the consent of the other Party (which consent shall not be unreasonably withheld), and the costs thereof shall be shared 70 (Alexion)/30 (XOMA) between the Parties (except as set forth in Section 9.2(b)).

(e) Enforcement of Joint Patent Rights. If such infringement relates to the Joint Patent Rights, Alexion shall (unless such Joint Patent Rights relate only to a particular Product in a particular Future Indication as to which Alexion has Opted Out and not Opted Back In) have the first right, at its own cost and expense and in its sole discretion, to initiate, prosecute and control such legal action, or to control the defense of any declaratory judgment action for non-infringement relating thereto, including the right to settle any such action. If Alexion does not commence any such action within ninety (90) days after notice of such infringement, then XOMA will (unless such Joint Patent Rights relate only to a particular Product in a particular Future Indication as to which XOMA has Opted Out and not Opted Back In) have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action. Expenses under this Section 9.3(d) shall be shared 70 (Alexion)/30 (XOMA) between the Parties (except as set forth in Section 9.2(b)).

(f) Cooperation. In connection with any action brought by either Party for patent infringement of the Joint Patents, Alexion and XOMA will reasonably cooperate and will provide each other with any information or assistance that either Party may reasonably request. Each Party shall keep the other Party informed of developments in any action, including the status of any settlement negotiations and the terms of any offer related thereto. The Party controlling such action, as provided in Section 9.3(d) or (e), shall consult with the other Party, and give due consideration to any concerns the other Party may raise, with respect to all significant matters relating to such action. Each Party may be represented by counsel of its choice. However, no settlement, compromise or other disposition of any such proceeding that concerns the validity of any Joint Patent or patents of the other Party shall be entered into without the prior written consent of both Parties, which consent shall not be unreasonably withheld or delayed.

(g) Recovery of costs and damages in infringement actions. Any recovery obtained as a result of infringement actions brought under Section 9.3(e), whether by judgment, award, decree or settlement, shall be shared 70 (Alexion)/30 (XOMA) between the Parties (unless such Joint Patent Rights relate only to a particular Product in a particular Future Indication as to which one Party has Opted Out and not Opted Back In, in which case all such recoveries shall be allocated to the other Party).

(h) Right to Abandon. If the Party controlling the enforcement or defense of any Patent Right in accordance with this Section 9.3 decides to abandon such enforcement or defense of such Patent Right, it shall so notify the other Party and the other Party shall have the right to take over the enforcement or defense of such Patent Right at its own expense and discretion, in which case the original enforcing or defending Party shall assign all of its rights and interest in such enforcement or defense to the other Party and shall waive any right to recovery with respect thereto under Section 9.3(g). Either Party may avoid sharing the costs associated with any enforcement or defense of a Patent Right governed by this Section 9.3 by assigning all of its rights and interests therein to the other Party without further consideration. Costs incurred prior to such assignment shall be shared 70 (Alexion)/30 (XOMA) between the Parties (except as set forth in Section 9.2(b)).

**9.4 Allegations of Infringement by Third Parties**. In the event that Alexion or XOMA receives notice that the use, development, manufacture, sale, import or export of a Product, or any other action by either of them under this Agreement, during the Term of this Agreement is alleged to be a violation of the patent or other intellectual property rights of a Third Party, it shall immediately notify the other Party. The JMC shall promptly determine an appropriate response and course of action. Alexion will (unless such allegations relate only to a particular Product in a particular Future Indication as to which Alexion has Opted Out and not Opted Back In) have the right to control any defense, using counsel selected by it with the consent of XOMA (which consent shall not be unreasonably withheld). The Party controlling such action, as provided in this Section 9.4, shall consult with the other Party, and give due consideration to any concerns the other Party may raise, with respect to all significant matters relating to such action. The costs thereof (including any damages, costs or expenses resulting from any action) shall be shared 70 (Alexion)/30 (XOMA) between the Parties (unless such allegations relate only to a particular Product in a particular Future Indication as to which one Party has Opted Out and not Opted Back In, in which case all such costs shall be borne by the other Party). Any recovery obtained as a result of infringement actions governed by this Section 9.4 shall be treated as provided in Section 9.3(g), and the Parties shall be entitled to abandon their efforts hereunder in the same manner as provided in Section 9.3(h).

**9.5 Trademarks and Trade Dress**. (a) Product Trademark. Alexion shall have the right to select, and shall register and maintain, at its expense, the Product Trademark(s) as shall be used for the promotion, marketing and sale of the Product in the Territory. Alexion shall own such Product Trademark(s) and all goodwill associated therewith.

(b) Product Trademark Use. XOMA recognizes that the Product Trademark(s) represent a valuable asset of Alexion, and that substantial recognition and goodwill are associated with such name, logo and trademarks. XOMA shall use the Product Trademark(s) only in the form, manner and logotype approved in writing by Alexion.

(c) Product Trademark Enforcement. If XOMA or Alexion has knowledge of any suspected infringement of the Product Trademark(s) by Third Parties, the Party having such knowledge shall promptly inform the other Party of such infringement. Alexion and XOMA

shall thereafter consult and cooperate fully to determine a course of action, including the commencement of legal action by Alexion to terminate any such infringement. In connection with any such action, XOMA will cooperate fully and will provide Alexion with any information or assistance that Alexion may reasonably request. Alexion may settle, compromise or otherwise dispose of any such proceeding that concerns the validity of any Product Trademark at its discretion, all costs of which will be considered Commercialization Expenses and all awards in connection therewith will be included in Gross Sales upon receipt.

(d) Product Trade Dress. Alexion shall be solely responsible for package design and trade dress used for Products in the Field in the Territory, except for Products in Future Indications as to which Alexion has Opted Out and not Opted Back In, in which case XOMA shall be solely responsible therefor.

