18-02530-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Friday, February 16, 2018 7:29 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.1 to the Form 8-K, as amended, filed by Pozen, Inc. on 1/11/2006. Confidential treatment was sought as to certain portions when initially filed with the Commission.

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

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

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

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

Office of FOIA Services

March 14, 2018

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

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02530-E

Dear Mr. Edwards:

This letter is in response to your request, dated February 16, 2018 and received in this office on February 20, 2018, for access to Exhibit 10.1 to the Form 8-K, as amended, filed by Pozen, Inc. on January 11, 2006.

In connection with a previous request, access was granted to the subject exhibit. Therefore, we have determined to release the same exhibit to you in CD format. No fees have been assessed in this instance.

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid
FOIA Lead Research Specialist

Enclosure

10.1

TABLE OF CONTENTS

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

DEVELOPMENT, OPTION AND LICENSE AGREEMENT

THIS DEVELOPMENT, OPTION AND LICENSE AGREEMENT (the **"Agreement"**) is entered into as of the 15th day of May, 2003 (the **"Effective Date"**), by and between **POZEN INC.**, a Delaware corporation, located at 1414 Raleigh Road, Suite 400, Chapel Hill, NC 27517 on behalf of itself and its Affiliates (collectively **"POZEN"**), and **NYCOMED DANMARK APS**, a Danish corporation, located at Langebjerg 1, DK-4000 Roskilde, Denmark on behalf of itself and its Affiliates (collectively **"Nycomed"**). POZEN and Nycomed are referred to in this Agreement individually as a **"Party"** and collectively as **"Parties."**

RECITALS

A. Nycomed and POZEN are engaged in the development, production, and commercialization of pharmaceutical products and possess information and technology relating to the manufacture, use, and formulation of such products.

B. POZEN desires to obtain the right to perform research based upon certain proprietary information owned or controlled by Nycomed, and the option to license certain intellectual property and proprietary information of Nycomed for the development and commercialization of certain pharmaceutical products upon the terms and conditions set forth in this Agreement.

C. Nycomed desires to grant such research rights and option to POZEN upon the terms and conditions set forth in this Agreement.

D. The Parties desire to enter into an arrangement for the supply of active drug substance for use in the commercial manufacture of certain pharmaceutical products developed by POZEN pursuant to this Agreement.

AGREEMENT

In consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of

which is hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

The capitalized terms used in this Agreement will have the meanings given to them in this Section 1 and throughout this Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

1.1 **"Affiliate"** means a corporation or other business entity which, (i) directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with either POZEN INC. or Nycomed Danmark ApS, and (ii) from time to time either POZEN INC. or Nycomed Danmark ApS respectively desires to involve in the performance of this Agreement, and POZEN INC. will so involve any such corporation or other business entity, which has, either directly or indirectly, any requirements of LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof) for the purposes provided for under Section 7.1 of this Agreement. Each of POZEN INC. and Nycomed Danmark ApS will notify the other in writing if and as soon as it desires to involve any such corporation or other business entity in the performance of this Agreement and Nycomed Danmark ApS hereby notifies POZEN INC. that it will so involve Nycomed Austria GmbH, St. Peter-Straße 25, A-4020 Linz, Austria. For purposes of this definition only, "control" and, with corresponding meanings, the terms "controlled by" and "under common control with" means: (a) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a legal entity.

1.2 **"Buyer"** means each of POZEN and Sublicensees.

1.3 **"cGMP"** means current good manufacturing practices for medicinal products established by regulations in the United States (including 21 CFR §§ 210 and 211, and, with respect to any Nycomed Product and placebo used in clinical trials, subject to the FDA's March 1991 Guideline on the Preparation of Investigational New Drug Products, each as amended, and any successor regulations thereto), and the

corresponding rules, regulations, or guidelines in the European Union and Canada.

1.4 **"Combination Product"** means a pharmaceutical product containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more additional active drug substances, and (a) developed or manufactured by or on behalf of POZEN or Sublicensees using or referencing the Licensed Technology or any part thereof, or (b) the use, manufacture or sale of which would, but for the licenses granted herein, infringe any Licensed Patents or intellectual property right other than Patents included in the Licensed Technology.

1.5 **"Commercialization"** means the marketing, promotion, advertising, selling or distribution for sale of a POZEN Product in a country after Marketing Approval has been obtained in such country. The term "Commercialize" has a corresponding meaning.

1.6 **"Commercially reasonable efforts"** means, with respect to a Party, those efforts, consistent with the exercise of prudent scientific and business judgment, to conduct a particular activity hereunder that would be applied to a similar activity conducted by other companies in the pharmaceutical industry, and, if related to the development or Commercialization of POZEN Products, those efforts, consistent with the exercise of prudent scientific and business judgement, to conduct a particular activity hereunder that would be applied to a similar activity conducted by other companies in the pharmaceutical industry with respect to other pharmaceutical products of similar economic potential, risk and market size.

1.7 **"Control"** means, with respect to an entity and any Know-How, Patent or intellectual property right other than Patents, that such entity owns a transferable interest in or has a license or sublicense (for so long as such license or sublicense is in effect) to practice such Patent, right or Know-How and has the ability to grant another entity access, a license, or a sublicense (as applicable) to practice such Patent, right or Know-How without breaching an agreement with any Third Party and without imposing on such entity an obligation to make any payments to a Third Party as a result of such grant of access, license or sublicense or the exercise thereof by such entity.

1.8 **"Cost"** means any direct and indirect costs incurred by Nycomed in connection with the manufacture, quality control or release of Nycomed Products or placebo, calculated in accordance with international generally accepted accounting principles, consistently applied.

1.9 **"DMF"** means a drug master file filed in accordance with 21 CFR 314.420 and maintained with the FDA or the equivalent thereof, as applicable, in jurisdictions outside the United States.

1.10 **"Exclusive Manufacturing Period"** means, on a Buyer-by-Buyer basis: (a) with respect to the Exclusive Territory, the period commencing on the Option Exercise Date and continuing until the date five years after: either (i) the date of first commercial sale of the first POZEN Product sold in the United States by such Buyer, if such Buyer's territory to Commercialize such POZEN Product includes both the United States and Canada, or (ii) otherwise, the date of first commercial sale of the first POZEN Product sold anywhere in the Exclusive Territory by such Buyer; and (b) with respect to the Limited Territory, the period commencing on the Option Exercise Date and continuing until the date five years after: either (i) the date of first commercial sale of the first Combination Product sold in the United Kingdom, France or Germany by such Buyer, if such Buyer's territory to Commercialize such Combination Product includes one or more of those three countries; or (ii) otherwise, the date of first commercial sale of the first Combination Product sold anywhere in the Limited Territory by such Buyer.

1.11 **"Exclusive Territory"** means the United States (including the following territories and possessions: American Samoa, Commonwealth of Northern Marianas, Guam, Micronesia, Puerto Rico, U.S. Virgin Islands) and Canada.

1.12 **"Existing Nycomed Products"** means the pharmaceutical products which were developed by Nycomed and for which Nycomed filed for Marketing Approval prior to the Effective Date or which Nycomed commercialized prior to the Effective Date, containing Lornoxicam as the single active drug substance, a complete list of which is included as **Exhibit A** to this Agreement, attached hereto and hereby incorporated in this Agreement by reference, but excluding the products listed thereon as exceptions.

1.13 **"Existing Nycomed Product Deliverables"** means the materials listed in **Exhibit B** to this Agreement (attached hereto and hereby incorporated in this Agreement by reference) in such quantities as set forth in **Exhibit B** and conforming to the applicable Specifications.

1.14 **"FDA"** means the United States Food and Drug Administration, or any successor agency.

1.15 **"Field"** means the diagnosis, treatment, and prevention of human diseases and conditions.

1.16 **"IND"** means an investigational new drug application filed with the FDA.

1.17 **"IND Deliverables"** means the materials listed in **Exhibit C** and **Schedule C-1** to this Agreement (attached hereto and hereby incorporated in this Agreement by reference).

1.18 **"Initial Development Program"** has the meaning set forth in Section 2.2 of this Agreement.

1.19 **"Invention"** means any invention or discovery, whether or not patentable, conceived or reduced to practice by or on behalf of POZEN or Sublicensees in connection with this Agreement or a Sublicense Agreement.

1.20 **"Isomer Product"** means a pharmaceutical product containing an isomer of Lornoxicam as either the single active drug substance or as an active drug substance in combination with one or more other active drug substances, developed solely by Nycomed, and for which Nycomed files an IND or equivalent filing in the Exclusive Territory within five (5) years of the Effective Date.

1.21 **"Know-How"** means all non-public inventions, data, information, methods, procedures and processes relating to the manufacture, development, testing or use of a Nycomed Product or POZEN Product, including but not limited to, biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data (other than such Know-How which is or becomes the subject of a Patent).

1.22 **"Latent Defect"** means any failure of a shipment of Materials or portion thereof to conform at the date of delivery to the Product Warranty (as defined in Section 8.1) that would not be discoverable prior to the deadline for notice of rejection under Section 8.4.1(a) upon reasonable physical inspection or standard testing of such Materials in accordance with standards in the pharmaceutical industry, including in any event testing for purity and assay according to the methods included in the applicable Specifications.

1.23 **"Licensed Patents"** means the Patents listed on **Exhibit G** attached to this Agreement and hereby incorporated in this Agreement by reference.

1.24 **"Licensed Technology"** means any Know-How, Licensed Patents and intellectual property right other than Patents relating to the Nycomed Products and Controlled by Nycomed in the Exclusive Territory or the Limited Territory, as applicable, but excluding, in any event, (i) any Know-How, Patents, intellectual property right other than Patents Controlled by Nycomed that are related to the Process or to any other manufacturing process for LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof), and (ii) any trademark, trade name and trade dress of Nycomed and any Nycomed-specific packaging.

1.25 **"Limited Territory"** means the following countries: all member states of the European Union as of the Effective Date (excluding Spain, Portugal, and Italy), Armenia, Azerbaijan, Belarus, Estonia, Georgia, Iceland, Kazakhstan, Kyrgyzstan, Latvia, Liechtenstein, Lithuania, Moldova, Norway, Russia, Switzerland, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan.

1.26 **"Lornoxicam"** means the active drug substance known as lornoxicam, having the chemical structure set forth in **Exhibit D** to this Agreement (attached hereto and hereby incorporated in this Agreement by reference).

1.27 **"LX Bulk Drug Substance"** means Lornoxicam in bulk form, conforming to the applicable Specifications (as hereinafter defined).

1.28 **"MAA"** means any marketing authorization application submitted to the appropriate regulatory authorities to obtain approval for the marketing of a pharmaceutical product in any country of the European

Union and any corresponding submissions in any other country of the Territory, except the United States.

1.29 **"Manufacturing Approval"** means all filings, applications, licenses, permits, and other authorizations which are required for the manufacture of the Materials in compliance with applicable laws and regulations of the country of manufacture.

1.30 **"Marketing Approval"** means (i) approval of an NDA or the approval of an MAA; and (ii) any pricing and reimbursement approvals in any country of the Territory, to the extent the applicable regulatory authorities in such country require a pricing or reimbursement approval prior to commercialization of a pharmaceutical product in such country.

1.31 **"Materials"** means any Nycomed Product, placebo, or LX Bulk Drug Substance supplied by Nycomed to POZEN under this Agreement.

1.32 **"NDA"** means a new drug application submitted to the FDA to obtain FDA approval for the marketing of a pharmaceutical product in the United States.

1.33 **"Net Sales"** means with respect to any POZEN Product, the gross amount invoiced by POZEN or Sublicensees to Third Party customers for the sale of such POZEN Product, less: (i) allowances and credits extended to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned POZEN Products; (ii) the amounts of trade and cash discounts actually allowed on account of the purchase of POZEN Products; (iii) sales taxes, excise taxes, use taxes and import/export duties actually due or incurred in connection with the sales of a POZEN Product to any Third Party customer; (iv) allowances, adjustments, reimbursements, discounts, chargebacks and rebates granted to Third Party customers, including, but not limited to, rebates given to health care organizations or other Third Party customers who bought or pay for a POZEN Product; (v) any bona fide payment made to government agencies with respect to sales of POZEN Products in order to be allowed to tender the sale of the POZEN Products in a given country, and any bona fide payment made by POZEN to any Third Party customers for assistance provided to POZEN in this process; (vi) freight, postage, shipping, insurance, and packaging costs and other outbound transportation charges prepaid or allowed to the extent included as part of the invoiced amount;

and (vii) any amounts actually written off or specifically identified as uncollectible, in accordance with consistently applied accounting policies of POZEN; *provided, however,* that if the right to commercialize a POZEN Product is licensed to a Sublicensee, "Net Sales" as used herein with respect to such POZEN Product and such Sublicensee will have the meaning set forth in the applicable Sublicense Agreement with such Sublicensee, which definition will be substantially similar to the definition above. In any event, "Net Sales" excludes (a) the transfer of reasonable and customary quantities of free samples of POZEN Product to physicians for professional use, other than for subsequent resale, (b) the transfer of POZEN Product as clinical trial materials, other than for subsequent resale, and (c) the transfer of POZEN Product to any regulatory agency in a country in the Territory for use by such agency in connection with securing Marketing Approval for such POZEN Product in such country.

1.34 **"Nycomed Improvement Product"** means any pharmaceutical product containing Lornoxicam (including salts, solvates and polymorphs thereof) as the single active drug substance, developed solely by Nycomed, and: (a) for which Nycomed Controls all Know-How, Patents, and intellectual property rights other than Patents claiming the composition of matter, use or formulation of such product, and (b) for which Nycomed files for Regulatory Approval after the Effective Date or which Nycomed first commercializes after the Effective Date, and (c) which is an improvement (including a new dosage strength, dosage form, or indication) of an Existing Nycomed Product.

1.35 **"Nycomed Improvement Product Deliverables"** means the materials listed in **Exhibit E** to this Agreement (attached hereto and hereby incorporated in this Agreement by reference) in such quantities as set forth in **Exhibit E** and conforming to the applicable Specifications.

1.36 **"Nycomed IND"** means the IND with file # 28,285, filed with the FDA on April 23, 1986 and withdrawn on August 05, 1997.

1.37 **"Nycomed Product"** means any Existing Nycomed Product Nycomed Improvement Product.

1.38 **"Nycomed Product Deliverables"** means the Exis Nycomed Product Deliverables and the Nycomed Improvement Pro Deliverables.

1.39 **"Option"** has the meaning set forth in Section 3.1 of this Agreement.

1.40 **"Option Exercise Date"** means the date upon which POZEN provides Nycomed with the written notice of exercise described in Section 3.1 of this Agreement.

1.41 **"Option Period"** has the meaning set forth in Section 3.2 of this Agreement.

1.42 **"Patent"** means (a) all patents and patent applications in any country or supranational jurisdiction and (b) any substitutions, divisions, continuations, continuations in part, reissues, renewals, registrations, confirmations, reexaminations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications.

1.43 **"POZEN Product"** means any Combination Product or Single Entity Product.

1.44 **"Process"** means either the manufacturing process used by Nycomed as of the Effective Date for the manufacture of the LX Bulk Drug Substance or such process as changed by Nycomed from time to time in accordance with Section 9.6 of this Agreement.

1.45 **"Regulatory Approval"** means any approvals and any master files, establishment licenses, registrations or authorizations of any national, federal, state or local regulatory agency, department, bureau or other governmental entity necessary for the manufacture, use, storage, export, import, transport or sale of a pharmaceutical product in a country or other regulatory jurisdiction (including Marketing Approvals and the filing of an IND or a DMF).

1.46 **"Single Entity Product"** means a pharmaceutical product containing Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active drug substance, and (a) developed or manufactured by or on behalf of POZEN or Sublicensees using or referencing the Licensed Technology or any part thereof, or (b) the use, manufacture or sale of which would, but for the licenses granted herein, infringe any Licensed Patents or intellectual property right other than Patents included in the Licensed Technology.

1.47 **"Specifications"** means, with respect to Materials either, the specific chemical and physical properties pertaining to such Materials set forth on **Exhibit F** (attached hereto and hereby incorporated in this Agreement by reference), or such properties changed by Nycomed from time to time in accordance with Section 9.6 of this Agreement.