**9.6 Improvements to Certain Excluded Technology**. Notwithstanding anything in this Agreement to the contrary, all additions, developments, modifications, enhancements, adaptations and improvements developed hereunder which relate to XOMA Ireland Limited's bacterial cell expression technology ("Improvements"), including any new patents or patent applications included therein, whether from work by or on behalf of Alexion or XOMA, shall be owned by XOMA, XOMA Ireland Limited or their Affiliates and not by Alexion, any of its Affiliates or any Third Party, except to the extent, but only to the extent, that one or more employees, consultants or agents of Alexion or any other persons obligated to assign such Improvement to Alexion is an inventor thereof under United States patent law. XOMA will procure for the benefit of Alexion or a designee of Alexion a non-exclusive, royalty-free, fully paid-up, license under such Improvements to discover, use, develop, make, have made, sell, offer for sale, import or export Products. [*]

## 10. CONFIDENTIALITY

**10.1 Confidentiality**. Except as specifically permitted hereunder, each Party hereby agrees to hold in confidence and not use on behalf of others all (a) data, samples, technical and economic information (including the economic terms hereof), commercialization, clinical and research strategies, know-how and other information provided by one Party (the "Disclosing Party") to the other (the "Receiving Party") during the Term of this Agreement and (b) all data, results and information developed pursuant to the Collaboration and owned solely by the other Party (collectively, the "Confidential Information"), except that the term "Confidential Information" shall not include:

(a) information that is or becomes part of the public domain through no fault of the Receiving Party or its Affiliates;

(b) information that is obtained after the date hereof by the Receiving Party or one of its Affiliates from any Third Party that is lawfully in possession of such Confidential Information and not in violation of any contractual or legal obligation to the Disclosing Party with respect to such Confidential Information;

(c) information that is known to the Receiving Party prior to disclosure by the Disclosing Party, as evidenced by the Receiving Party's written records;

(d) information that is necessary or advantageous to be disclosed to any Regulatory Authorities or pursuant to any regulatory filings, *provided* that in such case the Receiving Party notifies the Disclosing Party reasonably in advance of such disclosure and cooperates with the Disclosing Party to minimize the scope and content of such disclosure;

(e) Information that is, in the opinion of legal counsel to the Receiving Party required to be disclosed pursuant to any relevant law, rule or regulation or under order of a court of competent jurisdiction, *provided* that in such case the Receiving Party notifies the Disclosing Party reasonably in advance of such disclosure and cooperates with the Disclosing Party to minimize the scope and content of such disclosure; and

(f) Information that either Party determines is reasonably necessary to be disclosed to any potential or actual Marketing/Development Partner or other Third Party involved in the use, development, manufacture, sale, importation or exportation of a Product.

Notwithstanding the foregoing, any information meeting the criteria of clauses (d), (e) or (f) of this Section 10.1 shall nonetheless retain its status as Confidential Information in the hands of the Receiving Party with respect to any Third Parties other than those described in the applicable clause (d), (e) or (f).

**10.2 Survival**. The obligations of this Article 10 shall survive for the longer of (i) the last to expire Valid Claim and (ii) five (5) years following the expiration or termination of this Agreement except to the extent required by any longer obligations of confidentiality to a Third Party that are disclosed to the Receiving Party prior to termination of this Agreement.

**10.3 Publicity**. All publicity, press releases and other announcements relating to this Agreement or the transactions contemplated hereby shall be reviewed in advance by and subject to the approval of both Parties; except that such review and approvals shall not be required for any announcement that discloses the existence of this Agreement without disclosing any of its non-public material terms. The parties hereby agree to the release of a press release in the form attached hereto as Schedule 10.3 upon full execution of this Agreement and that the consummation of this Agreement, as well as such terms as are expressly described in such press release, shall be deemed to be in the public domain.

**10.4 Publication**. The Parties shall cooperate in appropriate publication of the results of research and development work performed pursuant to this Agreement, but subject to the predominating interest to obtain patent protection for any patentable subject matter and to maximize the commercial potential of any Products. Prior to any public disclosure of any such results, the Party proposing disclosure shall send the Development Committee a copy of the information to be disclosed, and shall allow the Development Committee thirty (30) days from the date of receipt in which to review the proposed disclosure. If notification is not received during the thirty (30) day period, the Party proposing disclosure shall be free to proceed with the disclosure. If due to a business reason or a belief by the Development Committee that the disclosure contains subject matter for which a patentable invention should be sought, then prior to the expiration of the thirty (30) day period, the Development Committee shall so notify the disclosing Party, who shall then delay public disclosure of the information for an additional period of up to ninety (90) days to permit the preparation and filing of a patent application on the subject matter to be

disclosed or other action to be taken. The Party proposing disclosure shall thereafter be free to publish or disclose the information, subject to any reductions or modifications requested by the Development Committee. The determination of authorship for any paper shall be in accordance with accepted scientific practice. Nothing in this Section 10.4 will be construed to allow either Party to disclose the Confidential Information of the other Party in any publication or other disclosure without the express written consent of such other Party.

## 11. REPRESENTATIONS AND WARRANTIES

**11.1 Legal Authority**. Each Party represents and warrants to the other that it has the legal power, authority and right to enter into this Agreement and to perform its respective obligations set forth herein.

**11.2 No Conflicts**. Each Party represents and warrants that as of the date of this Agreement it is not a party to any agreement or arrangement with any Third Party or under any obligation or restriction, including pursuant to its organizational documents, which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement.

**11.3 Others Bound**. Each Party represents and warrants that anyone performing services under this Agreement on its behalf shall be bound by all of the conditions of this Agreement.

**11.4 Survival**. The foregoing representations and warranties shall survive the execution, delivery and performance of this Agreement, notwithstanding any investigation by or on behalf of either Party.

## 12. DISPUTE RESOLUTION

**12.1 Disputes**. (a) Generally. The Parties recognize that disputes as to certain matters may from time to time arise under this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 12 if and when a dispute arises under this Agreement. Disputes among the Parties will be resolved as follows: for matters not within the purview of the Development Committee or in the event the Development Committee has authority to resolve such matter but fails to do so, the JMC, upon written notice by any Party, shall seek to resolve the dispute. If the JMC is unable to resolve such dispute within fourteen (14) days of being requested to do so or the JMC agrees in advance of fourteen (14) days that it is unable to resolve a dispute among its members, the dispute will be referred to the President of Alexion and the Chief Executive Officer or Chief Operating Officer of XOMA. If after twenty-one (21) days from such referral a dispute remains unresolved, the Parties agree to refer the matter to mediation pursuant to Section 12.2(a). If after thirty (30) days from referral to such mediation (as extended with the mutual consent of the Parties, not to be unreasonably withheld), a dispute (except any dispute relating to intellectual property described in Section 12.4) cannot be resolved by mediation, then (A) as to any such dispute relating to any activities or decisions (including without limitation any failure to act or decide) (I) concerning any Product [*] and (II) concerning [*] matters regarding any Product [*] (any dispute described in this clause (A), an "[*] Dispute"), the Parties agree to

submit to arbitration pursuant to Section 12.2(b) and (B) as to any such dispute that is not an [*] Dispute, Alexion shall be entitled to make a final determination of the dispute following good faith participation in the procedures set forth in this Section 12.1(a), except for an Arbitrable Dispute, which shall be submitted to arbitration pursuant to Section 12.2(b). Any final determination by Alexion made pursuant to [*] shall (1) be accompanied by a written explanation thereof setting forth in reasonable detail Alexion's basis for making such determination, together with any supporting materials necessary for a reasonably complete understanding of such determination, and (2) shall follow Alexion's good faith review of [*]. In no event shall the provisions of this Section 12.1 be considered a waiver by either Party of any of its or the other Party's contractual rights and obligations under this Agreement. For the avoidance of doubt, non-Arbitrable Disputes shall be resolved by Alexion, subject only to this Section 12.1(a).

(b) Section 5.1 Disputes. Notwithstanding anything herein to the contrary, any Section 5.1 Dispute will be subject to the provisions of this Article 12 with the following modifications: (i) a Section 5.1 Dispute will be referred immediately to the President of Alexion and the Chief Executive Officer or Chief Operating Officer of XOMA, without deliberation by the Development Committee or further deliberation by the JMC; and (ii) if after five (5) business days from such referral a Section 5.1 Dispute remains unresolved, the Parties agree to submit directly to arbitration pursuant to Section 12.2(b).

**12.2 Mediation and Arbitration**. (a) Mediation. If a dispute arises between the Parties under this Agreement for which mediation is required pursuant to Section 12.1, the Parties agree to try in good faith to resolve such dispute in an expeditious manner by mediation administered by the CPR Institute for Dispute Resolution or its successor organization ("CPR") in accordance with its Mediation Procedure. The mediation proceeding shall be conducted at the location of the Party not originally requesting the resolution of the dispute. The Parties agree that they shall share equally the cost of the mediation filing and hearing fees and the cost of the mediator. Each Party must bear its own attorney's fees and associated costs and expenses. For the avoidance of doubt, nothing in connection with such mediation shall be binding on either Party, except for the provisions regarding sharing of costs set forth in this Section 12.2(a).

(b) Arbitration. (i) If an Arbitrable Dispute cannot be resolved pursuant to Section 12.2(a) within the time period provided in Section 12.1, then, upon ten (10) days written notice, either Party may initiate arbitration by giving notice to that effect to the other Party and by filing the notice with the CPR in accordance with its Rules for Non-Administered Arbitration. Such dispute shall then be settled by arbitration in New York in accordance with the Rules for Non-Administered Arbitration of the CPR or other rules agreed to by the Parties, by a panel of three neutral arbitrators, who shall be selected by the Parties using the procedures for arbitrator selection of the CPR. Discovery shall be limited to that which the panel determines is appropriate in the circumstances, taking into account the needs of the Parties and the desirability of making discovery expeditious and cost-effective. The Parties acknowledge that the primary purpose of this Section 12.2 is to promote dispute resolution in a fair and expeditious manner.

(ii) The Parties acknowledge that this Agreement evidences a transaction involving interstate commerce. Insofar as it applies, the United States Arbitration Act shall govern the interpretation of, enforcement of, and proceedings pursuant to the arbitration clause in this Agreement. Except insofar as the United States Arbitration Act applies to such matters, the agreement to arbitrate set forth in this Section 12.2(b) shall be construed, and the legal relations among the Parties shall be determined in accordance with, the substantive laws of New York.

(iii) The panel shall render its decision and award, including a statement of reasons upon which such award is based, within thirty (30) days after the arbitration hearing. The decision of the panel shall be determined by majority vote among the arbitrators, shall be in writing and shall be binding upon the Parties, final and non-appealable. Judgment upon the award rendered by the panel may be entered in any court having jurisdiction thereof in accordance with Section 12.3.

(iv) Except as required under the United States Arbitration Act and as set forth in Section 12.4, no action at law or in equity based upon any dispute that is subject to arbitration under this Section 12.2(b) shall be instituted.

(v) All expenses of any arbitration pursuant to this Section 12.2(b), including fees and expenses of the Parties' attorneys, fees and expenses of the arbitrators, and fees and expenses of any witness or the cost of any proof produced at the request of the arbitrators, shall be (A) if the arbitration is of a Section 5.1 Dispute, shared equally by the Parties, and (B) if the arbitration is of a dispute other than a Section 5.1 Dispute, paid by the non-prevailing Party. In the latter case, the panel of arbitrators shall determine which Party is the non-prevailing Party.

**12.3 Jurisdiction**. For the purposes of this Article 12, the Parties agree to accept the jurisdiction of the federal courts located in the Southern District of New York for the purposes of enforcing the agreements reflected in this Article 12.

**12.4 Determination of Patents and Other Intellectual Property**. Any dispute relating to the determination of ownership, validity or infringement by the other Party of a Party's patents shall be submitted exclusively to the federal courts located in the Southern District of New York, and the Parties hereby consent to the jurisdiction and venue of such court.

**13. TERM AND TERMINATION**

**13.1 Term**. This Agreement shall commence as of the Effective Date. Unless sooner terminated as provided herein and except as provided below, the provisions of this Agreement relating to Development, Commercialization (including the sharing of Operating Profits/Losses) and Manufacture of Products in the Field (including any Future Indication as to which both parties are participating) shall continue in effect until, and such provisions shall expire upon, the date on which all such Development has been discontinued and all Products Developed hereunder are no longer being sold in any country of the Territory.