1.48 **"Sublicense Agreement"** means any agreement in which a Third Party is granted a sublicense under the licenses granted by Nycomed to POZEN in this Agreement, whether by POZEN or its sublicensee.

1.49 **"Sublicensee"** means any entity other than POZEN that is a party to a Sublicense Agreement.

1.50 **"Sublicense Revenues"** means any amount received by POZEN from a Sublicensee pursuant to a Sublicense Agreement as an upfront license fee or milestone payment.

1.51 **"Term"** has the meaning set forth in Section 16.1 of this Agreement.

1.52 **"Territory"** means the Exclusive Territory and the Limited Territory.

1.53 **"Third Party"** means any individual or entity other than POZEN INC., Nycomed Danmark ApS, and their respective Affiliates.

2. INITIAL DEVELOPMENT PROGRAM

2.1 **Re-Analysis of Carcinogenicity Data**. Within 30 days after the Effective Date, Nycomed will deliver to POZEN copies of all raw data and study reports generated by or on behalf of Nycomed in connection with the carcinogenicity studies conducted with Lornoxicam in rats and mice (collectively the **"Carcinogenicity Data"**). Nycomed will ship such copies DDU (ICC Incoterms 2000) to a place of destination to be named by POZEN within 10 days after the Effective Date. POZEN and/or its consultants (for and on behalf of POZEN) will, at POZEN's expense, commence with re-analyzing the Carcinogenicity Data promptly after delivery of the Carcinogenicity Data to POZEN. POZEN will use commercially reasonable efforts to complete such re-analysis as soon as reasonably practicable. POZEN will provide the results of such re-analysis to Nycomed upon completion thereof free of charge. Nycomed may use

such results for its internal research and development purposes and will otherwise treat such results as Confidential Information of POZEN subject to the terms and conditions set forth in Section 15 of this Agreement.

2.2 **Scope of Initial Development Program.** During the Option Period, POZEN will: (a) conduct development work for POZEN Products, including, by way of example, formulation studies and clinical proof of concept studies for POZEN Products, (b) use reasonable efforts to prepare and file an IND for a POZEN Product within 180 days from the delivery by Nycomed to POZEN of the IND Deliverables and the Existing Nycomed Product Deliverables (excluding any additional shipments thereof requested by POZEN pursuant to the delivery schedule set forth in **Exhibit B**), and (c) after acceptance of the IND, use reasonable efforts to perform such clinical studies for the POZEN Products as POZEN deems appropriate to determine its interest in exercising the Option (the **"Initial Development Program"**). POZEN will perform the Initial Development Program at its own expense. Nycomed understands and agrees that POZEN will have the right to reference the Nycomed IND and to use the IND Deliverables for the preparation and filing of new INDs for POZEN Products and the performance of the Initial Development Program. POZEN understands and agrees that the Nycomed IND was never updated and that Nycomed will not re-open or update such Nycomed IND in the future. POZEN further agrees that it will provide Nycomed as soon as reasonably practicable with a copy of the table of contents of any IND filed during the Option Period by or on behalf of POZEN for any POZEN Product, which POZEN may redact to avoid disclosure of the identity of the specific POZEN Product to which the IND relates.

2.3 **Nycomed Deliverables.** Nycomed will deliver, or use commercially reasonable efforts to deliver (as provided for in the applicable Exhibit), to POZEN at no charge the following materials for use in the Initial Development Program: (a) the Existing Nycomed Product Deliverables, in accordance with the delivery schedule set forth in **Exhibit B**; (b) the Nycomed Improvement Product Deliverables (if any), in accordance with the delivery schedule set forth in **Exhibit E**; and (c) the IND Deliverables, in accordance with the delivery schedule set forth in **Exhibit C**; *provided, however,* that in no event will Nycomed be obligated to supply POZEN with Nycomed Products or placebo for use in any Phase III or IV clinical trials. For the avoidance of doubt, nothing in this Section 2.3 will be construed as requiring Nycomed to generate new data, documentation or any

translations that may be needed by POZEN. The supply of Materials included in the Nycomed Product Deliverables to POZEN by Nycomed pursuant to this Section 2.3 will be subject to the warranties, terms and conditions set forth in Section 8 of this Agreement.

2.4 **Grant of Development License.** Nycomed hereby grants to POZEN an exclusive (even as to Nycomed), fully paid, royalty-free license, in the Field in the Exclusive Territory to use the Nycomed Product Deliverables and IND Deliverables to make, have made under contract, use, develop and have developed under contract pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active drug substance and pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more other active drug substances, in each case during the Option Period solely in connection with the Initial Development Program. Nycomed hereby grants to POZEN an exclusive (except as to Nycomed or its licensees or sublicensees pursuant to subsections 4.2.4 and 4.2.5 of this Agreement), fully paid, royalty-free license, in the Field in the Limited Territory to use the Nycomed Product Deliverables and IND Deliverables to make, have made under contract, use, develop and have developed under contract pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more other active drug substances during the Option Period solely in connection with the Initial Development Program.

2.5 **Use of Nycomed Product.** POZEN will provide Nycomed with advance written notice of any clinical trials that POZEN intends to perform during the Initial Development Program to the extent that such trials would require the use or testing of Nycomed Products. POZEN will accompany each such notice with clinical trial protocols for the relevant studies. POZEN, at its sole discretion, may redact the protocols submitted to Nycomed to avoid disclosure of the identity of the specific POZEN Product to which such studies relate. POZEN will not initiate any clinical trial for which it has submitted protocols to Nycomed under this Section 2.5 prior to receipt of Nycomed's approval; *provided, however,* that such approval will not be unreasonably withheld or delayed for more than 2 weeks following receipt of such protocols by Nycomed, and Nycomed's failure to respond to such protocols within 2 weeks of receipt thereof shall be deemed to constitute Nycomed's approval of such protocols.

3. GRANT OF OPTION

3.1 **Option**. Nycomed hereby grants POZEN an exclusive option (the **"Option"**) during the Option Period to license the Licensed Technology for the research, development and Commercialization of POZEN Products on the terms set forth in this Agreement. POZEN may exercise the Option during the Option Period by providing Nycomed with written notice stating that POZEN exercises the Option. Upon exercise of the Option during the Option Period, POZEN will be entitled to fully use and exploit the license granted to POZEN in Section 4.1 of this Agreement.

3.2 **Option Period**. The Option may be exercised by POZEN during a period commencing on the Effective Date and ending on the earlier of: (a) the date 18 months following the date on which POZEN files the first IND for a POZEN Product, and (b) the date 24 months after delivery by Nycomed to POZEN of the Existing Nycomed Product Deliverables (excluding any additional shipments thereof requested by POZEN pursuant to the delivery schedule set forth in **Exhibit B**) and IND Deliverables (the **"Option Period"**).

3.3 **Exclusivity**. During the Option Period, Nycomed will not negotiate, offer, enter into, or otherwise discuss with any Third Party any agreement that would prevent Nycomed from granting the rights or performing the obligations set forth in this Agreement in case that POZEN exercises the Option during the Option Period.

4. LICENSES AND OTHER RIGHTS

4.1 License Grants to POZEN.

4.1.1 Subject to exercise of the Option by POZEN during the Option Period, and subject to the terms set forth in Section 4.2 below, Nycomed grants to POZEN, and POZEN accepts, an exclusive (even as to Nycomed), royalty-bearing license, with the right to grant sublicenses, under the Licensed Technology to develop, have developed under contract, use, offer to sell, sell, have sold, distribute and import pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active drug substance and pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more other active drug substances in the Exclusive Territory in the Field.

4.1.2 Subject to exercise of the Option by POZEN during the Option Period, and subject to the terms set forth in Section 4.2 below, Nycomed grants to POZEN, and POZEN accepts, an exclusive (except as to Nycomed or its licensees or sublicensees pursuant to subsections 4.2.4 and 4.2.5 of this Agreement), royalty-bearing license, with the right to grant sublicenses, under the Licensed Technology to develop, have developed under contract, use, offer to sell, sell, have sold, distribute and import pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more other active drug substances in the Limited Territory in the Field.

4.1.3 Subject to exercise of the Option by POZEN during the Option Period, and subject to the terms set forth in Section 4.2 below, Nycomed grants to POZEN, and POZEN accepts, an exclusive (even as to Nycomed), royalty-bearing license, with the right to grant sublicenses, under the Licensed Technology to make and have made under contract pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active drug substance and pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more other active drug substances for the Field in the Exclusive Territory.

4.1.4 Subject to exercise of the Option by POZEN during the Option Period, and subject to the terms set forth in Section 4.2 below, Nycomed grants to POZEN, and POZEN accepts, a non-exclusive , royalty-bearing license under the Licensed Technology, with the right to grant sublicenses, to make and have made under contract pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active drug substance and pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance in combination with one or more other active drug substances for the Field outside the Exclusive Territory, excluding any country listed on **Exhibit I**. POZEN may request from Nycomed the expansion of the non-exclusive license granted in this Section 4.1.4 to any country listed on **Exhibit I**, and any such request will not be unreasonably refused by Nycomed.

4.2 Limitations; Exclusivity.

4.2.1 POZEN understands and agrees that the licenses granted in Section 4.1 of this Agreement are not granted and may not be used prior to the exercise of the Option by POZEN.

4.2.2 Notwithstanding the limited geographical scope of the license granted to POZEN in Section 4.1.1 of this Agreement with respect to Single Entity Products, POZEN will have: (a) the right to use Single Entity Products or Nycomed Products in clinical comparison studies with Combination Products in the Limited Territory in the Field if such studies are required by regulatory agencies to obtain Marketing Approval to Commercialize such Combination Product in one or more countries in the Limited Territory, and (b) the right to reference any MAA filed by Nycomed for Nycomed Products in the Field in the Limited Territory in a filing for Marketing Approval to Commercialize such Combination Product in one or more countries in the Territory.

4.2.3 Nycomed will not itself or through any Third Party (whether through the grant of a license or otherwise): (a) conduct in the Field pre-clinical tests in animals or clinical trials in humans with, or commercialize pharmaceutical products containing Lornoxicam or any salts, solvates or polymorphs of Lornoxicam in the Exclusive Territory, regardless of whether Lornoxicam or such salt, solvate or polymorph is the sole active drug substance contained therein or is combined with one or more other active drug substances, or (b) develop or commercialize pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) in combination with other active drug substances in the Field in the Limited Territory, except as set forth in Sections 4.2.4 and 4.2.5 below.

4.2.4 Nycomed will retain the right to use the Licensed Technology to develop, have developed under contract by a contract research organization, make, have made under contract by a contract manufacturer, use, offer to sell, sell, have sold, import and distribute in the Field in the Limited Territory pharmaceutical products containing Lornoxicam (or any salts, solvates or polymorphs thereof) in combination with one or more additional active drug substances, and to license such products, including the Licensed Technology, to Third Parties in the Limited Territory; *provided, however,* that Nycomed will not license any such

product to any Third Party prior to the completion of Phase I development for such product. The retention of rights set forth in this Section 4.2.4 is not, and will not be construed as, a grant by POZEN to Nycomed of any right or license with respect to Combination Products.

4.2.5 Nycomed will retain the right to license from one or more Third Parties the right to develop, have developed under contract by a contract research organization, make, have made under contract by a contract manufacturer, use, offer to sell, sell, have sold, import and distribute in the Limited Territory in the Field products containing Lornoxicam (or any salts, solvates or polymorphs thereof) in combination with one or more additional active drug substances, and to sublicense any such product, including the Licensed Technology, to Third Parties in the Limited Territory; *provided, however,* that Nycomed will not license any such product to any Third Party prior to the completion of Phase I development for such product.

4.2.6 POZEN will have the right to sublicense any of the rights and licenses granted to POZEN pursuant to Sections 4.1 and 4.2.2 of this Agreement and its right to reference DMFs pursuant to Section 9.3 of this Agreement and to authorize POZEN's Sublicensees to grant up to one level of further sublicenses.

4.2.7 Promptly after execution of any Sublicense Agreement POZEN will communicate to Nycomed the name and address of the applicable Sublicensee and provide Nycomed with the term and territory of the Sublicense Agreement. POZEN will further promptly communicate to Nycomed any major amendments to any Sublicense Agreement, including any termination of any Sublicense Agreement prior to its expiration.

4.2.8 POZEN will ensure that no Sublicense Agreement or any term or condition thereof is inconsistent or conflicting with this Agreement or any term or condition thereof.

4.2.9 POZEN will ensure that all of its obligations under this Agreement reasonably related to the rights and licenses sublicensed under a Sublicense Agreement to a Sublicensee will be passed to such Sublicensee, and POZEN will be responsible and liable for any breach of these obligations by such Sublicensee. For purposes of clarification, POZEN will not be responsible or liable for any breach by a Sublicensee of

a commercial supply agreement between Nycomed and such Sublicensee as set forth in Section 7.1 of this Agreement; *provided, however,* that POZEN shall use commercially reasonable efforts to cause each Sublicensee to comply with its obligation to purchase its entire requirements of LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof) for use in the manufacture of POZEN Products from Nycomed during the applicable Exclusive Manufacturing Period in accordance with Section 7.1 of this Agreement.

4.3 Option Grant to Nycomed.

4.3.1 Subject to Section 4.3.2, POZEN hereby grants to Nycomed, and Nycomed hereby accepts, a right of first refusal (the **"Nycomed Option"**) on the terms set forth in this Section 4.3 for an exclusive license, with the right to grant sublicenses, under any applicable Patent, Know-How or intellectual property other than Patents Controlled by POZEN relating to a Combination Product to develop, have developed under contract, make, have made under contract, use, offer to sell, sell, have sold, distribute and import any Combination Product in the Field within the following countries: Iceland, Denmark, Norway, Sweden, Finland, Lithuania, Latvia, Estonia, Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan and Ukraine (the **"Nycomed Option Territory"**).

4.3.2 The Nycomed Option will not apply with respect to any Combination Product that is claimed by a Patent or intellectual property other than Patents, or that embodies Know-How, Controlled by a Third Party. With respect to each such Combination Product, POZEN will use good faith efforts to introduce Nycomed to such Third Parties from which POZEN has secured a license to such Patent or intellectual property other than Patents or Know-How for the purpose of enabling Nycomed to negotiate a license to such Patent or intellectual property other than Patents or Know-How in the Nycomed Option Territory. If Nycomed is successful in obtaining such a license, then the Nycomed Option will subsequently apply to each Combination Product for which a license was obtained.

4.3.3 With respect to each Combination Product, POZEN will notify Nycomed upon the earlier of: (a) completion of the final study report for the last Phase II clinical trial of such Combination Product, and (b)

POZEN's intent for bona fide business purposes to license the commercialization rights for such Combination Product to a Third Party in the Nycomed Option Territory. Such notice shall identify the active drug substances contained in the applicable Combination Product and the presentation form(s) thereof. After sending each such notice, POZEN will provide Nycomed in a due diligence meeting with: (1) access at POZEN's facilities to up-to-date pre-clinical and clinical data (including safety and stability data), the IND, reports available and other reasonably requested documentation relating to such Combination Product, and (2) a term sheet setting forth terms and conditions under which POZEN proposes to grant Nycomed an exclusive license to such Combination Product in the Nycomed Option Territory, which may include, without limitation, commercially reasonable upfront payments, milestone payments and royalties payable to POZEN for a license to the applicable Combination Product.

4.3.4 The period during which Nycomed may exercise the Nycomed Option will commence upon receipt by Nycomed of the notice described in Section 4.3.3 of this Agreement and terminate 60 days after the due diligence meeting at POZEN's facilities described in Section 4.3.3. The due diligence meeting at POZEN's facilities described in Section 4.3.3 will take place within 30 days after receipt by Nycomed of such notice.

4.3.5 Nycomed may exercise the Nycomed Option with respect to a particular Combination Product by written notice to POZEN setting forth the countries within the Nycomed Option Territory for which Nycomed desires to negotiate a license. If POZEN does not receive a notice of exercise of the Nycomed Option for a particular country within the Nycomed Option Territory during the 60-day exercise period described in Section 4.3.4 of this Agreement, then POZEN will have the right to enter into licensing arrangements of the applicable Combination Product with Third Party licensees, or itself commercialize such Combination Product, in each such country without further obligation to grant a license to Nycomed for such Combination Product in such countries.