**13.2 Termination Rights**. (a) XOMA Without Cause. XOMA may terminate this Agreement without cause following six (6) months written notice to Alexion. XOMA shall honor all of its obligations, including financial, during such six (6) month term.

(b) Either Party for Breach. Upon any material breach of this Agreement by a Party (the "Breaching Party"), the other Party (the "Non-Breaching Party") may terminate this Agreement by providing thirty (30) day's written notice to the Breaching Party in the case of a breach of a payment obligation and sixty (60) days' written notice to the Breaching Party in the case of any other material breach. Such notice shall describe the alleged breach with sufficient

particularity to allow the Breaching Party to remedy or otherwise respond, and shall expressly state the intent to terminate under this Section 13.2(b). The termination shall become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period. Notwithstanding the foregoing, (i) if such breach, by its nature, is incurable, the Non-Breaching Party may terminate this Agreement immediately upon written notice to the Breaching Party and (ii) if such breach (other than a payment breach), by its nature, is curable, but not within the forgoing cure period, then such cure period shall be extended if the Breaching Party provides a written plan for curing such breach to the Non-Breaching Party and uses commercially reasonable efforts to cure such breach in accordance with such written plan; *provided*, that no such extension shall exceed ninety (90) days without the consent of the Non-Breaching Party.

(c) Either Party For Bankruptcy. If voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within sixty (60) days after the date of filing, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within sixty (60) days thereafter, the other Party may immediately terminate this Agreement effective upon notice of such termination.

**13.3 Pre-Termination Rights**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination or expiration. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

**13.4 Remedies**. In the event of any breach of any provision of this Agreement, in addition to the termination rights set forth herein, each Party shall have all other rights and remedies at law or equity to enforce this Agreement.

**13.5 Post-Termination Rights**. (a) In the event of termination by Alexion under Section 13.2(b) or (c) or by XOMA under Section 13.2(a), XOMA will (i) in the event of a termination pursuant to Section 13.2(a) or (b), at Alexion's request continue to honor all of its obligations hereunder for the six (6) month period following notice of termination by XOMA under Section 13.2(a) or the six (6) month period following written notice of termination by Alexion under Section 13.2(b), including cost obligations, (ii) at Alexion's request, in good faith negotiate to enter into a manufacturing agreement with Alexion, on commercial terms similar to those being made available by XOMA for manufacturing at that time, for the manufacture and supply of Product sufficient to satisfy reasonably anticipated demand (clinical and/or commercial) for a period of (x) in the event such termination occurs prior to completion (i.e., last patient dosing) of the first Phase III Study of a Product in the Field, eighteen (18) months following such termination, and (y) in the event such termination occurs after completion of the first Phase III Study of a Product in the Field, three (3) years following such termination, and (iii) at Alexion's request, (A) provide technology transfer and other assistance reasonably necessary to establish Alexion, Alexion's Affiliates or any Third Party as a manufacturer of Product, in which case Alexion will reimburse all of XOMA's reasonable costs associated with such transfer and assistance, (B) Alexion shall have an exclusive (even as to XOMA), royalty-free, fully paid-up, sublicensable

license under the XOMA Technology to use, develop, make, have made, sell, have sold, offer for sale, import and export Product in the Territory, and (C) notwithstanding that nothing in this Agreement shall constitute a license to XOMA Ireland Limited's bacterial cell expression technology, if necessary, procure from XOMA Ireland Limited a license to such technology for the benefit of such a Third Party manufacturer of a scope substantially similar to the Non-Exclusive XOMA Ireland License on commercial terms that have the same net effect on Alexion as the commercial terms being made available by XOMA Ireland Limited for licenses to such technology at that time. Alexion shall use commercially reasonable efforts to procure the manufacture and supply of Product as soon as practicable following any such termination. The eighteen (18) month and three (3) year periods referred to in clause (ii) above shall be reduced to the extent XOMA provides Alexion an inventory of the Product in question, taking into account the estimated shelf life of such Product, sufficient to satisfy the reasonably anticipated demand (pursuant to any existing forecast or reasonably agreed forecasts if one does not exist) that could be manufactured during such eighteen (18) month or three (3) year period, as the case may be.

(b) In the event of termination by XOMA under Section 13.2(c), (i) Alexion will, at XOMA's request, provide technology transfer and other assistance reasonably necessary for the Development or Commercialization of any Product in the Field, in which case XOMA will reimburse all of Alexion's reasonable costs associated with such transfer and assistance, and (ii) XOMA shall have an exclusive (even as to Alexion), royalty-free, fully paid-up, sublicensable license under the Alexion Technology to use, develop, make, have made, sell, have sold, offer for sale, import and export Product in the Field in the Territory. In the event of termination by XOMA under Section 13.2(b), XOMA will have recourse to seek damages under law or equity, without application of Article 12.

(c) Upon expiration of this Agreement pursuant to Section 13.1, *provided* that XOMA has at the time of expiration completed a Phase II Study for a Product in any Future Indication which Alexion has not Opted Back In to prior to such expiration, XOMA shall have an exclusive (even as to Alexion), sublicensable license under the Alexion Technology to use, develop, make, have made, sell, have sold, offer for sale, import and export Products only for such Future Indication(s) in the Territory. In respect of such Product(s), XOMA shall pay Alexion the royalty provided in Section 7.5(a). Upon expiration of this Agreement pursuant to Section 13.1, *provided* that Alexion has at the time of expiration completed a Phase II Study for a Product in any Future Indication which XOMA has not Opted Back In to prior to such expiration, Alexion shall have an exclusive (even as to XOMA), sublicensable license under the XOMA Technology to use, develop, make, have made, sell, have sold, offer for sale, import and export Products only for such Future Indication(s) in the Territory. In respect of such Product(s), Alexion shall pay XOMA the royalty provided in Section 7.5(a).