4.3.6 Upon the exercise by Nycomed of the Nycomed Option with respect to a Combination Product in one or more countries within the Nycomed Option Territory, Nycomed and POZEN will meet within 10 days to negotiate in good faith an appropriate license agreement for up to 100 days after such exercise. If the Parties have not executed a license

agreement with respect to a particular country within the Nycomed Option Territory as of the date 100 days following Nycomed's exercise of the Nycomed Option, then POZEN will have the right to enter into licensing arrangements of the applicable Combination Product with Third Party licensees, or itself commercialize such Combination Product, in each such country without further obligation to grant a license to Nycomed for such Combination Product in such countries.

4.3.7 For the avoidance of doubt, nothing in this Section 4.3 will be construed as a Party's acceptance of any terms and conditions proposed by the other Party in a term sheet and none of such terms and conditions will be binding on such Party, and each Party will only be bound after full execution of an aforesaid license agreement.

4.3.8 If Nycomed participates in the due diligence meeting described in Section 4.3.3 above with respect to a Combination Product but does not enter into a license agreement with POZEN as set forth in Section 4.3.6 with respect to such Combination Product, then, during the Term, Nycomed will not commercialize any pharmaceutical product containing the same combination of active drug substances as the Combination Product for which Nycomed did not enter into such license agreement.

4.4 Isomer Option.

4.4.1 Subject to Section 4.4.2, Nycomed hereby grants to POZEN, and POZEN hereby accepts, a right of first refusal (the **"Isomer Option"**) on the terms set forth in this Section 4.4 for an exclusive license, with the right to grant sublicenses, under any applicable Patent, Know-How or intellectual property other than Patents, Controlled by Nycomed relating to any Isomer Product to develop, have developed under contract, make, have made under contract, use, offer to sell, sell, have sold, distribute and import such Isomer Product in the Field in the Exclusive Territory.

4.4.2 The Isomer Option will not apply with respect to any Isomer Product that is claimed by a Patent or intellectual property other than Patents, or that embodies Know-How, Controlled by a Third Party. With respect to each such Isomer Product that is claimed by a Patent or intellectual property other than Patents, or that embodies Know-How, Controlled by a Third Party, Nycomed will use good faith efforts to introduce POZEN to such Third Parties from which Nycomed has secured

a license to such Patent or Know-How for the purpose of enabling POZEN to negotiate a license to such Patent or Know-How in the Exclusive Territory. If POZEN is successful in obtaining such a license, then the Isomer Option will subsequently apply to each Isomer Product claimed by a Patent or intellectual property other than Patents, or embodying Know-How, Controlled by a Third Party for which a license was obtained.

4.4.3 With respect to each Isomer Product, Nycomed will notify POZEN upon the earlier of: (a) completion of the final study report for the last Phase II clinical trial of such Isomer Product, and (b) Nycomed's intent for bona fide business purposes to license the commercialization rights for such Isomer Product to a Third Party in the Exclusive Territory. Such notice shall identify the active drug substance(s) contained in the applicable Isomer Product and the presentation form(s) thereof. After sending each such notice, Nycomed will provide POZEN in a due diligence meeting with: (1) access at Nycomed's facilities to up-to-date pre-clinical and clinical data (including safety and stability data), the IND or equivalent filing, reports available and other reasonably requested documentation relating to such Isomer Product, and (2) a term sheet setting forth terms and conditions under which Nycomed proposes to grant POZEN an exclusive license to such Isomer Product in the Field in the Exclusive Territory, which may include, without limitation, commercially reasonable upfront payments, milestone payments and royalties payable to Nycomed for a license to the applicable Isomer Product.

4.4.4 The period during which POZEN may exercise the Isomer Option will commence upon receipt by POZEN of the notice described in Section 4.4.3 of this Agreement and terminate 60 days after the due diligence meeting at Nycomed's facilities described in Section 4.4.3. The due diligence meeting at Nycomed's facilities described in Section 4.4.3 will take place within 30 days after receipt by POZEN of such notice.

4.4.5 POZEN may exercise the Isomer Option with respect to a particular Isomer Product by written notice to Nycomed that POZEN desires to negotiate a license. If Nycomed does not receive a notice of exercise of the Isomer Option during the 60-day exercise period described in Section 4.4.4 of this Agreement, then Nycomed will have the right to enter into licensing arrangements of the applicable Isomer Product with Third Party licensees, or itself commercialize such Isomer Product, in the

Exclusive Territory without further obligation to grant a license to POZEN for such Isomer Product in the Exclusive Territory.

4.4.6 Upon the exercise by POZEN of the Isomer Option with respect to an Isomer Product in the Exclusive Territory, POZEN and Nycomed will meet within 10 days to negotiate in good faith an appropriate license agreement for up to 100 days after such exercise. If the Parties have not executed a license agreement with respect to such Isomer Product in the Exclusive Territory as of the date 100 days following POZEN's exercise of the Isomer Option, then Nycomed will have the right to enter into licensing arrangements of the applicable Isomer Product with Third Party licensees, or itself commercialize such Isomer Product, in the Exclusive Territory without further obligation to grant a license to POZEN for such Isomer Product in the Exclusive Territory.

4.4.7 For the avoidance of doubt, nothing in this Section 4.4 will be construed as a Party's acceptance of any terms and conditions proposed by the other Party in a term sheet and none of such terms and conditions will be binding on such Party, and each Party will only be bound after full execution of an aforesaid license agreement.

4.4.8 If POZEN participates in the due diligence meeting described in Section 4.4.3 above with respect to an Isomer Product but does not enter into a license agreement with Nycomed as set forth in Section 4.4.6 with respect to such Isomer Product, then, during the Term, POZEN will not commercialize any pharmaceutical product containing the same combination of active drug substances as the Isomer Product for which POZEN did not enter into such license agreement.

4.5 **Negative Covenants**. POZEN hereby covenants and agrees not to: (a) use Materials supplied by Nycomed under this Agreement for any other purpose than expressly provided for under this Agreement, or (b) actively promote, market or sell Single Entity Products outside the Exclusive Territory, or (c) actively promote, market or sell Combination Products outside the Territory.

5. DEVELOPMENT PROGRAM

5.1 **Development and Costs**. POZEN will be responsible for the pre-clinical and clinical development of the POZEN Products, and will prepare and file all applications for Marketing Approval of POZEN

Products, at POZEN's expense. Nycomed will, throughout the Term, provide reasonable technical and scientific support to assist POZEN in obtaining and maintaining Marketing Approvals in the Territory. POZEN will reimburse Nycomed for any internal costs (at then-standard FTE rates, up to US$1,800.00 per day and per Nycomed employee engaged), pro-rated for any partial day (based on an eight-hour day), and for reasonable and documented out-of-pocket expenses incurred by Nycomed in connection with such provision of support. Prior to initiating any particular technical and/or scientific support services requested by POZEN under this Section 5.1, Nycomed shall provide to POZEN for its approval a good faith written estimate of its anticipated internal costs (including FTE rate(s) of Nycomed personnel who would provide such services) and out-of-pocket expenses of providing such services, and if POZEN notifies Nycomed within 20 days of receipt of such estimate that POZEN does not wish to incur such costs and expenses, Nycomed shall not provide such services unless otherwise agreed by the Parties.

5.2 **Supply of Materials**. After the Initial Development Program, Nycomed will use commercially reasonable efforts to deliver to POZEN, LX Bulk Drug Substance, which shall be provided at 85% of the lowest supply price set forth in Section 7.7 for use in pre-clinical studies and clinical trials for POZEN Products in such quantities as may be reasonably requested by POZEN from time to time. In addition, during a period of up to 5 years from the Option Exercise Date, Nycomed will use commercially reasonable efforts to deliver to POZEN Nycomed Products and placebo, which shall be provided at Cost, in such quantities as may be reasonably requested by POZEN from time to time; *provided, however,* that in no event will Nycomed be obligated to supply POZEN with Nycomed Products or placebo for use in any Phase III or IV clinical trials.

5.3 **Order Process for Materials**. To order Materials from Nycomed pursuant to Section 5.2 above, POZEN will submit a purchase order to Nycomed specifying the amount of such Materials and the delivery date. Unless otherwise agreed by the Parties, Nycomed will not be required to supply Materials ordered by POZEN if the delivery date set forth on the applicable purchase order for such Materials is less than 120 days after the date of receipt of such purchase order by Nycomed.

5.4 **Shipping**. Nycomed will package and label the applicable Materials pursuant to Section 5.2 above for shipment in accordance with

applicable law and in accordance with Nycomed's standard practices. Nycomed will ship the Materials DDU (ICC Incoterms 2000) to a place of destination named by POZEN in the applicable purchase order. Each shipment will be made according to the schedule and in the amounts specified in the applicable purchase order and under the terms and conditions set forth in this Agreement. Should Nycomed at any time during the Term have reason to believe that it will be unable to meet a delivery date of a shipment, Nycomed will promptly notify POZEN of the cause for such delay and the steps undertaken by Nycomed to avoid or minimize such delay.

5.5 **Invoices.** Nycomed will send an invoice to POZEN via facsimile upon shipment of Materials under this Section 5 and will enclose such invoice with each shipment of Materials under this Section 5. Each such invoice will set forth a detailed account of the quantities and price of Materials included in such shipment. All invoices submitted to POZEN by Nycomed under this Section 5.5 will be payable within 30 days of the invoice date.

5.6 **Other Supply Provisions**. The supply of Materials to POZEN by Nycomed pursuant to this Section 5 will be subject to the warranties, terms and conditions set forth in Section 8 of this Agreement.

5.7 **Use of Nycomed Product**. POZEN will provide Nycomed with advance written notice of any clinical trials that POZEN intends to perform during the pre-clinical and clinical development of POZEN Products to the extent that such trials would require the use or testing of Nycomed Products. POZEN will accompany each such notice with clinical trial protocols for the relevant studies. POZEN, at its sole discretion, may redact the protocols submitted to Nycomed to avoid disclosure of the identity of the specific POZEN Product to which such studies relate. POZEN will not initiate any clinical trial for which it has submitted protocols to Nycomed under this Section 5.7 prior to receipt of Nycomed's approval; *provided, however,* that such approval will not be unreasonably withheld or delayed, and Nycomed's failure to respond to such protocols within 2 weeks of receipt thereof shall be deemed to constitute Nycomed's approval of such protocols.

5.8 **Access to Know-How**. During pre-clinical and clinical development of the POZEN Products, after the Initial Development

Program, and upon 30 days' written notice by POZEN to Nycomed specifying the Know-How to which POZEN would like access, Nycomed will grant POZEN, at Nycomed's facilities and during such number of days per calendar year as POZEN reasonably requests (not to exceed a total of two weeks per year), access to Nycomed's Know-How that is available at Nycomed or its then-current contractors and included in the Licensed Technology. For the avoidance of doubt, nothing in this Section 5.8 will be construed as requiring Nycomed to generate new data, documentation or any translations.

6. COMMERCIALIZATION

6.1 **Principles of Commercialization**. POZEN will be responsible for Commercializing the POZEN Products in the Field in the Territory during the Term, at POZEN's expense. However, the Parties acknowledge and agree that POZEN may grant some of its responsibilities to Nycomed after execution of a license agreement contemplated in Section 4.3 of this Agreement.

6.2 **Regulatory Obligations**. POZEN will be responsible for all activities in connection with the Regulatory Approvals for a POZEN Product in the Territory (other than the Manufacturing Approvals necessary for Nycomed's manufacture of LX Bulk Drug Substance), including communicating and preparing and filing all reports with the applicable regulatory authority. Nycomed will, throughout the Term, provide reasonable technical and scientific support to assist POZEN in preparing and filing such reports. POZEN will reimburse Nycomed for any internal costs (at then-standard FTE rates, up to US$1,800.00 per day and per Nycomed employee engaged), pro-rated for any partial day (based on an eight-hour day), and for reasonable and documented out-of-pocket expenses incurred by Nycomed in connection with such provision of support. Prior to initiating any particular technical and/or scientific support services requested by POZEN under this Section 6.2, Nycomed shall provide to POZEN for its approval a good faith written estimate of its anticipated internal costs (including FTE rate(s) of Nycomed personnel who would provide such services) and out-of-pocket expenses of providing such services, and if POZEN notifies Nycomed within 20 days of receipt of such estimate that POZEN does not wish to incur such costs and expenses, Nycomed shall not provide such services unless otherwise agreed by the

Parties. POZEN will pay all fees associated with filing, obtaining and maintaining such Regulatory Approvals.

6.3 **Diligence**. POZEN will use commercially reasonable efforts to develop (including preparing and filing applications for and obtaining Regulatory Approvals) and to Commercialize at least one POZEN Product in the Field in the United States (excluding its territories and possessions), France, Germany and the United Kingdom as soon as reasonably practicable, and to apply commercially reasonable efforts and resources to maximize sales of POZEN Products throughout the Territory, and at least equal to the efforts and resources normally used by POZEN for another pharmaceutical product owned by it that has a similar market potential and is at a similar stage in its product life cycle as the applicable POZEN Product. If either (a) development of a POZEN Product ceases or (b) Regulatory Approval of a POZEN Product is granted in a particular country in the Territory but POZEN does not launch such POZEN Product in such country as soon as reasonably practicable after Regulatory Approval, POZEN shall provide Nycomed with a reasonable explanation for such decision; *provided, however,* that the foregoing obligation shall cease upon launch of the first POZEN Product in the United States (excluding its territories and possessions), France, Germany and the United Kingdom (which need not be the same POZEN Product in all of such countries).

7. COMMERCIAL SUPPLY OF LX BULK DRUG SUBSTANCE

7.1 **Exclusivity of Supply of LX Bulk Drug Substance**. During the Exclusive Manufacturing Period(s) applicable to POZEN, POZEN will subject to Section 7.5 of this Agreement purchase from Nycomed and Nycomed will use commercially reasonable efforts to provide to POZEN, 100% of POZEN's requirements of LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof), to be provided by Nycomed in the form of LX Bulk Drug Substance, for use in the manufacture of any POZEN Product. For purposes of clarification, for any POZEN Product manufactured after the applicable Exclusive Manufacturing Period, POZEN will have the right to source LX Bulk Drug Substance or Lornoxicam (or any salt, solvate or polymorph thereof) from any entity. POZEN will ensure that either no Sublicense Agreement shall become effective unless and until the Sublicensee enters into a supply agreement with Nycomed in substantially the same form as the supply agreement attached to this Agreement as **Exhibit J** (attached to this Agreement and incorporated in this Agreement

by reference) or, at POZEN's election, POZEN undertakes to purchase 100% of such Sublicensee's requirements of LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof), to be provided by Nycomed in the form of LX Bulk Drug Substance, for use in the manufacture of any POZEN Product under the terms and conditions set forth in this Agreement for supply to POZEN. Nycomed will use commercially reasonable efforts to enter into such a supply agreement with each Sublicensee, and POZEN will use commercially reasonable efforts to cause each Sublicensee to enter into such a supply agreement, as promptly as practicable. In the event that a supply agreement between Nycomed and a Sublicensee is terminated for any reason other than material breach by Nycomed prior to the expiration of the applicable Exclusive Manufacturing Period(s), Nycomed shall provide POZEN with written notice of such termination, and POZEN shall promptly terminate or cause the termination of such Sublicensee's Sublicense Agreement with respect to the Licensed Technology or any portion thereof that is sublicensed to such Sublicensee. For purposes of clarification, if a Sublicensee has entered into a supply agreement with Nycomed, POZEN, in its discretion, may supply such Sublicensee with all or any portion of such Sublicensee's requirements of LX Bulk Drug Substance, out of POZEN's own stock of LX Bulk Drug Substance purchased from Nycomed.

7.2 **Optional Extension.** The Parties may extend the Exclusive Manufacturing Period(s) applicable to POZEN for successive one-year terms, upon terms to be agreed upon at such time by the Parties.

7.3 **Optional Termination.** On or after January 1, 2014, either Party may provide the other Party with written notice of its intention to terminate the supply of LX Bulk Drug Substance to POZEN by Nycomed under this Agreement, in which case Nycomed's obligation to supply POZEN with LX Bulk Drug Substance under this Section 7 will terminate on the date 24 months after the date such notice is received by such other Party.