**13.6 Third Party Obligations**. The Parties anticipate that they each may enter into certain contracts with Third Parties in connection with the Development, Manufacture and/or Commercialization of Products in accordance with the relevant Development Plan and related budget ("Third Party Contracts"). In the event that XOMA terminates this Agreement under Section 13.2(a) or Alexion terminates this Agreement under Section 13.2(b) or (c), then XOMA will promptly reimburse Alexion thirty percent (30%) of all cancellation or other costs incurred by Alexion in connection with termination of any Third Party Contracts within nine (9) months following termination of this Agreement. In the event that XOMA terminates this Agreement

under Section 13.2(b) or (c), then Alexion will promptly reimburse XOMA seventy percent (70%) of all cancellation or other costs incurred by XOMA in connection with termination of any Third Party Contracts within nine (9) months following termination of this Agreement.

## 14. GENERAL PROVISIONS

**14.1 Certain Claims**. (a) Alexion and XOMA each agrees to indemnify and hold harmless the other Party and its Affiliates and their respective employees, agents, officers, directors and permitted assigns (such Party's "Indemnified Group") from and against any claims, judgments, expenses (including reasonable attorneys' fees), damages and awards (collectively a "Claim") arising out of or resulting from (i) its negligence or misconduct in regard to any Product and (ii) a breach of any of its representations or warranties hereunder, except to the extent that such Claim arises out of or results from the negligence or misconduct of a Party seeking to be indemnified and held harmless or the negligence or misconduct of a member of such Party's Indemnified Group. An indemnified Party shall promptly give notice to the indemnifying Party of any information from which it should reasonably conclude an incident has occurred that could give rise to a Claim, and in the event a Claim is made or a suit is brought, all indemnified parties shall assist the indemnifying Party and cooperate in the gathering of information with respect to the time, place, and circumstances and in obtaining the names and addresses of any injured parties and available witnesses. The failure to give the notice referred to in the preceding sentence shall not relieve a Party of its indemnification obligations, except to the extent such failure prejudices the ability of the indemnifying Party to defend against such claim. No indemnified Party shall, except at its own cost, voluntarily make any payment or incur any expense in connection with any such Claim or suit without the prior written consent of the indemnifying Party. Each indemnified Party shall permit the indemnifying Party to assume the defense and settlement of any Claim. The obligations set forth in this Section 14.1(a) shall survive the expiration or termination of this Agreement.

(b) In the event of any Claim, including Claims related to products liability, arising out of or resulting from the Development, Commercialization, Manufacture, sale or clinical use of a Product but not arising out of or resulting from either Party's negligence or misconduct, such Claim shall be shared 70 (Alexion)/30 (XOMA) between the Parties (unless such Claim relates only to a particular Product in a particular Future Indication as to which one Party has Opted Out and not Opted Back In, in which case all such costs shall be borne by the other Party). Each Party shall promptly give notice to the other Party of any information from which it reasonably concludes an incident has occurred that could give rise to a Claim covered by this Section 14.1(b), and in the event such a Claim is made or a suit is brought, each Party shall assist the other Party and shall cooperate in the gathering of information with respect to the time, place, and circumstances, in obtaining the names and addresses of any injured parties and available witnesses and with all reasonable requests of its and the other Party's insurer or insurers. The failure to give the notice referred to in the preceding sentence shall not relieve a Party of its cost sharing obligations, except to the extent such failure prejudices the ability of the Party to defend against such claim. Each Party shall be entitled to utilize its own counsel in connection with any such Claim and, upon consent (not to be unreasonably withheld) by the other Party to the retention of such counsel, the fees and expenses of such counsel shall be shared as provided above. Alexion shall, and XOMA shall permit Alexion to, assume the defense and settlement of any such Claim (unless such Claim relates only to a particular Product in a particular Future

Indication as to which Alexion has Opted Out and not Opted Back In, in which case XOMA shall assume such defense); *provided* that XOMA retains the right, at its own expense, to be represented by its own counsel in connection with any such Claim. The obligations set forth in this Section 14.1(b) shall survive the expiration or termination of this Agreement.

(c) The Parties acknowledge that drug development, manufacturing and commercialization is risky and success is uncertain. Neither Party shall be liable to the other for consequential, punitive or other indirect damages for whatever reason in connection with performance or non-performance of its obligations and activities under this Agreement.

**14.2 Assignment/Change of Control**. (a) This Agreement may be assigned by either Party and shall be binding upon and inure to the benefit of the assignor's successors, legal representatives and assigns. In no event will any assignment relieve the assigning Party of its obligations hereunder. No assignment shall take effect until the assignee notifies the non-assigning Party of such assignment and the assignee agrees to be bound by all the terms, conditions and obligations of this Agreement.

(b) In the event of (i) a merger, consolidation, plan of exchange or other reorganization of XOMA Ltd. in which XOMA Ltd. is not the surviving party, or any other transaction or series of transactions that result in a Third Party (together with such entity's Affiliates) controlling XOMA Ltd., or (ii) the assignment by XOMA of this Agreement to any entity other than an Affiliate, and, in the case of either clause (i) or clause (ii), Alexion does not consent thereto (which consent shall not be unreasonably withheld), Alexion may terminate XOMA's right to Co-Promote Products hereunder. For the avoidance of doubt and without limitation, it shall not be unreasonable for Alexion to withhold its consent to assignment by XOMA to a competitor (meaning a Third Party that is developing or commercializing an identified product that is reasonably likely to be used in the same indication as, or to be clinically substitutable for, one or more Products being developed hereunder) of Alexion, or to a party with whom Alexion has had negotiations in which Alexion's participation was substantial or has had a commercial relationship in the past.

**14.3 Non-Waiver**. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

**14.4 Governing Law**. This Agreement shall be construed and interpreted in accordance with the laws of the State of New York, other than those provisions governing conflicts of law. Both Parties hereby submit to the exclusive personal jurisdiction of the state and federal courts sitting in New York State.