7.4 **Supply Diligence.**

7.4.1 Nycomed will use commercially reasonable efforts to maintain a reasonable inventory of LX Bulk Drug Substance, at Nycomed's expense, for use in filling orders of LX Bulk Drug Substance conforming to the Specifications and as forecasted in the binding portion of a forecast by

POZEN in accordance with this Section 7, at Nycomed. Similarly, POZEN will use commercially reasonable efforts to maintain a reasonable inventory of LX Bulk Drug Substance supplied by Nycomed, at POZEN's expense .

7.4.2 If Nycomed has reason to believe that it will be unable to manufacture and fill a particular order made in accordance with this Section 7 of LX Bulk Drug Substance conforming to the Specifications despite the safeguards described in Section 7.4.1 above, then Nycomed will promptly notify POZEN of the cause for such projected shortfall and POZEN will have the right pursuant to Section 7.5 of this Agreement to use an alternate source to supply the actual shortfall.

7.4.3 If Nycomed has reason to believe that it will be unable, on an ongoing basis, to manufacture and fill orders by POZEN of LX Bulk Drug Substance conforming to the Specifications forecasted in accordance with this Section 7, then Nycomed will notify POZEN of the cause for such projected shortfall, and use commercially reasonable efforts to establish a contract manufacturer to manufacture such shortfall for Nycomed for supply to POZEN. Nycomed will not retain any contract manufacturer of which Nycomed has reason to believe that it would be unable to manufacture LX Bulk Drug Substance in accordance with the Product Warranty (as defined in Section 8.1 of this Agreement). If Nycomed has reason to believe that it will be unable to establish, or establish in due time, such a contract manufacturer and to have manufactured such projected shortfall, then Nycomed will promptly notify POZEN thereof and POZEN will then have the right pursuant to Section 7.5 of this Agreement to use an alternate source to supply the greater of: (a) any quantities that Nycomed will be unable to supply of LX Bulk Drug Substance conforming to the Specifications forecasted by POZEN, and (b) the minimum total order quantity of LX Bulk Drug Substance required by POZEN's second source, provided that POZEN shall use commercially reasonable efforts to negotiate the lowest possible minimum total order quantity available at a commercially reasonable price from such second source.

7.5 Establishment of Alternate Source.

7.5.1 During the Exclusive Manufacturing Period(s) applicable to POZEN, POZEN will have the right to manufacture or have manufactured and supplied to it LX Bulk Drug Substance for further processing into a POZEN Product by an alternate source to the extent

Nycomed fails to supply POZEN's requirement of LX Bulk Drug Substance as described in Section 7.4; *provided, however,* that in no event will POZEN use any Patents Controlled by, or use or disclose Confidential Information of, Nycomed and related to the Process or to any other manufacturing process for LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof).

7.5.2 If POZEN purchases from an alternate source a quantity of LX Bulk Drug Substance that Nycomed failed to supply as described above and if such failure is related to Nycomed's gross negligence or willful misconduct or Nycomed's material breach of this Agreement, then, if the price paid by POZEN to such alternate source for such quantity of LX Bulk Drug Substance is greater than the applicable supply price under this Agreement for such quantity of LX Bulk Drug Substance, Nycomed will reimburse POZEN the amount of the difference between the supply price per kilogram paid to the alternate source and the supply price per kilogram that would have been applicable hereunder, up to a maximum amount corresponding to 50% of the applicable supply price under this Agreement for such quantity, multiplied by the number of kilograms purchased from such alternate source.

7.6 **Failure to Supply; End of Exclusive Manufacturing Periods.** POZEN will have the right to terminate the Exclusive Manufacturing Period applicable to it:

(a) upon the failure of Nycomed to supply for any reason, excluding force majeure, at least 90% of POZEN's requirement of LX Bulk Drug Substance conforming to the Specifications forecasted and ordered in accordance with this Section 7 for any 2 consecutive orders, or for 3 orders in any 8 consecutive orders, in each case, unless Nycomed remedies such shortfall either (i) within 30 days of the scheduled delivery date in the case of failure to deliver at least 90% of ordered quantities of LX Bulk Drug Substance, or (ii) in accordance with Section 8.4 in the case of failure of at least 90% of such LX Bulk Drug Substance delivered to conform to the Specifications. The termination right set forth in this subsection (a) will expire with respect to a particular failure described above if not exercised within 30 days of the expiration of Nycomed's rights to remedy such failure; or

(b) upon the failure of Nycomed to supply for any reason, excluding force majeure, at least 90% of POZEN's requirement of LX Bulk Drug Substance conforming to the Specifications forecasted and ordered in accordance with this Section 7 during any calendar year, unless Nycomed remedies such shortfall either (i) within 30 days of the scheduled delivery date in the case of failure to deliver at least 90% of ordered quantities of LX Bulk Drug Substance, or (ii) in accordance with Section 8.4 in the case of failure of at least 90% of such LX Bulk Drug Substance delivered to conform to the Specifications. The termination right set forth in this subsection (b) will expire with respect to a particular failure described above if not exercised within 30 days of the expiration of Nycomed's rights to remedy such failure.

7.7 **Supply Price.** All supply of LX Bulk Drug Substance by Nycomed to POZEN for further processing into POZEN Products intended for commercial sale will be made at the prices set forth on the following table:

Quantity of LX Bulk Drug Substance ordered by POZEN for delivery during a calendar year:	Price per kg of LX Bulk Drug Substance:
Up to 100 kg	€4000 per kg
More than 100 kg, up to 200 kg	€3900 per kg
More than 200 kg, up to 300 kg	€3800 per kg
More than 300 kg	€3600 per kg

By way of example, if POZEN orders, in one or more orders during a calendar year, 320 kg of LX Bulk Drug Substance for delivery, the price for the first 100 kg is € 400,000; for the second 100 kg, € 390,000; for the third 100 kg, € 380,000; and for the remaining 20 kg, € 72,000.

7.8 **Price Increases.** If any changes to cGMP or any changes to applicable laws or regulations are adopted after the Effective Date, and if Nycomed's compliance with such changed cGMP, laws or regulations will result in an increase in the direct manufacturing costs of Nycomed for LX Bulk Drug Substance, then Nycomed will promptly inform POZEN and may reasonably increase the prices set forth in Section 7.6 of this Agreement; *provided, however,* if any such price increase would lead to an increase of

the prices set forth in Section 7.6 of this Agreement of more than 15%, then POZEN will have the right to terminate any Exclusive Manufacturing Period applicable to POZEN within 30 days from receipt of Nycomed's notification of such price increase. POZEN's notice of termination shall become effective between 180 and 360 days from receipt by Nycomed as specified in such termination notice (unless Nycomed reduces the price increase exceeding such 15% to 15%, and such price change and the effective date thereof are communicated to POZEN within 30 days of receipt of POZEN's notice), provided that POZEN will continue to purchase LX Bulk Drug Substance during such period at the increased price and such increased price will be subject to any further price increases that result from additional changes to cGMP, laws or regulations during such period.

7.9 **Forecasts**. No later than one calendar quarter prior to the beginning of the calendar quarter in which POZEN desires the first delivery of LX Bulk Drug Substance from Nycomed under this Section 7 (the **"Initial Quarter"**), POZEN will provide Nycomed with a forecast setting forth POZEN's requirements of LX Bulk Drug Substance for the 6 calendar quarters comprising the Initial Quarter and the 5 subsequent calendar quarters. Thereafter, on or before the first business day of each calendar quarter following the calendar quarter in which the first forecast was provided by POZEN to Nycomed, POZEN will provide Nycomed with an updated rolling 6-calendar-quarter forecast. The quantities of LX Bulk Drug Substance set forth for the first 2 calendar quarters set forth in any forecast will be binding on the Parties; *provided, however,* that the quantity of LX Bulk Drug Substance set forth in the second calendar quarter in any forecast will be greater than 85%, and less than 115%, of the quantity of LX Bulk Drug Substance forecast for such calendar quarter in the previous forecast submitted by POZEN under this Section 7.9. All quantities of LX Bulk Drug Substance set forth for the fourth through sixth calendar quarters in any forecast provided under this Section 7.9 are to be considered non-binding good faith estimates, and are provided to Nycomed only for preliminary planning purposes. The following table provides an example of the forecasts described by this Section 7.9:

	Forecast submitted on first business day, 1Q2005	Forecast submitted on first business day, 2Q2005
Quantity for delivery during	100kg	---

2Q2005	(binding)	
Quantity for delivery during 3Q2005	200kg (binding)	200kg (binding)
Quantity for delivery during 4Q2005	300kg (non-binding)	300kg ± 15% (binding)
Quantity for delivery during 1Q2006	350kg (non-binding)	400kg (non-binding)
Quantity for delivery during 2Q2006	400kg (non-binding)	200kg (non-binding)
Quantity for delivery during 3Q2006	400kg (non-binding)	700kg (non-binding)
Quantity for delivery during 4Q2006	---	500 kg (non-binding)

The obligations of this Section 7.9 will terminate with respect to POZEN upon the expiration of the Exclusive Manufacturing Period(s) applicable to POZEN.

7.10 **Order Process.** Together with each forecast provided by POZEN pursuant to Section 7.9 above, POZEN will submit a purchase order to Nycomed for the quantities of LX Bulk Drug Substance in any binding forecasts that are not covered by a previous purchase order, specifying such quantities of LX Bulk Drug Substance and the delivery dates thereof. Except with the prior agreement of Nycomed, POZEN will not designate in a purchase order less than 20 kg of LX Bulk Drug Substance for delivery on any particular delivery date. Nycomed will use commercially reasonable efforts to supply to POZEN the quantities of LX Bulk Drug Substance ordered on the delivery dates set forth in a purchase order.

7.11 **Shipping.** Nycomed will package and label the LX Bulk Drug Substance for shipment in accordance with applicable law and in accordance with Nycomed's standard practices. Nycomed will ship the LX Bulk Drug Substance on the relevant purchase order FCA (ICC Incoterms 2000) either Nycomed's facility in Linz, Austria or any other place named by Nycomed and by a carrier designated by POZEN in the applicable purchase order. Each shipment will be made according to the schedule and in the amounts specified in the applicable purchase order and under

the terms and conditions set forth in this Agreement. Each batch of LX Bulk Drug Substance will be tested and Nycomed will enclose with each shipment of LX Bulk Drug Substance a material safety data sheet and a certificate of analysis in accordance with Section 8.3 of this Agreement. Nycomed will enclose any other required shipping documentation with each shipment of LX Bulk Drug Substance. Should Nycomed at any time during the Term have reason to believe that it will be unable to meet a delivery date of a shipment, Nycomed will promptly notify POZEN of the cause for such delay and the steps undertaken by Nycomed to avoid or minimize such delay.

7.12 **Invoices**. Nycomed will send an invoice to POZEN via facsimile upon transferring a shipment of Materials under this Section 7 to the carrier designated by POZEN, and will enclose such invoice with each shipment of Materials under this Section 7. Each such invoice will set forth a detailed account of the quantities and price of LX Bulk Drug Substance included in such shipment. All invoices submitted to POZEN by Nycomed under this Agreement will be payable within 30 days of invoice date.

8. WARRANTIES; ACCEPTANCE AND REJECTION OF MATERIALS

8.1 **Product Warranty**. Nycomed hereby warrants: (a) that at the date of delivery, any Materials, including LX Bulk Drug Substance, supplied by Nycomed under this Agreement will (i) conform to the applicable Specifications, (ii) be manufactured in compliance with cGMP and the applicable laws of the country of manufacture, and (iii) not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended (**"FD&C Act"**); and (b) that at the date of delivery any LX Bulk Drug Substance supplied by Nycomed under this Agreement will (1) conform to the applicable DMF, (2) be manufactured in accordance with the Process, and (3) comply with current USP and EP monographs and ICH guidelines (collectively, the **"Product Warranty"**). Failure of a delivery of Materials to comply with clause (a)(ii) of this Section 8.1 will not be deemed a breach of the Product Warranty to the extent that (A) in the case of Nycomed Products or placebo, such materials may, in accordance with applicable law, be used for the development or testing, as applicable, of POZEN Products, and (B) in the case of LX Bulk Drug Substance, such LX Bulk Drug Substance may, in accordance with applicable law, be used for the manufacture of POZEN Products for development, testing or commercial sale, as applicable.

8.2 **Process Warranty**. Nycomed hereby warrants that, as of the Effective Date, it has not been served with any interference action, litigation or other notice alleging that (i) the Process infringes the intellectual property rights of any person or entity or (ii) that the Process constitutes a misappropriation of the trade secrets or other intellectual property rights of any person or entity within the Territory.

8.3 **Certificates of Analysis**. Nycomed will enclose a certificate of analysis with each shipment of Materials supplied hereunder. Such certificate of analysis will contain the results of the analysis of such Materials conducted as required in the Specifications, and will certify with respect to each shipment and lot (identified by lot number): (i) the quantity of the shipment, and (ii) that such Materials conform to the Product Warranty.

8.4 **Acceptance Testing**. If a shipment of a lot of Materials or any portion thereof fails to conform to the Product Warranty, then POZEN will have the right to either reject such nonconforming shipment of Materials or the nonconforming portion thereof, as the case may be, in accordance with the terms set forth in this Section 8.4.

8.4.1 **Notice Period**.

(a) Within 45 days (or, in the case of the first shipment of each type of Materials under this Agreement, 90 days) after delivery by Nycomed to POZEN of any shipment of any Materials that does not conform, in whole or in part, with the Product Warranty, POZEN may give written notice to Nycomed of its rejection of either such shipment or portion thereof, as the case may be, specifying the grounds for such rejection, and deliver to Nycomed samples of the rejected Materials. If POZEN fails to give the aforesaid notice to Nycomed within the applicable period set forth above, POZEN will be deemed to have unconditionally accepted the applicable Materials as in conformity with the Product Warranty, except as to Latent Defects.

(b) Within 20 days after POZEN's discovery that a shipment of any Materials or portion thereof contains a Latent Defect, POZEN may give written notice to Nycomed of its rejection of either such shipment or portion thereof, as the case may be, specifying the grounds for such rejection, and deliver to Nycomed samples of the rejected Materials.

If POZEN fails to give the aforesaid notice to Nycomed within the applicable period set forth above, POZEN will be deemed to have unconditionally accepted the applicable Materials as free of the identified Latent Defect.

8.4.2 **Disputes Regarding Conformity**. After receipt of a rejection notice and samples from POZEN pursuant to the preceding subsection 8.4.1, Nycomed will be permitted, for a period of 30 business days, to analyze the Materials rejected by POZEN for nonconformity to the Product Warranty, and to present its findings with respect to such Materials to POZEN. If the Parties cannot agree on whether such Materials conform to the Product Warranty within 40 business days of Nycomed's receipt of POZEN's written notice of rejection and samples, then, as soon as reasonably practicable, each Party will deliver samples of the Materials in question to an independent laboratory selected by Nycomed as soon as reasonably practicable and reasonably acceptable to POZEN, and the independent laboratory will analyze such samples according to the methods included in the Specifications and determine whether or not such Materials conform to the Product Warranty. Nycomed will use commercially reasonable efforts to cause the independent laboratory to complete such analysis as soon as reasonably practicable. The definitive result of such analysis by the independent laboratory will be binding on the Parties. The cost of such analysis will be borne by the Party whose assessment was incorrect.

8.4.3 **Remedies**. If POZEN rejects a shipment of Materials and POZEN and Nycomed agree, or the independent laboratory determines, that such shipment of Materials does not conform to the Product Warranty, such nonconforming Materials will be held for Nycomed's disposition, or will be returned to Nycomed (unless prohibited by applicable laws or regulations), in each case at Nycomed's expense, as directed by Nycomed. Nycomed will use commercially reasonable efforts to replace each nonconforming shipment of Materials, or the nonconforming portion thereof on a batch-by-batch basis, with conforming Materials as soon as reasonably practicable or will promptly provide POZEN with a credit therefor, at POZEN's election.

8.4.4 **Notice of Latent Defects**. If Nycomed becomes aware of a Latent Defect in any shipment of Materials or portion thereof, Nycomed will immediately notify POZEN as to the shipment involved, and, at

POZEN's election (to be communicated to Nycomed within 10 days), either such shipment or portion thereof, as the case may be, will be deemed rejected as of the date of POZEN's communication, and such nonconforming Materials will be held for Nycomed's disposition, or will be returned to Nycomed (unless prohibited by applicable laws or regulations), in each case at Nycomed's expense, as directed by Nycomed. Nycomed will use commercially reasonable efforts to replace each nonconforming shipment, or the nonconforming portion thereof, with conforming Materials as soon as reasonably practicable, or will promptly provide POZEN with a credit therefor, at POZEN's election.

8.5 **Recalls**. If a Party believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any POZEN Product (a **"Recall"**), Nycomed and POZEN will consult with each other as to how best to proceed, it being understood and agreed that the final decision as to any such Recall with respect to a POZEN Product will be made by POZEN or Sublicensees, and the final decision as to any such Recall with respect to LX Bulk Drug Substance that has not yet been processed into a POZEN Product will be made by Nycomed.

8.6 **Adverse Drug Events**. Any adverse drug event or reaction complaint reports or any other reports or information received by POZEN indicating that any POZEN Product has any toxicity, sensitivity reaction, or is otherwise alleged to cause illness or injury of any kind or is adulterated or misbranded, which toxicity, sensitivity reaction, illness or injury is caused or alleged to be caused by the LX Bulk Drug Substance contained therein, will be reported promptly by POZEN to Nycomed, or as otherwise may be required under any applicable laws, rules or regulations, with copies of any such written reports, and Nycomed will thereafter expeditiously investigate the information contained in such reports and communicate such results promptly to POZEN upon conclusion of such investigation. POZEN will copy Nycomed on all correspondence with regulatory authorities relating to adverse drug events in relation to the LX Bulk Drug Substance supplied by Nycomed or any POZEN Products or Nycomed Products.

9. QUALITY REGULATIONS

9.1 **Documentation and Record Keeping**. Nycomed will keep complete, accurate and authentic accounts, notes, data and resources of

all of work performed by Nycomed related to LX Bulk Drug Substance under this Agreement, including, but not limited to, complete and adequate records pertaining to the methods and facilities used for the manufacture in accordance with master production records, batch production records, product related documents (e.g., master formulae, validation packages, specifications, clinical trial batch related documents, batch specific deviation reports, certificates of analysis) and standard operating procedures ("SOPs"). As soon as reasonably practicable following receipt of NDA approval for any POZEN Product, POZEN shall provide Nycomed with written notice of the date of such NDA approval, which notice shall identify by lot number the lots of LX Bulk Drug Substance, Nycomed Products and placebo that correspond to such NDA approval, and Nycomed shall maintain such records with respect to such lots of LX Bulk Drug Substance, Nycomed Products and placebo for a minimum of 2 years after NDA approval. With respect to each lot of LX Bulk Drug Substance supplied by Nycomed under Section 7 of this Agreement, Nycomed will maintain such records for 2 years after the expiration date of any POZEN Product that contains such lot of LX Bulk Drug Substance. POZEN will notify Nycomed in writing of the expiration date of any POZEN Product and of any changes thereto. An SOP will be maintained for 5 years after it is superseded or deleted.

9.2 Inspections and Audits.

9.2.1 During any period in which Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed will permit designated representatives or consultants of POZEN together with designated representatives or consultants of Sublicensees to inspect and visit once during each calendar year the facilities at which the LX Bulk Drug Substance is manufactured, stored or tested for the purpose of determining compliance with this Agreement, as well as all pertinent regulatory requirements. Such inspections will occur during regular business hours upon reasonable advance notice to Nycomed. In addition, if (i) Nycomed receives any Warning Letters (as defined in subsection 9.2.3 below) or (ii) POZEN has properly rejected a shipment of Materials in accordance with the rejection procedures of Section 8.4 of this Agreement for failure to conform to the Product Warranty, then POZEN will have the right promptly thereafter to conduct an audit according to the terms specified in this subsection 9.2.1 (which audit shall not count towards the limit of one audit per calendar year as set forth above).

9.2.2 Nycomed will inform POZEN of the results of any inspection of Nycomed's manufacturing facilities by a regulatory authority that could adversely affect the manufacture and supply of the LX Bulk Drug Substance by Nycomed, regardless of whether or not such inspection was conducted in connection with the LX Bulk Drug Substance manufacture, at the conclusion of each calendar year (or earlier as expressly provided in this Agreement). If such an inspection is in connection with the LX Bulk Drug Substance manufacture, Nycomed will additionally provide POZEN with a summary of the regulatory authority final report within 5 business days of Nycomed's receipt of such report.

9.2.3 During any period in which Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed will provide POZEN within 5 business days of receipt with copies of any Form No. 483 notification, Notice of Adverse Finding, or their analogous forms from any regulatory authorities (**"Warning Letters"**), as well as any subsequent responses by Nycomed or the regulatory authorities relating to the manufacture of LX Bulk Drug Substance or Nycomed's manufacturing facilities used for such manufacture. Nycomed will have the right to redact from any documentation provided to POZEN under this subsection 9.2.3 any information that is specific to products other than the LX Bulk Drug Substance or that is related to details of the Process.

9.2.4 During any period in which Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed agrees to inform POZEN within 10 business days of receipt of any notice of inquiry or inspection with respect to a facility where LX Bulk Drug Substance is manufactured by any regulatory authority from a country in which POZEN or Sublicensees plan to submit (as notified to Nycomed) or have submitted dossiers for regulatory approval of POZEN Products containing LX Bulk Drug Substance (as notified to Nycomed) if such notice could adversely affect the manufacture or use of LX Bulk Drug Substance, and Nycomed will provide POZEN with copies of any written communications received from regulatory authorities related to the manufacture of LX Bulk Drug Substance, and Nycomed may at its discretion redact any proprietary information relating to the Process or to products other than POZEN Products and Nycomed Products. Nycomed will inform POZEN of the content of any proposed response to such an inquiry or inspection. POZEN shall provide written comments to Nycomed within 2 business days and Nycomed will consider POZEN's comments in good faith. Nycomed

will provide POZEN with a copy of Nycomed's final response within 3 days of submission to the applicable regulatory authority, and Nycomed may at its discretion redact any proprietary information relating to the Process or to products other than POZEN Products and Nycomed Products.

9.3 **DMFs and Manufacturing Approvals**. Nycomed and POZEN will coordinate Nycomed's filing of DMFs in accordance with POZEN's or the Sublicensees' clinical development plan for the POZEN Products. Thereafter, for so long as Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed will be responsible for filing and maintaining at its expense, and will use commercially reasonable efforts to file and maintain, in the applicable country(ies) of the Territory all DMFs necessary for the manufacture of LX Bulk Drug Substance supplied by Nycomed under this Agreement for pre-clinical and clinical trials performed by POZEN or its Sublicensees and the commercial sale of POZEN Products after Marketing Approvals have been obtained for such POZEN Products. POZEN will have the right to reference any DMF filed by Nycomed for LX Bulk Drug Substance in connection with the development of POZEN Products contemplated hereunder. For so long as Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed will be responsible for filing and maintaining at its expense, and will use commercially reasonable efforts to file and maintain, the Manufacturing Approval for LX Bulk Drug Substance supplied by Nycomed under this Agreement. During the period in which Nycomed will supply Nycomed Products and placebo to POZEN under this Agreement, Nycomed will be responsible for filing and maintaining at its expense and will use commercially reasonable efforts to file and maintain the Manufacturing Approval for such Materials supplied by Nycomed under this Agreement.

9.4 **Personnel**. Neither Party will use in any capacity, in connection with any manufacturing or other services to be performed under this Agreement, any individual who has been debarred pursuant to the FD&C Act or who is subject to an action, suit, claim, investigation or legal or administrative proceeding that could reasonably be expected to lead to a debarment of Nycomed, POZEN or any person performing manufacturing or other services hereunder. Either Party will, if so requested by the other Party, prepare and submit a certification statement as necessary to satisfy the requirements of the FD&C Act. Either Party agrees to immediately inform the other Party in writing if any person who is performing services hereunder is debarred or if such person becomes subject to an action, suit,

claim, investigation or legal or administrative proceeding that could lead to a debarment of such person.

9.5 **Records.** Nycomed will notify POZEN that Nycomed has submitted to regulatory authorities in the Territory as required by applicable law any annual reports or updates in connection with the maintenance of DMFs under this Agreement within 30 days of the filing of such reports or updates with any regulatory authority in the Territory.

9.6 **Change Management.**

9.6.1 **Exhibit K** (attached hereto and hereby incorporated by reference) sets forth the meanings of the terms "Major Change", "Moderate Change", "Minor Change" and "Change" used in this Section 9.6.

9.6.2 If Nycomed proposes to make a Major Change related to the Materials (including the manufacture or quality control thereof), Nycomed will notify POZEN and provide information to POZEN regarding such change at a level reasonably sufficient to allow POZEN to evaluate the impact of such change on the POZEN Products. Nycomed will not implement any such change prior to receipt of POZEN's approval; provided, however, that such approval will not be unreasonably withheld or delayed for more than 30 days following receipt of Nycomed's above notification, and POZEN's failure to respond to such notification within 30 days of receipt thereof shall be deemed to constitute POZEN's approval of the proposed Major Change. Notwithstanding the aforesaid, if Nycomed proposes to make a Major Change related to the Materials (including the manufacture or quality control thereof) and such change is required by cGMP or applicable laws or regulations, then Nycomed may implement such change without POZEN's approval and will provide POZEN with prompt written notice of its decision to implement such change.

9.6.3 If Nycomed proposes to make a Moderate Change related to the Materials (including the manufacture or quality control thereof), Nycomed will notify POZEN and provide information to POZEN regarding such change at a level reasonably sufficient to allow POZEN to evaluate the impact of such change on the POZEN Products. Nycomed will notify POZEN as soon as such change has been implemented; provided, however, that any such implementation does not require POZEN's approval.

9.6.4 Any Minor Changes related to the Materials (including the manufacture or quality control thereof) do not require any notification of POZEN or approval from POZEN prior to implementation.

9.6.5 When required or requested to do so by a regulatory authority of competent jurisdiction, POZEN may in writing propose a Change in the Specifications or in the Process, and the Parties will discuss in good faith and use reasonable efforts to agree to a specific procedure and the costs necessary to implement such a Change and which Party will bear such costs; provided, however, that, if reasonably requested by Nycomed and appropriate under the circumstances, POZEN will use reasonable efforts to negotiate with the applicable regulatory authority for either the waiver or modification of its requirement or request. Prior to the agreement on the aforesaid procedure and cost, Nycomed will not be obligated to implement any such Change.

9.6.6 Additionally, POZEN may, from time to time, in writing reasonably suggest Changes in the Specifications other than the Changes provided for in subsection 9.6.5 above, and in the case of Nycomed's approval (which will not be unreasonably withheld), the Parties will discuss in good faith and use reasonable efforts to agree on a specific procedure and the costs necessary to implement such other Changes to the Specifications and which Party will bear such costs. Prior to Nycomed's approval and the agreement on the aforesaid procedure and cost, Nycomed will not be obligated to implement any such other Change.

9.6.7 If there are any additional questions regarding notification and approval of Changes that arise during the Term, Nycomed will submit the questions to POZEN to determine the level of review/notification that may be required by the proposed Change.

9.6.8 Nycomed will establish cGMP-compliant Change control procedures which register and allow the tracking of any and all Changes made by Nycomed related to the Materials (including the manufacture or quality control thereof).

10. COMPENSATION

10.1 **Option Fee.** POZEN will pay to Nycomed a one-time, non-refundable, non-creditable option fee of US$50,000 within 10 days after the Effective Date.

10.2 **Option Period Milestones**. POZEN will make the following one-time, non-refundable, non-creditable payments in the amounts set forth below within 30 days after occurrence of the events described below:

MILESTONE EVENT	MILESTONE PAYMENT
1. Earlier of: (a) completion by POZEN of the re-analysis of Carcinogenicity Data pursuant to Section 2.1 of this Agreement, and (b) 180 days after delivery by Nycomed of the Carcinogenicity Data, IND Deliverables and Existing Nycomed Product Deliverables (excluding any additional shipments requested by POZEN pursuant to the delivery schedule of **Exhibit B**)	US$150,000
2. Delivery by Nycomed of first shipment of LX Bulk Drug Substance and 8 mg quick release tablets and matching placebos pursuant to the delivery schedule of **Exhibit B**	US$50,000
3. Earlier of: (a) 180 days after filing by POZEN of the first IND for the first POZEN Product, or (b) delivery by Nycomed of second shipment of LX Bulk Drug Substance and oral formulations of Existing Nycomed Products and matching placebos pursuant to the delivery schedule of **Exhibit B**	US$50,000
4. Delivery by Nycomed of all Existing Nycomed Product Deliverables (excluding any additional shipments requested by POZEN pursuant to the delivery schedule of **Exhibit B**) and IND Deliverables	US$50,000
5. Earlier of: (a) filing by POZEN of the first IND for the first POZEN Product, and (b) 180 days after delivery by Nycomed of the IND Deliverables and Existing Nycomed Product Deliverables (excluding any additional shipments requested by POZEN pursuant to the delivery schedule of **Exhibit B**)	US$150,000

10.3 **Option Exercise Fee**. Within 10 days of exercise of the Option by POZEN, POZEN will pay to Nycomed a one-time, non-refundable, non-creditable exercise fee of US$500,000.

10.4 **Marketing Approval Milestone Payments**. POZEN will make the following non-refundable, non-creditable payments in the amounts set forth below within 30 days of occurrence of the events described below:

MILESTONE EVENT	MILESTONE PAYMENT
1. Receipt of Marketing Approval by or on behalf of POZEN or a Sublicensee (excluding pricing and reimbursement approval) for first Single Entity Product in the first country in the Exclusive Territory	US$250,000
2. Receipt of Marketing Approval by or on behalf of POZEN or a Sublicensee (excluding pricing and reimbursement approval) for first Combination Product in the first country in the Territory	US$250,000

10.5 **Royalties**.

10.5.1 **Royalties on Net Sales.**

(a) Subject to the adjustments provided for in Section 10.5.4 of this Agreement, POZEN will pay to Nycomed in U.S. Dollars (with respect to Net Sales in the Exclusive Territory) or Euros (with respect to Net Sales in the Limited Territory) a royalty on Net Sales of POZEN Products based on the following royalty rates: (i) 5% of Net Sales of any Single Entity Product; and (ii) 2% of Net Sales of any Combination Product.

(b) Once the obligation to pay royalties commences, POZEN will pay royalties within 30 days from the last day of each calendar quarter based on the Net Sales of POZEN Products during such calendar quarter.

(c) No royalties will be payable on sales among POZEN INC., its Affiliates and Sublicensees, but royalties will be payable on subsequent sales by POZEN INC., its Affiliates and Sublicensees to a Third Party customer. No multiple royalty will be payable under this Agreement because the manufacture, use or sale of a POZEN Product is covered by more than one Licensed Patent or is subject to both Know-How included in the Licensed Technology and a Licensed Patent.

10.5.2 **Royalties on Sublicense Revenues.**

(a) POZEN will pay to Nycomed in United States Dollars a royalty on Sublicense Revenues in the following amounts: (i) 5% of Sublicense Revenues for Single Entity Products, up to a maximum royalty of US$1,000,000 based on Sublicense Revenues received from the same Sublicensee for Single Entity Products; and (ii) 2% of Sublicense Revenues for Combination Products, up to a maximum royalty of US$1,000,000 based on Sublicense Revenues received from the same Sublicensee for Combination Products.

(b) Once the obligation to pay royalties commences, POZEN will pay royalties within 30 days from the last day of each calendar quarter based on the Sublicense Revenues of POZEN Products during such calendar quarter.

10.5.3 **Royalty Term.** Royalties due under Sections 10.5.1 and 10.5.2 of this Agreement will be payable for each POZEN Product on a country-by-country basis until 10 years from the date of first commercial sale of such POZEN Product in such country by POZEN or Sublicensees.