**14.5 Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by one Party to the other are, for all purposes of Section 365(n) of Title XI of the United States Code ("Title XI"), licenses of rights to "intellectual property" as defined in Title XI. During the Term of this Agreement each Party shall create and maintain current copies to the extent practicable of all such intellectual property. If a bankruptcy proceeding is commenced by or against one Party under Title XI, the other Party shall be entitled to a copy of any and all such intellectual property and all embodiments of such intellectual property, and the same, if not in the

possession of such other Party, shall be promptly delivered to it (a) upon such Party's written request following the commencement of such bankruptcy proceeding, unless the Party subject to such bankruptcy proceeding, or its trustee or receiver, elects within thirty (30) days to continue to perform all of its obligations under this Agreement, or (b) if not delivered as provided under clause (a) above, upon such other Party's request following the rejection of this Agreement by or on behalf of the Party subject to such bankruptcy proceeding. If a Party has taken possession of all applicable embodiments of the intellectual property of the other Party pursuant to this Section 14.5 and the trustee in bankruptcy of the other Party does not reject this Agreement, the Party in possession of such intellectual property shall return such embodiments upon request. If a Party seeks or involuntarily is placed under Title XI and the trustee rejects this Agreement as contemplated under 11 U.S.C. 365(n)(1), the other Party hereby elects, pursuant to Section 365(n) of Title XI, to retain all rights granted to it under this Agreement to the extent permitted by law.

**14.6 Partial Invalidity**. If and to the extent that any court or tribunal of competent jurisdiction holds any of the terms or provisions of this Agreement, or the application thereof to any circumstances, to be invalid or unenforceable in a final nonappealable order, the Parties shall use commercially reasonable efforts to reform the portions of this Agreement declared invalid to realize the intent of the Parties as fully as practicable, and the remainder of this Agreement and the application of such invalid term or provision to circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each of the remaining terms and provisions of this Agreement shall remain valid and enforceable to the fullest extent of the law.

**14.7 Notice**. Any notice to be given to a Party under this Agreement shall be in writing and shall be (i) personally delivered, (ii) delivered by a internationally recognized overnight courier or (iii) delivered by certified mail, postage prepaid, return receipt requested to the Party at the address set forth below for such Party:

To Alexion:

Alexion Pharmaceuticals, Inc.
President and Chief Operating Officer
352 Knotter Drive Cheshire,
Connecticut 06410

With a copy to

Vice President and General Counsel
Alexion Pharmaceuticals, Inc.
352 Knotter Drive
Cheshire, Connecticut 06410

To XOMA:

XOMA (US) LLC
2910 Seventh Street
Berkeley, California 94710
Attention: Legal Department

With a copy to

Vice President, Business Development
XOMA (US) LLC
2910 Seventh Street
Berkeley, California 94710

or to such other address as to which the Party has given notice thereof. Such notices shall be deemed given upon receipt.

**14.8 Headings**. The headings appearing herein have been inserted solely for the convenience of the Parties hereto and shall not affect the construction, meaning or interpretation of this Agreement or any of its terms and conditions.

**14.9 No Implied Licenses or Warranties**. No right or license under any patent application, issued patent, know-how or other proprietary information is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement. Neither Party warrants that any particular clinical or other studies will be conducted, or the success of those studies if conducted. Except as otherwise expressly stated herein, Alexion hereby disclaims any warranty expressed or implied as to any Product manufactured by or for, used, sold or placed in commerce by or on behalf of Alexion.

**14.10 Force Majeure**. No failure or omission by the Parties hereto in the performance of any obligation of this Agreement (other than a payment obligation) shall be deemed a breach of this Agreement, nor shall it create any liability, if the same shall arise from any cause or causes beyond the reasonable control of the affected Party, including, but not limited to, the following, which for purposes of this Agreement shall be regarded as beyond the control of the Party in question: acts of nature; acts or omissions of any government; any rules, regulations, or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; insurrection; riot; invasion; strikes; and lockouts or the like; *provided* that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes or nonperformance and shall continue performance hereunder with the utmost dispatch whenever such causes are removed.

**14.11 Survival**. Termination or expiration of the Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either party prior to such termination or expiration, including damages arising from any breach hereunder. In addition, Sections 4.14, 4.15, 4.16, 6.5, 8.1, 9.1, 9.4 and 9.6 and Articles 1, 10, 11, 12, 13 and 14 shall survive any such termination or expiration.

**14.12 Entire Agreement**. This Agreement constitutes the entire understanding between the Parties with respect to the subject matter contained herein and supersedes any and all prior agreements, understandings and arrangements whether oral or written between the Parties relating to the subject matter hereof. For the avoidance of doubt, the Non-Exclusive XOMA Ireland License continues in full force and effect.

**14.13 Amendments**. No amendment, change, modification or alteration of the terms and conditions of this Agreement shall be binding upon either Party unless in writing and signed by the Parties.

**14.14 Independent Contractors**. It is understood that both Parties hereto are independent contractors and engage in the operation of their own respective businesses, and neither Party hereto is to be considered the agent or partner of the other Party for any purpose whatsoever. Neither Party has any authority to enter into any contracts or assume any obligations for the other Party or make any warranties or representations on behalf of the other Party.

**14.15 Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed an original and both of which together shall constitute one and the same instrument.

**14.16 Conflicts**. In the event that there is a conflict between the text of this Agreement and any Schedule hereto, the text of this Agreement shall control.

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

| XOMA (US) LLC | | ALEXION PHARMACEUTICALS, INC. | |
|---|---|---|---|
| By: | /s/ Clarence L. Dellio | By: | /s/ Steven P. Squinto |
| Name: | Clarence L. Dellio | Name: | Steven P. Squinto, Ph.D. |
| Title: | Senior Vice President and Chief Operating Officer | Title: | Executive Vice President and Head of Research |

**SCHEDULE A**

**ANTIBODY 116**

[*]

**SCHEDULE B**

**DETERMINATION OF OPERATING PROFIT/LOSS**

**1. Definitions**. For the purpose of this Schedule B and where otherwise used in this Agreement, the following terms shall have the meanings set forth below:

**1.1** "Allocable Overhead" means costs incurred by a Party or for its account that are attributable to a Party's facilities and occupancy costs, corporate bonus (to the extent not charged directly to a department), and its supervisory, payroll, information systems, human relations and purchasing functions and that are allocated to company departments based on space occupied or headcount or other activity-based method. Allocable Overhead shall not include any costs attributable to general corporate activities, including, by way of example, executive management, investor relations, business development, legal affairs and finance.

**1.2** "Allowable Expenses" means the sum of the following (without any item being accounted for more than once):

(a) Costs of Goods Sold;

(b) Distribution Expenses;

(c) Sales and Marketing Expenses; and

(d) Commercialization Expenses.

**1.3** "Commercialization Expenses" means all actual costs and expenses (including labor) that are attributable to Commercialization activities, including Allocable Overhead. Commercialization Expenses shall include: (i) costs and expenses related to Phase III(b)/IV Studies related to Product, (ii) infrastructure required to support and maintain patient/safety surveillance as required by applicable Regulatory Authorities attributable to Product, including medical staff support and pharmacovigilence systems and procedures; (iii) out-of-pocket patent prosecution, enforcement and/or defense costs and expenses incurred by a Party in connection with claims instituted by either Party pursuant to Article 9 hereof, (iv) out-of-pocket costs and expenses of maintaining Regulatory Approvals in the Territory, (v) royalty and other amounts paid by a Party to Third Parties in connection with the use of Third Party technology related to the use or sale of Product, and all payments made to XOMA Ireland Limited under the Non-Exclusive XOMA Ireland License by Alexion (net of any amounts paid to Alexion by XOMA in respect thereof), (vi) the costs of product recalls, product liability claims, awards and damages, and Product liability insurance premiums, and (vii) costs and expenses incurred in connection with pricing and reimbursement matters, managed care and formulary management, and governmental affairs activities directly relating to a Product.

**1.4** "Cost of Goods Sold" or "COGS" means, to the extent that Product is sourced from XOMA, standard unit cost of manufacture of Product (i.e., direct material and direct labor costs, plus manufacturing overhead specifically attributable to Product, all calculated in

accordance with generally accepted accounting principles, consistently applied). Direct material costs means the actual costs incurred in manufacturing or purchasing materials, including freight-in costs, sales and excise taxes imposed thereon and customs duty and charges levied by government authorities, and all costs of packaging components. Direct labor costs means the actual cost of employees engaged in direct manufacturing activities and direct or indirect quality control and quality assurance activities who are directly employed in manufacturing and packaging Product. Overhead attributable to Product will include a reasonable allocation of indirect labor (not previously included in direct labor costs), a reasonable allocation of administrative costs, and a reasonable allocation of facilities costs, all in accordance with generally accepted accounting principles, consistently applied. Overhead will not include corporate administrative overhead or plant start-up costs or costs associated with excess capacity. All allocations will be based on the assumption that XOMA's plant and equipment are utilized to their reasonable full capacity. XOMA shall prepare a detailed breakdown of the components of Cost of Goods Sold from time to time upon request by the JMC.

To the extent that Product is sourced from a Third Party manufacturer, the actual price paid by a Party to the Third Party for the manufacture, supply and packaging of the Product shall be the Cost of Goods Sold.

**1.5** "Distribution Expenses" means Alexion's reasonable costs and expenses (including labor) related to storage and distribution of Product, including (i) handling and transportation to fulfill orders, (ii) customer services, including order entry, billing and adjustments, inquiry and credit and collection, (iii) cost of facilities and labor utilized for the storage and/or distribution of the Product and/or (iv) amounts paid to Third Parties in respect of storage and/or distribution of Product.

**1.6** "Gross Sales" means the gross amount invoiced for sales of a Product sold by Alexion or its Affiliates to Third Parties less reasonable Sales Returns and Allowances. In the case of any sale of a Product between or among Alexion or its Affiliates, Gross Sales shall be calculated only on the value charged or invoiced on the first arm's length sale thereof to a Third Party.

In the event a Product is sold as part of a Combination Product (as defined below), the Gross Sales from the Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Gross Sales of the Combination Product, during the applicable reporting period, by the fraction, A/(A+B), where A is the weighted average sale price of the Product when sold separately in finished form in the country in which the Combination Product is sold and B is the weighted average sale price of the other product(s) included in the Combination Product when sold separately in finished form in the country in which the Combination Product is sold, in each case during the applicable royalty reporting period. In the event that such average sale price cannot be determined for both the Product and all other product(s) included in the Combination Product, Gross Sales shall be mutually agreed by the Parties in good faith based on the relative value contributed by each component. As used above, the term "Combination Product" means any product that comprises the Product and other active compounds and/or active ingredients that are not themselves the Product.

**1.7** "Marketing/Development Partner Revenue" means all license fees, royalties, milestone payments and other income or items of value received by Alexion or XOMA from a Marketing/Development Partner in respect of a Product, less any amounts specifically incurred in connection with acquiring such income (e.g., attorneys' fees to establish underlying agreements with a Marketing/Development Partner or any potential Marketing/Development Partner) and less any reasonable amounts for indemnity actually paid by Alexion or XOMA under any agreements with a Marketing/Development Partner.

**1.8** "Sales and Marketing Expenses" means all reasonable costs and expenses (including labor) that are attributable to the distribution, sale, promotion and marketing of a Product (including all pre-launch activities), calculated on a fully burdened basis, including Allocable Overhead attributable thereto. Sales and Marketing Expenses include the following:

"Advertising" means all media costs and expenses associated with Product advertising including: production expense/artwork including set up; design and art work for an advertisement; the cost of securing print space, air time, etc. in newspapers, magazines, trade journals, television, radio, billboards, etc.

"Consumer Promotion" means all costs and expenses associated with programs to promote a Product directly to the prescriber or end user, including expenses associated with promoting the Product directly to the professional community such as professional samples, professional literature, promotional material costs, patient aids and detailing aids.

"Education" means all costs and expenses associated with professional education with respect to a Product through any means, including articles appearing in journals, newspapers, magazines or other media; seminars, and conventions; symposia, advisory boards and opinion leader development activities; and the costs and expense of medical liaisons.

"Market and Consumer Research" means all compensation and departmental expenses for market and consumer research personnel and payments to Third Parties related to conducting and monitoring professional and consumer appraisals of existing, new or proposed competitors to the Product, such as market share services (e.g., IMS data), special research testing and focus groups.

"Marketing Management" means all product management and sales promotion management compensation and departmental costs and expenses, including costs associated with developing overall sales and marketing strategies (e.g., product line or customer segment), as well as planning and programs for the Product. In addition, payments to Third Parties in connection with trademark selection, filing, prosecution and enforcement will be included in this category.