10.5.4 **Royalty Adjustments.**

(a) The royalty rate set forth in Section 10.5.1 of this Agreement for each Single Entity Product will be reduced, cumulatively:

(i) by 1 percentage point in a country of the Exclusive Territory during such time as the sale of such Single Entity Product by an unlicensed Third Party in such country would infringe a Patent in the Field owned or Controlled by POZEN or Sublicensees in such country; and

(ii) by a total of 1 percentage point throughout the Exclusive Territory if POZEN or Sublicensees incurs out-of-pocket expenses of: (A) US$3,500,000 or more for additional studies required for Marketing Approval for such Single Entity Product in the Exclusive Territory of an indication for which Nycomed has, as of the Effective Date, received Marketing Approval for a Nycomed Product; or (B) US$4,500,000 or more for studies required for Marketing Approval for such Single Entity Product in the Exclusive Territory of an indication for which Nycomed has not, as of the Effective Date, received Marketing Approval for a Nycomed Product.

(b) The royalty rate set forth in Section 10.5.1 of this Agreement for each Single Entity Product, as adjusted, if applicable, by the preceding subsection 10.5.4(a), will be reduced by 50% in any country in the Exclusive Territory in which one or more Generic Products in the same presentation form as such Single Entity Product are commercially sold by a Third Party (excluding Sublicensees) in the Field and if and as long as such Generic Products constitute, in the aggregate, 20% or more of combined prescriptions in such country of such Single Entity Product and such Generic Products. For purposes of this subsection 10.5.4(b) only, a "Generic Product" means any pharmaceutical product containing Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active ingredient, provided that if POZEN or a Sublicensee owns or Controls a Patent that is infringed by the manufacture, use or sale of such Generic Product, POZEN will use commercially reasonable efforts to stop such infringement or, as applicable, to ensure that such Sublicensee will use commercially reasonable efforts to stop such infringement.

10.6 **Payments and Reports**. All payments made by POZEN to Nycomed pursuant to royalty or other payment obligations provided herein will be accompanied by a written report setting forth in reasonable detail the calculation of the amount of the payment made. Such report will include, for example, a calculation of any royalties being paid and, with respect to such royalties, will include the amount of Net Sales and Sublicense Revenues of such POZEN Products on a country-by-country basis.

10.7 **Payment Method; Currency; Interest.** All payments hereunder will be made in United States Dollars or Euros, as specified in this Agreement, by wire transfer in immediately available funds to an account designated by the receiving Party. For the purpose of determining royalties payable under this Agreement, any Net Sales or Sublicense Revenues denominated in currencies other than U.S. Dollars or Euros will be converted into U.S. Dollars or Euros, respectively, according to the conversion rate listed in the The Wall Street Journal, Eastern Edition, on the last business day of the applicable calendar quarter. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a per annum rate equal to the prime rate as published in the The Wall Street Journal, Eastern Edition, on the first day of each calendar quarter in which such payments are overdue, plus 2 percentage points, calculated on the number

of days such payment is delinquent, compounded monthly, except that such rate shall not exceed the maximum rate permitted by applicable law.

10.8 **Taxes**. POZEN will have the right to withhold taxes in the event that authorities in any country require the withholding of taxes on amounts paid hereunder to Nycomed. Such taxes will be deducted by POZEN from such payment and will be paid by POZEN to the proper taxing authority on behalf of Nycomed. POZEN will promptly secure and send to Nycomed proof evidencing payment of such taxes withheld and paid by POZEN for the benefit of Nycomed. POZEN will assist Nycomed in claiming exemption from or reducing such deductions or withholdings under any applicable income tax treaty by providing or filing such documentation (including certificates of residence provided by Nycomed) as may be reasonably required by Nycomed to claim such exemption or reduction.

10.9 **Audit Rights; Adjustments**.

10.9.1 POZEN will permit an independent certified public accountant designated by Nycomed and reasonably acceptable to POZEN (the **"Auditor"**), to have access to POZEN's records and books during regular business hours for the sole purpose of determining the accuracy of the amounts reported and actually paid or otherwise payable to Nycomed under the terms of this Agreement (the **"Audit"**). Any Audit will cover a period not to exceed 3 years immediately preceding such audit. Nycomed will bear all costs and expenses in connection with the Audit; *provided, however,* that if any Audit reveals an understatement of Net Sales greater than 5% of the stated amount, then POZEN will bear all costs and expenses in connection with such Audit. Any such Audit will be performed upon at least 30 calendar days' prior written notice during regular business hours, and not more than once in each calendar year during the Term and during each calendar year in the 3-year period following expiration or termination of this Agreement.

10.9.2 Nycomed acknowledges that POZEN will require the Auditor to execute a written confidentiality agreement containing reasonable terms and conditions with POZEN and that such Auditor will disclose to Nycomed only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement. The Auditor will send a copy of the report to POZEN at the same time it is sent to

Nycomed. The report sent to POZEN will also include the methodology and calculations used to determine the results.

10.9.3 If the Audit results in a determination that Net Sales or Sublicense Revenues have been overstated, then Nycomed will credit the amount of such overpayment towards the amounts owed by POZEN under this Agreement.

10.9.4 If the Audit results in a determination that Net Sales or Sublicense Revenues have been understated, then such understated amount will be paid to Nycomed with interest from the date originally due at the rate set forth in Section 10.7 of this Agreement for late payments, within 30 days after the date on which Nycomed notifies POZEN.

11. INTELLECTUAL PROPERTY

11.1 Ownership.

11.1.1 **Licensed Technology**. All right, title and interest in and to the Licensed Technology will remain exclusively owned by Nycomed, subject only to the licenses granted to POZEN hereunder.

11.1.2 **Inventions**. POZEN will own all right, title and interest in and to any Inventions. Except with Nycomed's prior written consent, POZEN will not file any applications for Patents claiming or covering one or more Inventions containing or referencing any Confidential Information of Nycomed.

11.2 **Disclosure of Patents**. Within 30 days of the Effective Date, Nycomed will disclose to POZEN the complete text of all pending patent applications included in the Licensed Technology as well as copies of all correspondence concerning the prosecution thereof made or received by or on behalf of Nycomed to or from patent offices and any information or correspondence received by or on behalf of Nycomed from patent offices concerning the institution of any interference, opposition, re-examination, reissue, revocation, nullification or any official proceeding involving any Licensed Patents included in the Licensed Technology. Nycomed will ship such materials DDU (ICC Incoterms 2000) to a place of destination to be named by POZEN within 10 days after the Effective Date.

11.3 **Enforcement Rights.**

11.3.1 **Notification of Infringement.** If either Party learns of any misappropriation or infringement or threatened infringement by a Third Party of the Licensed Technology, in each case, in the Field and in the Territory, such Party will promptly notify the other Party and will provide such other Party with all available evidence of such misappropriation or infringement.

11.3.2 **Enforcement of Patents and Product Rights in the Territory.**

(a) Nycomed will have the first right, but not the obligation, to institute, prosecute and control at its own expense any action or proceeding with respect to misappropriation or infringement in the Field and in the Territory of the Licensed Technology, by counsel of its own choice, and will consult with POZEN on any actions that Nycomed proposes to take in such action or proceeding. If Nycomed fails to bring an action or proceeding or otherwise take appropriate action in Nycomed's discretion to abate such infringement in the Field and in the Territory within a period of 90 days of written notice by POZEN to Nycomed requesting such action, POZEN will have the right, but not the obligation, to bring and control, by counsel of its own choice, any such action or proceeding.

(b) If a Party brings any action or proceeding under this subsection 11.3.2, the other Party agrees, at the request and expense of the first Party, to be joined as a Party plaintiff to the extent necessary to prosecute the action or proceeding. Each Party will reasonably cooperate with the other Party in any such action or proceeding brought by a Party against a Third Party. Each Party will have the right to consult with the other Party and to participate in and be represented by independent counsel in any such action or proceeding at its own expense.

11.3.3 **Settlement with a Third Party.** The Party that controls the prosecution of a given action under subsection 11.3.2 will also have the right to control settlement of such action; *provided, however,* that no settlement will be entered into with respect to the Licensed Technology without the written consent of Nycomed, such consent not to be unreasonably withheld.

11.3.4 **Awards**. Any damage award resulting from any action or proceeding pursuant to subsection 11.3.2 will be retained by the Party to which such damage award is granted.

11.4 **Covenant**. POZEN hereby covenants and agrees not to enforce against Nycomed or any direct or indirect licensee, sublicensee or contractor of Nycomed any Patent claiming or covering one or more Inventions that would be infringed by the development, use, manufacture or sale of Existing Nycomed Products outside the Exclusive Territory or, after expiration or termination of this Agreement, throughout the entire world.

11.5 **Maintenance**. Nycomed will use commercially reasonable efforts to maintain and prosecute the Licensed Patents included in the Licensed Technology in a reasonable scope; *provided, however,* that such obligation of Nycomed shall cease after 5 years from the Effective Date with respect to such Licensed Patents included in the Licensed Technology which at that date even in absence of the licenses granted hereunder would not be infringed by the manufacture, use or sale of POZEN Products by POZEN, except in case POZEN agrees to reimburse to Nycomed all costs and expenses related to the maintenance or prosecution of such Licensed Patents included in the Licensed Technology. Nycomed agrees to provide POZEN with (a) written notice of any issuance of a Patent from a patent application included in the Licensed Patents as soon as reasonably practicable and (b) written notice of Nycomed's decision to cease prosecution and maintenance of a patent application included in the Licensed Patents as soon as reasonably practicable.

12. REPRESENTATIONS AND WARRANTIES

12.1 **Mutual Representations and Warranties**. Each of the Parties hereby represents and warrants to the other Party as follows:

12.1.1 such Party is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated;

12.1.2 this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to applicable bankruptcy, reorganization, insolvency, moratorium and other laws affecting creditors' rights generally from time to time in effect and to general principles of equity and the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement,

instrument or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it. Each Party expressly represents and warrants that it has the full power and authority to enter into this Agreement and to carry out the obligations contemplated hereby; and

12.1.3 it has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement.

12.2 **Representations and Warranties of Nycomed**. Nycomed represents and warrants to POZEN that:

12.2.1 Nycomed will not, during the Term, grant any right to any Third Party relating to the Licensed Technology in the Field in the Territory which would conflict with the rights granted to POZEN hereunder;

12.2.2 To the best of Nycomed's knowledge as of the Effective Date, there is no Third Party infringing any of the Licensed Patents included in the Licensed Technology in the Territory or misappropriating or using any of the Know-How included in the Licensed Technology in the Territory contrary to the rights granted to POZEN pursuant to this Agreement;

12.2.3 Nycomed has obtained the assignment of all interests and all rights of any and all Third Parties (including, but not limited to employees) with respect to any Licensed Patents included in the Licensed Technology;

12.2.4 As of the Effective Date, Nycomed has not been served with any interference action or litigation with respect to any Licensed Patents included in the Licensed Technology, and Nycomed has not received any written communication which expressly threatens interference actions or other litigation before any patent office, court, or any other governmental entity in any jurisdiction in regard to any such Patents;

12.2.5 **Exhibit A** (excluding any products listed thereon as exceptions) contains a complete list of all pharmaceutical products developed by Nycomed and for which Nycomed filed for Marketing Approval prior to the Effective Date, or which Nycomed commercialized

prior to the Effective Date, that contain or comprise Lornoxicam (or any salts, solvates or polymorphs thereof) as the single active drug substance;

12.2.6 To the best of Nycomed's knowledge as of the Effective Date, Nycomed Controls all Patents in the Territory claiming the products listed on **Exhibit A**, excluding the products listed thereon as exceptions (with respect to which Nycomed does not Control all related Patents);

12.2.7 **Exhibit G** contains a complete list of the Patents Controlled by Nycomed as of the Effective Date that would be infringed by the use or sale of Nycomed Products by an unlicensed Third Party, but excluding any Patents relating solely to the manufacture of LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof);

12.2.8 **Exhibit H** contains a complete list of the materials described in Section 11.2 of this Agreement; and

12.2.9 As of the Effective Date, Nycomed has not undertaken, and has no plans to undertake, efforts to develop, market, or commercialize any pharmaceutical product containing an isomer of Lornoxicam as an active substance.

12.3 **Limitation of Warranty**. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT, WITH RESPECT TO ANY MATERIALS, INFORMATION, SERVICES, OR LICENSES PROVIDED TO THE OTHER PARTY PURSUANT TO THIS AGREEMENT.

13. INDEMNIFICATION

13.1 **Indemnification by POZEN**. POZEN will indemnify, defend and hold Nycomed and its directors, officers and employees (each a **"Nycomed Indemnitee"**) harmless from and against any damages, costs or expenses, including reasonable attorneys' fees and expenses (collectively, **"Losses"**) incurred by a Nycomed Indemnitee in connection with any claim, lawsuit or other action by a Third Party (**"Third Party Claim"**) to the extent such Losses arise out of, relate to or result from: (a) the development, testing, manufacture, use, sale, offer to sell, sale,

importation or distribution (including distribution free of charge) of POZEN Products or use of Materials or use of any information, data or documentation provided by Nycomed in connection with this Agreement by or on behalf of POZEN or Sublicensees (other than Nycomed) after the Effective Date; (b) the breach by POZEN of any of its representations, warranties, covenants or obligations contained within this Agreement; or (c) the gross negligence or willful misconduct of POZEN, its directors, officers or employees in connection with this Agreement. Notwithstanding the foregoing, POZEN will have no obligation under this Section 13.1 with respect to any Losses for which a POZEN Indemnitee is entitled to indemnification pursuant to Section 13.2 of this Agreement.

13.2 **Indemnification by Nycomed.** Nycomed will indemnify, defend and hold POZEN and its directors, officers and employees, (each a **"POZEN Indemnitee"**) harmless from and against any Losses incurred by a POZEN Indemnitee in connection with any Third Party Claim to the extent such Losses arise out of, relate to or result from: (a) the breach by Nycomed of any of its representations, warranties, covenants or obligations contained within this Agreement, including the supply by Nycomed of Materials that do not conform to the Product Warranty (except to the extent POZEN did not perform reasonable physical inspection or standard testing of such Materials in accordance with standards in the pharmaceutical industry, including in any event testing for purity and assay according to the methods included in the applicable Specifications); or (b) the gross negligence or willful misconduct of Nycomed, its directors, officers or employees in connection with this Agreement. Notwithstanding the foregoing, Nycomed will have no obligation under this Section 13.2 with respect to any Losses for which a Nycomed Indemnitee is entitled to indemnification pursuant to Section 13.1 of this Agreement.

13.3 **Indemnification Procedures.** A Party which or whose officers, directors or employees intend to claim indemnification under Section 13.1 or 13.2 of this Agreement (the **"Indemnitee"**) will promptly notify the other Party (the **"Indemnitor"**) in writing of any claim, lawsuit or other action in respect of which the Indemnitee or any of its directors, officers or employees intend to claim such indemnification as soon as reasonably practicable after the assertion of such claim; *provided, however,* that the failure to provide written notice of such claim as soon as reasonably practicable will not relieve the Indemnitor of any of its obligations hereunder, except to the extent that the Indemnitor is prejudiced by such

failure to provide prompt notice. For purposes of clarification, an officer, director or employee of a Party will not have the right to claim indemnification directly from the other Party under this Section 13 and shall instead make any such claim solely through the Party employing such officer, director or employee; *provided, however,* that the foregoing shall not be construed to limit any right to indemnification that any officer, director or employee of a Party may have other than under this Agreement (e.g., under applicable laws or regulations). The Indemnitor will have the right to assume the complete control of the defense, compromise or settlement of any such claim with the prior written consent of such Indemnitee, which such consent will not be unreasonably withheld or restricted or withdrawn or restricted at a later stage; *provided, however,* that Indemnitee will have the right to withhold consent to any compromise or settlement in its sole discretion if such compromise or settlement includes any admission of wrongdoing on the part of an Indemnitee, or limits the scope of any claims in or enforceability of any Patents owned by or licensed to the Indemnitee. Subject to the aforesaid, the Indemnitor may at its own expense, employ legal counsel to defend the claim at issue and at any time after Indemnitor has assumed defense of a claim, the Indemnitor may exercise, on behalf of the Indemnitee, any rights which may mitigate the extent or amount of such claim; *provided, however,* the Indemnitee: (a) may, in its sole discretion and at its own expense, employ legal counsel to represent it (in addition to the legal counsel employed by the Indemnitor) in any such matter, and in such event legal counsels selected by the Indemnitee and the Indemnitor will be required to confer and cooperate with each other in such defense, compromise or settlement for the purpose of informing and sharing information; (b) will, at its own expense, make available to Indemnitor those employees, officers and directors of Indemnitee whose assistance, testimony or presence is necessary, useful or appropriate to assist the Indemnitor in evaluating and in defending any such claim; *provided, however,* that any such access will be conducted in such a manner as not to interfere unreasonably with the operations of the businesses of Indemnitee; and (c) will otherwise reasonably cooperate with the Indemnitor and its legal counsel in the investigation and defense of such claim.

13.4 **Insurance**. During the Term and for 5 years thereafter, each Party will maintain commercially reasonable insurance coverage commensurate with its obligations under this Agreement.

14. LIABILITY

14.1 **Limitation**. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATING IN ANY WAY TO THIS AGREEMENT (EXCEPT WITH RESPECT TO THE PROVISIONS SET FORTH IN SECTIONS 13 AND 15 OF THIS AGREEMENT), INCLUDING, BUT NOT LIMITED TO, ANY CLAIM FOR DAMAGES BASED UPON LOST PROFITS.

14.2 **Affiliates**. Each of POZEN INC. and Nycomed Danmark ApS will be responsible and liable to each other for any of its Affiliates', contractors' or consultants' acts, performances, omissions or failures to perform in connection with this Agreement, as if such acts, performances, omissions or failures were made by themselves.

15. CONFIDENTIALITY, PUBLICATIONS, PUBLICITY

15.1 **Confidential Information**. Any information or materials communicated by one Party to the other Party, or as to which one Party provides the other Party with access, in connection with this Agreement will be deemed "Confidential Information" of the disclosing Party if either (a) marked "confidential" or with a similar legend, or (b) if disclosed orally or visually, if identified as being confidential at the time of such oral or visual disclosure, and thereafter reduced to writing, marked "confidential" or with a similar legend, and sent to the other Party within 30 days of such oral or visual disclosure, or (c) if the nature of such information or materials or circumstances of disclosure would suggest to a reasonable person that such disclosure was confidential, which will in any event apply to the Nycomed Product Deliverables, the IND Deliverables and any information or materials that POZEN accesses at Nycomed's facilities. Notwithstanding the preceding sentence, "Confidential Information" will not be deemed to include information or materials that the receiving Party can demonstrate, by competent written proof:

15.1.1 At the time of disclosure is published or is publicly known or otherwise in the public domain, other than through any act or omission by the receiving Party;

15.1.2 Was already known to the receiving Party, other than under an obligation of confidentiality or non-use, prior to the time of disclosure by the disclosing Party;

15.1.3 Is disclosed to the receiving Party in good faith, without an obligation of confidentiality, by a Third Party not under any obligation of confidence with respect to such information, after the time of disclosure by the disclosing Party; or

15.1.4 Is independently developed by employees of the receiving Party who had no access to the disclosing Party's Confidential Information.

15.2 **Treatment of Confidential Information**. The Parties agree that during the Term and for 10 years after the expiration or termination of this Agreement for any reason whatsoever, a Party receiving Confidential Information of the other Party will: (a) treat any such Confidential Information disclosed to it by the other Party as strictly confidential; (b) not disclose such Confidential Information to Third Parties without the prior written consent of the other Party, other than to the extent necessary in the performance of this Agreement to Sublicensees, its contractors or any consultants, provided that such disclosure be under confidentiality agreements with provisions substantially similar to those contained in this Agreement and further provided that the Party so disclosing Confidential Information shall be fully responsible and liable for any breach of any such confidentiality agreement by any Sublicensee, contractor or consultant; (c) not use such Confidential Information for purposes other than those authorized expressly herein; and (d) use reasonable efforts to prevent unauthorized access to such Confidential Information.

15.3 **Access**. Access to Confidential Information will be limited to those employees of the Party receiving Confidential Information who reasonably require such Confidential Information in order to carry out activities authorized pursuant to this Agreement, provided that such access be under confidentiality agreements with provisions substantially similar to those contained in this Agreement and further provided that such Party shall be fully responsible and liable for any breach of any such confidentiality agreement by any such employee.

15.4 **Permitted Disclosures**. Notwithstanding any other provision in this Agreement, a receiving Party may disclose Confidential Information

of the disclosing Party to the extent such disclosure is required by law or court order, provided that the receiving Party gives the disclosing Party prompt written notice of the requirement to disclose and reasonably cooperates with the disclosing Party to seek a protective order or other restrictions on the disclosure of such Confidential Information of the disclosing Party. Any such required disclosure will be limited only to that Confidential Information that is required to be disclosed and such disclosed Confidential Information will remain Confidential Information hereunder despite the required disclosure.

15.5 **Return of Confidential Information**. Upon termination or expiration of this Agreement for any reason whatsoever, each Party hereto will return or destroy (and certify the destruction of), as instructed by the disclosing Party, all Confidential Information of the other Party in its, its contractors' or consultants' or the Sublicensees' possession to the other Party; *provided, however,* that each Party may retain: (a) a single archival copy of the Confidential Information of the other Party solely for the purpose of determining the extent of disclosure of Confidential Information hereunder and assuring compliance with the surviving provisions of this Agreement (b) subject to the non-use and non-disclosure provisions of this Section 15, any portion of the Confidential Information of the other Party which is contained in laboratory notebooks; and (c) subject to the non-use and non-disclosure provisions of this Section 15, any portion of the Confidential Information of the other Party which a Party is required by mandatory applicable law to retain.

15.6 **Confidentiality of the Agreement Terms**. During the 3-month period following the Effective Date, neither Party will disclose or announce to any Third Party the fact that this Agreement has been executed unless such disclosure or announcement is mutually agreed to by the Parties, except that either Party may disclose the execution of this Agreement to its accountants, attorneys and insurers who are bound by law or contract to maintain the confidentiality of such information. The first press release announcing the execution of this Agreement will be subject to mutual agreement of the Parties in advance and, unless otherwise mutually agreed by the Parties, will occur promptly after the end of the 3-month period following the Effective Date. The foregoing provisions of this Section 15.6 shall be deemed material obligations of the Parties. For purposes of clarification, the preceding sentence shall not be construed to mean or suggest that any other particular obligation of either Party hereunder is or is

not material. Neither Party will disclose the terms of this Agreement to any Third Party without the prior written consent of the other Party; *provided, however,* that either Party may disclose the terms of this Agreement to actual or prospective investors and corporate partners (including Sublicensees), to a Party's accountants, attorneys, insurers and other professional advisors, and as required by applicable laws and regulations of the U.S. Securities and Exchange Commission and any stock exchange on which a Party's stock is traded.

16. TERM AND TERMINATION

16.1 **Term of the Agreement.** The term of this Agreement (the **"Term"**) will commence on the Effective Date and end upon the first to occur of: (a) the date of expiration of all royalty obligations in all countries in the Territory as provided in Section 10 of this Agreement, and (b) termination of this Agreement as provided in this Section 16.

16.2 **Termination for Material Breach.** In the event of a material breach of this Agreement by either Party, the non-breaching Party will have the right to terminate this Agreement by written notification to the other Party, effective immediately upon receipt, if such breach is not cured within 60 days after receipt of written notice of such breach from the non-breaching Party.

16.3 **Expiration of Option Period.** This Agreement will terminate upon expiration of the Option Period if POZEN has not exercised the Option pursuant to Section 3.1 of this Agreement during the Option Period.

16.4 **Termination at Will.** In the event that, despite exercising its commercially reasonable efforts to develop and Commercialize POZEN Products in accordance with Section 6.3, POZEN determines in good faith that it is not commercially or scientifically feasible to continue development and Commercialization efforts with respect to POZEN Products, POZEN may provide Nycomed with written notice of such determination, in which event the Parties shall within 30 days commence good faith negotiations regarding how to proceed and shall continue such good faith negotiations for up to 90 days. If the Parties are unable to reach agreement prior to the end of such 90-day negotiation period, POZEN shall have the right to terminate this Agreement by providing written notice of termination to

Nycomed within 30 days after the end of such 90-day period, effective immediately upon receipt.

16.5 **Force Majeure**. The Party not subject to force majeure will have the right to terminate this Agreement pursuant to Section 19.8 of this Agreement, effective immediately upon receipt of written notice of termination.

16.6 **Severability**. This Agreement may be terminated in accordance with Section 19.6 of this Agreement.

16.7 **No Challenge**. Nycomed has the right to terminate this Agreement at any time in the event POZEN or a Sublicensee initiates a lawsuit or other proceeding challenging the validity or enforceability of any Licensed Patent included in the Licensed Technology. Such termination shall be (a) effective immediately upon notice to POZEN in the case of a lawsuit or proceeding initiated by POZEN, and (b) effective upon 30 days' notice to POZEN in the case of a lawsuit or proceeding initiated by a Sublicensee, unless POZEN has caused such Sublicensee to cease such activity within such 30-day period.

16.8 **Insolvency**. If either POZEN INC. or Nycomed Danmark ApS commences as a debtor any proceedings under any bankruptcy, insolvency, reorganization, dissolution or liquidation law or if any such proceedings are commenced against either POZEN INC. or Nycomed Danmark ApS, the other Party will have the right to terminate this Agreement, effective immediately upon receipt of written notice of termination.

17. CONSEQUENCES OF EXPIRATION AND TERMINATION

17.1 **Expiration**. If this Agreement expires pursuant to Section 16.1(a) above, the licenses granted by Nycomed in Section 4.1 of this Agreement will survive as non-exclusive and become perpetual, fully-paid and royalty-free.

17.2 **Termination**. If this Agreement terminates for whatsoever reason, POZEN will promptly: (a) refrain from using the Licensed Technology or any portion thereof and exercising any of its licenses granted under this Agreement, and (b) terminate or cause the termination of all Sublicense Agreements with respect to the Licensed Technology or

any portion thereof that is sublicensed to the Sublicensees, and (c) at Nycomed's request, return to Nycomed all unused Materials (except to the extent that retention of such Materials is required by applicable laws or regulations, and except LX Bulk Drug Substance supplied by Nycomed pursuant to Section 7 of this Agreement) and destroy all Materials which have been modified with POZEN's proprietary methods (except to the extent that retention of such Materials is required by applicable laws or regulations and except LX Bulk Drug Substance supplied by Nycomed pursuant to Section 7 of this Agreement), and (d) permit Nycomed to cancel with any regulatory authority (including the FDA) any POZEN right of reference to Nycomed's INDs, DMFs or MAAs. Notwithstanding the aforesaid, if this Agreement terminates pursuant to Section 16.2 for breach by POZEN, Section 16.3 or Section 16.4, POZEN will promptly withdraw all filed and granted INDs and all filed and granted Regulatory Approvals pertaining to POZEN Products. Notwithstanding the aforesaid, if this Agreement terminates pursuant to Section 16.4 before the end of the Option Period, POZEN will promptly pay to Nycomed an appropriate percentage (to be agreed upon in good faith by the Parties) of any unpaid milestone payment under Section 10.2 for which Nycomed has performed all or part of the applicable activities under Section 2.3 (as reasonably evidenced by Nycomed and set forth in writing), based on the efforts expended by Nycomed up to the date of termination (not to exceed the applicable milestone payment).

17.3 **Accrued Claims.** No expiration or termination of this Agreement will relieve any Party hereto from any liability which, at the time of such expiration or termination, has already accrued to such Party prior to such expiration or termination or which is attributable to a period prior to such expiration or termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring prior to such expiration or termination.

17.4 **Survival.** In the event of expiration or termination of this Agreement, the following provisions will survive, together with the definitions of the defined terms used therein and any related provisions of the exhibits referenced therein: Sections 2.1 (only in respect to POZEN's obligation to provide the results set forth in Section 2.1 and Nycomed's right to use such results), 4.2.8, 4.2.9, 7.5 (only in respect to POZEN's obligation not to use the Patents, or use or disclose Confidential

Information, of Nycomed as set forth in Section 7.5.1), 8.1, 8.4, 8.5, 8.6, 9.1, 10.2 (only if this Agreement is terminated pursuant to Section 16.4), 10.6, 10.7, 10.8, 10.9, 11.1, 11.4, 12.3, 13, 14, 15, 17, 18 and 19. All other provisions, including all rights and obligations thereunder, will terminate and be of no further force and effect (except to the extent necessary with respect to liabilities accrued prior to expiration or termination as described in Section 17.3 above).

18. DISPUTE RESOLUTION

18.1 The Parties will try to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement (**"Dispute"**), a Party may notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within 20 days of receipt of the written notice by the other Party, such dispute will be resolved according to the procedures set forth elsewhere in this Agreement, or, absent such procedures, referred to the Chief Executive Officers of each of the Parties (or their respective designees) who will use their good faith efforts to resolve the Dispute within 15 days after such referral. Notwithstanding the aforesaid, a Party will not be obligated to comply with the procedures as provided in this Section 18.1 and may immediately invoke the procedures set forth in Section 18.2 if such compliance might result in such Party's claims becoming statute barred.

18.2 Any Dispute that is not resolved as provided in the preceding Section 18.1 will be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with such Rules. The language of any such arbitration proceeding will be English, and any such arbitration proceeding will take place in London, England. Nothing herein shall limit or restrict a Party's ability to seek injunctive or other equitable relief in the event of a breach or anticipated breach of Section 15. Notwithstanding the foregoing, either Party shall have the right to pursue an action in a court of competent jurisdiction to obtain injunctive or other equitable remedy, in order to preserve the status quo during the resolution of any Dispute under this provision.

19. MISCELLANEOUS

19.1 **Further Assurances.** At any time during the Term, each Party will, at the request of the other Party, use reasonable efforts to: (a) deliver to the other Party such records, data or other documents consistent with the provisions of this Agreement, (b) execute and deliver, or cause to be delivered, all such assignments, consents, documents or further instruments of transfer or license consistent with the terms of this Agreement, and (c) take or cause to be taken all such other actions, as a Party may reasonably deem necessary in order for such Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

19.2 **Assignment.** Neither POZEN INC. nor Nycomed Danmark ApS will assign its rights or obligations under this Agreement to any Third Party, without the prior written consent of the other, except that either POZEN INC. or Nycomed Danmark ApS may assign such rights and obligations to a Third Party in connection with a merger, consolidation, transfer or sale of all or substantially all of the assets (including those to which this Agreement relates) of the assignor. In addition, either POZEN INC. or Nycomed Danmark ApS may assign its rights and obligations under this Agreement to an Affiliate without the prior written consent of the other; *provided, however,* that in the case of assignment to an Affiliate, the assignor will be responsible and liable for the compliance of such Affiliate with this Agreement. All permitted assignments by either POZEN INC. or Nycomed Danmark ApS of any of its rights under this Agreement will be subject to all of the terms and conditions of this Agreement. All successors, permitted assignees of either POZEN INC. or Nycomed Danmark ApS will be subject to, and will be bound by, all the terms and conditions of this Agreement. Any purported assignment not permitted under the terms of this Agreement will be null, void, and of no effect.

19.3 **Independent Contractors.** The Parties hereto are independent contractors. Nothing contained herein will constitute either Party the agent of the other Party for any purpose whatsoever, or constitute the Parties as partners or joint venturers. Employees of each Party remain employees of said Party and will be considered at no time agents of or owing a fiduciary duty to the other Party. Neither Party hereto will have any implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any Third Party.

19.4 **Waiver**. The failure of either Party to enforce any provision of this Agreement at any time will not be construed as a present or future waiver of such or any other provision of this Agreement. The express waiver by either Party of any provision or requirement hereunder will not operate as a future waiver of such or any other provision or requirement and will be effective only if set forth in a written instrument signed by a duly authorized representative of the Party waiving such provision or requirement.

19.5 **Amendment**. The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but such amendment, modification or alteration will be valid and binding on either Party only if made by a written instrument that explicitly refers to this Agreement and that is signed by a duly authorized representative of each Party.

19.6 **Severability**. In the event that any provision in this Agreement is held to be unlawful or invalid in any jurisdiction, the meaning of such provision will be construed to the greatest extent possible so as to render it enforceable. If no such construction can render such provision enforceable, it will be severed. The remainder of this Agreement will remain in full force and effect, and the Parties will negotiate in good faith a reasonable substitute provision that is valid and enforceable in such jurisdiction. If the Parties are unable to agree on a substitute provision, and if a Party reasonably and in good faith determines that the unlawful or invalid provision was an essential element of this Agreement without which such Party would not have entered into this Agreement, as evidenced by this Agreement as a whole, then such Party may terminate this Agreement by written notice to the other Party effective upon receipt.