"Selling Expenses" means all costs directly associated with the efforts of field sales representatives with respect to the Product to the extent approved by the JMC, including field sales force; field sales offices; district, regional and home offices; staffs directly involved in the management of and the performance of the selling functions; sales

training and meetings; call reporting and other monitoring/tracking activities, and payments to Third Parties under contract sales and marketing agreements. The costs of detailing sales calls will be as approved by the JMC.

"Trade Promotion" means all allowances given to retailers, brokers, distributors, hospital buying groups, etc. for purchasing, promoting, and distribution of the Product, including purchasing, advertising, new distribution, and display allowances as well as free goods, wholesale allowances and reasonable field sales samples.

**1.9.** "Sales Returns and Allowances" with respect to a Product, means: (a) ordinary and customary trade discounts actually allowed; (b) credits, rebates and returns (including, but not limited to, wholesaler and retailer returns); (c) payments and rebates directly related to the sale of Product accrued, paid or deducted pursuant to agreements with managed care organizations or governmental regulations; (d) freight, postage, insurance and duties paid; (e) excise taxes, other consumption taxes, customs duties and compulsory payments to governmental authorities whether or not specifically identified as such in the invoice to the Third Party and (f) bad debt expense.

**2. Operating Profit/Loss**. Operating Profit/Loss shall be calculated by determining, in the manner provided in Section 3 below, the sum of Gross Sales of the Product and Marketing/Development Partner Revenue and then subtracting the Allowable Expenses incurred by Alexion and XOMA in respect of Products in the relevant time period.

**3. Quarterly Reporting and Reconciliation.**

**3.1** Within thirty-five (35) days after the end of each calendar quarter, XOMA shall submit a written report to Alexion setting forth in reasonable detail Marketing/Development Partner Revenues and Allowable Expenses incurred by or on behalf of XOMA in the Territory during such calendar quarter. Within forty-five (45) days after the end of each calendar quarter, Alexion shall submit a written report to XOMA setting forth in reasonable detail Gross Sales (including Sales Returns and Allowances), Marketing/Development Partner Revenues and Allowable Expenses (including Cost of Goods Sold, Distribution Expenses, Sales and Marketing Expenses and Commercialization Expenses) incurred by or on behalf of Alexion in the Territory during such calendar quarter. Such report shall also set forth in reasonable detail the calculation of Operating Profit/Loss and the calculation of any net amount owed by Alexion to XOMA or by XOMA to Alexion, as the case may be, in order to ensure the sharing of Operating Profit/Loss specified in Section 6.4. For the avoidance of doubt, the Parties intend that, after reconciliation, (A) Alexion will have paid for seventy percent (70%) of the Allowable Expenses and received seventy percent (70%) of the Operating Profit/Loss; and (B) XOMA will have paid for thirty percent (30%) of the Allowable Expenses and received thirty percent (30%) of the Operating Profit/Loss, except as provided in Section 3.6(a).

The net amounts payable under this subsection shall be paid by Alexion or XOMA, as the case may be, within forty-five (45) days after the end of the relevant calendar quarter.

**3.2** Costs and expenses included in Cost of Goods Sold, Distribution Expenses, Sales and Marketing Expenses and Commercialization Expenses shall not be double counted (i.e., any item of expense included in any expense category shall not also be included in any other expense category).

**SCHEDULE 3.2**

## INITIAL DEVELOPMENT PLAN

**Preclinical Research**

| Function [*] | Total Estimated Costs | Comments |
|---|---|---|
| **Cell & Analytical Biology** | | |
| [*] | | |
| Assay Development Sample Analysis | [*] | PK assay, immunogenicity assay for mouse, rat and/or rabbit/monkey. [*] |
| In vitro assay | [*] | [*] |
| Sub Total | [*] | |
| **Pharmacokinetics** | | |
| [*] | | |
| mouse, rat and rabbit/monkey PK/PD studies | [*] | PK studies in three species for lead candidate. Additional mouse PK studies with 2 back-up molecules. |
| Sub Total | [*] | |
| Pharmacology | | |
| [*] | | |
| in vitro and in vivo efficacy studies | [*] | [*]performing in vitro and in vivo efficacy studies. |
| Sub Total | [*] | |
| **Toxicology & Safety** | | IND-enabling studies for entry into phase 1 clinical trial |
| [*] | | |
| single-dose tox/tk | [*] | acute safety studies – 3 species |
| multi-dose tox/tk | [*] | 28 day toxicology rodent and non-rodent species |
| local tolerance study – GP | [*] | |
| tissue cross-reactivity | [*] | |
| hyper-immunization study | [*] | safety study – immunogenicity |
| protocol design/monitor studies/audit report | [*] | |
| Sub Total | [*] | |
| Total Preclinical Costs | [*] | |

| Function [*] | FTE | Timeframe | Estimated Cost |
|---|---|---|---|
| **Development Work** | | | |
| [*] | | | |
| Fermentation / Recovery / Purification | [*] | [*] months | [*] |
| Cell Banks (documents / preparation) | [*] | [*] months | [*] |
| Assay Development | [*] | [*] months | [*] |
| Quality (QA, QC, Doc Control) | [*] | [*] months | [*] |
| Development lot at scale | [*] | [*] month | [*] |
| Total | [*] | [*]months | [*] |
| **Production 2-3 GMP lots** | | | |
| [*] | | | |
| Ferm., Harvest, Purification | [*] | [*] months | [*] |
| Documents | [*] | [*] months | [*] |
| TM prep, testing, release | [*] | [*] months | [*] |
| Quality (QA, QC, Doc. Control) | [*] | [*] months | [*] |
| Purchasing & Materials | [*] | [*] months | [*] |
| IQA | [*] | [*] months | [*] |
| Total | [*] | [*] months | [*] |
| **Other Costs** | | | |
| [*] | | | |
| Prepare and File CMC | [*] | [*] months | [*] |
| Stability Studies | [*] | [*] months | [*] |
| Tech. Transfer to Mfg. | [*] | [*] months | [*] |
| Total | | [*] months | [*] |
| **Outside costs** | | | |
| [*] | | | |
| Cell bank characterization | | | [*] |

[*]