19.7 **Notice**. All notices hereunder must be given in writing and will be deemed given if delivered personally or by facsimile transmission (receipt confirmed), mailed by registered or certified mail (return receipt requested) with postage prepaid, or sent by express courier service (FedEx or other reputable, internationally recognized courier service), to the Parties at the following addresses (or at such other address for a Party as will be specified by like notice; provided that notices of a change of address will be effective only upon receipt thereof).

If to POZEN:

POZEN, Inc.
1414 Raleigh Road
Suite 400
Chapel Hill, NC 27517
Attention: President
Facsimile: +1 (919) 913 1039

If to Nycomed:

Nycomed Danmark ApS
Langebjerg 1
DK-4000 Roskilde
Denmark
Attention: Senior Vice President International Sales
Facsimile: +45 46 75 69 04

19.8 **Force Majeure**. Neither Party will be deemed to be in breach of this Agreement as a result of default, delay or failure to perform by such Party which is due to any cause beyond the reasonable control of such Party, including without limitation fire, earthquake, acts of God, severe weather, acts of war, strikes, lockouts or other labor disputes, riots, civil disturbances, actions or inactions of governmental authorities (except actions in response to a breach of applicable laws by such Party), or epidemics. In the event of any such force majeure, the Party affected will promptly notify the other Party, will use commercially reasonable efforts to overcome such force majeure, and will keep the other Party informed with respect thereto. If such force majeure continues for a period of more than 180 days and concerns a material obligation of a Party, the Party not subject to such force majeure may terminate this Agreement by written notice to the other Party, effective immediately upon receipt.

19.9 **Counterparts**. This Agreement may be executed by the Parties in one or more identical counterparts, all of which together will constitute this Agreement. If this Agreement is executed in counterparts, no signatory hereto will be bound until both Parties have duly executed a counterpart of this Agreement.

19.10 **Governing Law**. This Agreement will be governed by, and construed and interpreted in accordance with, the laws of Denmark, with the exclusion of the United Nations Convention on Contracts for the International Sale of Goods, without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of Denmark to the right and duties of the Parties.

19.11 **Construction**. Unless used in combination with the word "either," the word "or" is used throughout this Agreement in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein will mean including, without limiting the generality of any description preceding such term. This Agreement has been drafted and negotiated jointly by the Parties and will not be construed against a Party by virtue of such Party having drafted this Agreement or a particular provision hereof. Unless expressly provided herein to the contrary, all time limits, notice periods, deadlines or the like described herein will be governed by the following parameters: (i) all time periods that are 5 days in length or less will be deemed to be business days, and (ii) all time periods greater than 5 days in length will be deemed to be calendar days.

19.12 **English Language**. This Agreement has been written and executed in the English language. Any translation into any other language will not be an official version of this Agreement, and in the event of any conflict in interpretation between the English version and such translation, the English version will control.

19.13 **Entire Agreement**. This Agreement, including any Exhibits attached hereto, constitutes the entire agreement of the Parties with respect to the subject matter hereof, and supersedes all prior and contemporaneous agreements, understandings and negotiations, whether oral or written, with respect to such subject matter.

19.14 **Purchase Orders**. Notwithstanding anything to the contrary in this Agreement, in the event of any conflict between the terms set forth in any purchase order submitted by POZEN hereunder and this Agreement, the terms of this Agreement shall prevail, and no purchase order that conflicts with the terms of this Agreement will be binding on Nycomed.

19.15 **V.A.T.** All amounts to be paid by POZEN to Nycomed under this Agreement will be paid plus V.A.T. (if applicable).

[Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by signature of their duly authorized representatives.

POZEN INC.

By: _____

Name: _____

Title: _____

NYCOMED DANMARK APS

By: _____

Name: _____

Title: _____

EXHIBIT A

EXISTING NYCOMED PRODUCTS

FORMULATION:	DOSAGE STRENGTH:
Tablets	4 mg
Tablets	8 mg
Quick release tablets	8 mg
Vials	8 mg
EXCEPT:	
Tablets	2 mg/4 mg developed by Taisho, Japan
Scored Tablets	8 mg developed by Formenti, Italy
Suppositories	12 mg developed by Merckle, Germany

EXHIBIT B

DESCRIPTION OF EXISTING NYCOMED PRODUCT DELIVERABLES

1) (a) The following quantities of cGMP- and Specification-compliant blinded supplies of the oral formulations of the following Existing Nycomed Products and matching placebos, provided in bulk: 15,000 tablets of 8 mg quick release, and 15,000 matching placebo tablets;

(b) 10,000 vials and 10,000 placebo vials, provided in bulk, of blinded supplies of the injectable formulation of the Existing Nycomed Products and placebos, in the same form used by Nycomed in its clinical trials;

(c) 10 kilograms, provided in bulk, of cGMP- and Specification-compliant quantities of LX Bulk Drug Substance; and

(d) full copies of the batch records for the Materials described in 1(a) and 1(b), and one or more diagrams identifying the solvents and reagents used for the manufacture of the Materials described in 1(c).

2) All of the following, to the extent in existence as of the Effective Date and subject to Section 2.3 of the Agreement:

(a) Nycomed's current analytical methods, associated validation packages and reference standards relating to LX Bulk Drug Substance and to any Existing Nycomed Product;

(b) Nycomed's stability data for LX Bulk Drug Substance and for any Existing Nycomed Product;

(c) access at Nycomed's facilities to all of the clinical data and study reports relating to LX Bulk Drug Substance and Existing Nycomed Product specified in Schedule B – 1 attached hereto and hereby incorporated by reference;

(d) access at Nycomed's facilities to all of the preclinical data relating to LX Bulk Drug Substance and Existing Nycomed Product specified in Schedule B – 2 attached hereto and hereby incorporated by reference;

(e) full copies of all Phase I R02 and PK reports and the following Phase II/III reports: CT78, CT14, CT32, CT33, CT18, CT45, CT94, CT83, CT63, LO25; as well as copies of the final reports of the preclinical studies specified in part II of Schedule B-2; and

(f) a copy of the 2002 safety report for LX Bulk Drug Substance and any Existing Nycomed Product.

Delivery schedule:

Nycomed will use commercially reasonable efforts to deliver to POZEN the materials listed in clause 1 of this Exhibit B within 120 days after the Effective Date. Nycomed will deliver to POZEN the materials listed in clause 2 (other than 2(c) and (d)) of this Exhibit B within 120 days after the Effective Date. Nycomed will grant access to the materials listed in 2(c) and (d) as soon as reasonably practicable (but no later than 30 days from the Effective Date), whereupon such materials will be deemed to have been delivered. Nycomed agrees that, in accessing the materials listed in 2(c) and (d) at Nycomed's facilities, POZEN will have the right to bring its own electronic scanning equipment to Nycomed's facilities and to scan electronic copies of such materials using such equipment for POZEN's use in accordance with this Agreement.

Upon request by POZEN, Nycomed will use commercially reasonable efforts to deliver to POZEN up to two additional shipments of the Materials described in 1(a) and 1(c), as well as tablets of 4 mg and 8 mg and matching placebo, for use in the Initial Development Program. Each such shipment will not exceed (i) 15,000 tablets (of all oral formulations and strengths) of Existing Nycomed Products and matching placebos and (ii) such quantities of LX Bulk Drug Substance as POZEN requests and with respect to which POZEN demonstrates, in good faith discussions with Nycomed, a reasonable proposed use relating to the Initial Development Program. Upon receiving POZEN's request for such Materials, Nycomed will provide POZEN with a delivery date for such Materials. Nycomed will use commercially reasonable efforts to deliver such Materials on or before the specified delivery date.

Nycomed will ship all materials set forth in 1) and 2) (other than 2(c) and 2(d)) of this Exhibit B DDU (ICC Incoterms 2000) to a place of destination that POZEN will name within 30 days after the Effective Date, and the up to two additional shipments set forth in the previous paragraph DDU (ICC

Incoterms 2000) to a place of destination that POZEN will name in its request for such shipments.

EXHIBIT C

DESCRIPTION OF IND DELIVERABLES

All of the following, subject to Section 2.3 of the Agreement:

1) all of Nycomed's information and data specified in Schedule C-1 attached hereto and hereby incorporated by reference, to the extent in existence as of the Effective Date;

2) a copy of the global safety database (ADR and related information) established by or on behalf of Nycomed or its licensees in connection with the development and commercialization of Existing Nycomed Products (the content of the safety database is the same as the contents of the Periodic Safety Update Reports);

3) full copies of all communications, information and data filed by or on behalf of Nycomed (or its predecessor-in-interest) with the FDA, including a copy of the Nycomed IND, for any dosage form and strength of products containing Lornoxicam, and any communications received by or on behalf of Nycomed (or its predecessor-in-interest) from the FDA relating to such products, to the extent in existence as of the Effective Date and located at Nycomed's facilities, excluding in any event any information, data and communications relating to the manufacture of Lornoxicam. Nycomed represents and warrants to POZEN as of the Effective Date that, to the best of Nycomed's knowledge, the communications, information and data located at Nycomed's facilities constitute all of the communications, information and data filed by or on behalf of Nycomed (or its predecessor-in-interest) with, or received from, the FDA;

4) (a) to the extent available at Nycomed's facilities as of the Effective Date, access at Nycomed's facilities to all communications with any regulatory agencies outside the United States relating to the safety or efficacy of Lornoxicam, and (b) full copies of the communications with the regulatory agencies outside the United States relating to the safety or efficacy of Lornoxicam specified in Schedule C – 2 attached hereto and hereby incorporated by reference;

5) written confirmation that an up-to-date DMF regarding the manufacture of LX Bulk Drug Substance has been filed with the FDA;

6) a copy of a letter to the FDA providing for the right of POZEN to reference the DMF described in the preceding clause; and

7) a chart, to be updated annually until the filing of an NDA by POZEN, indicating each country where any Nycomed Product, including each dosage form thereof, is approved, pending approval, or has been withdrawn.

Delivery schedule:

Nycomed will deliver to POZEN the materials set forth on Schedule C-1 (excluding the materials listed in Section I. of such Schedule) within 90 days after the Effective Date and will deliver the remaining materials set forth on this Exhibit C (excluding the materials set forth in clause 4(a) above and any updates pursuant to clause (7) above) within 120 days after the Effective Date. Nycomed will grant access to the materials listed in 4(a) and the appropriate documentation set forth in the first paragraph of Schedule C-1 as soon as reasonably practicable (but no later than 30 days from the Effective Date), whereupon such materials will be deemed to have been delivered.

Nycomed will ship all materials set forth on this Exhibit C DDU (ICC Incoterms 2000) to a place of destination that POZEN will name within 30 days after the Effective Date.

SCHEDULE C-1

Nycomed will provide POZEN with the items listed in II. and III. below in written or electronic form. With respect to the items listed in I. below, Nycomed will, except to the extent to be provided under Exhibit B, provide POZEN with access at Nycomed's facilities to appropriate documentation containing such items, provided that Nycomed may redact any portions of such documentation that is proprietary to Nycomed and relates to the Process.

I. LX BULK DRUG SUBSTANCE

A. Description, Physical and Chemical Properties, and Structural Elucidation

1. Description

2. Physicochemical Characteristics

3. Structure Elucidation

B. Manufacturing Site

C. Method of Manufacture

1. Equipment

2. Specifications and Analytical Test Methods for Starting Materials, Reagents, Solvents and Auxiliary Materials

3. Synthesis

D. Reference Standard

1. Preparation

2. Structure Elucidation

3. Test Results

E. Specifications and Analytical Test Methods

1. Release Specifications and Analytical Test Methods

2. Test Results

F. Related Substances

1. Intermediates and Potential Impurities

2. Impurity Profile

G. Stability

1. Stability Study Designs and Storage Conditions

2. Stability Specifications and Test Methods

3. Test Results

4. Conclusion

H. Packaging and Labeling

1. Container/Closure System Components

2. Representative Label

II. EXISTING NYCOMED PRODUCT

A. Components

1. Qualitative Formula

2. Quantitative and Batch Formulae

B. Specifications and Analytical Test Methods for Existing Nycomed Product Inactive Ingredients

C. Manufacturer, Analytical Lab, and Packager

D. Method of Manufacture and Packaging

1. Production Operations

2. In-Process Controls

3. Equipment

E. Specifications and Analytical Test Methods for Existing Nycomed Product

1. Release Specifications and Analytical Test Methods
2. Test Results

F. Stability

1. Stability Study Designs and Storage Conditions
2. Stability Specifications and Test Methods
3. Degradation Products
4. Test Results
5. Conclusion

III. PLACEBO

A. Components

1. Placebo Qualitative Formula
2. Placebo Quantitative and Batch Formulae

B. Specifications and Analytical Test Methods for Placebo Ingredients

C. Manufacturer and Packager

D. Method of Manufacture and Packaging

1. Production Operations
2. In-Process Controls
3. Equipment

E. Specifications and Analytical Test Methods for Placebo

1. Release Specifications and Analytical Test Methods
2. Test Results

F. Stability

1. Stability Study Design and Storage Conditions
2. Stability Specifications and Analytical Test Methods
3. Test Results
4. Conclusion

EXHIBIT D

CHEMICAL STRUCTURE OF LORNOXICAM

EXHIBIT E

DESCRIPTION OF NYCOMED IMPROVEMENT PRODUCT DELIVERABLES

1) Quantities, provided in bulk, of cGMP- and specification-compliant blinded supplies of Nycomed Improvement Products and matching placebos, as reasonably requested by POZEN; and

2) All of the following, to the extent reasonably requested by POZEN, and subject to Section 2.3 of the Agreement:

   (a) Nycomed's specifications and analytical methods relating to any Nycomed Improvement Product and reference standards relating to LX Bulk Drug Substance;

   (b) Nycomed's stability data for LX Bulk Drug Substance and for any Nycomed Improvement Product; and

   (c) access at Nycomed's facilities to Nycomed's preclinical and clinical data relating to any Nycomed Improvement Product or LX Bulk Drug Substance.

Delivery schedule:

Within a reasonable time after receipt by Nycomed of POZEN's reasonable request for any of the foregoing materials, Nycomed will use commercially reasonable efforts to supply POZEN with the requested materials pursuant to 1) and 2) (a) and (b) and will grant POZEN access to the materials pursuant to 2) (c).

Nycomed will ship all materials set forth on this Exhibit E DDU (ICC Incoterms 2000) to a place of destination named by POZEN.

EXHIBIT F

DESCRIPTION OF SPECIFICATIONS

Existing Nycomed Product:

4 mg Tablets	as specified in Schedule F-1 attached hereto and hereby incorporated by reference
8 mg Tablets	as specified in Schedule F-2 attached hereto and hereby incorporated by reference
8 mg Quick release tablets	as specified in Schedule F-3 attached hereto and hereby incorporated by reference
8 mg Vials	as specified in Schedule F-4 attached hereto and hereby incorporated by reference

Placebos to Existing Nycomed Products

as specified and included in the above Schedules of the corresponding Existing Nycomed Product

LX Bulk Drug Substance: as specified in Schedule F-5 attached hereto and hereby incorporated by reference

Nycomed Improvement Product: as specified by Nycomed from time to time in its sole discretion.

Placebo to Nycomed Improvement Product: as specified by Nycomed from time to time in its sole discretion.

EXHIBIT G

LICENSED PATENTS

Lornoxicam substance				
Country	**Pat./appl. No.**	**Filing date**	**Expiry**	**SPC**
AT	AT 365199	05.09.1978	15.05.2000	15.05.2004
BE	EP 1113	06.09.1978	06.09.1998	06.09.2003
CH/LI	EP 1113	06.09.1978	06.09.1998	05.09.2003
DK	DK 148280	05.09.1978	05.09.1998	05.09.2003
FI	EP 1113	06.09.1978	06.09.1998	06.09.2003
GB	EP 1113	06.09.1978	06.09.1998	04.09.2003
LU	EP 1113	06.09.1978	06.09.1998	06.09.2003
SE	EP 1113	06.09.1978	06.09.1998	06.09.2003

Lornoxicam QR					
Country	**Pat./appl. No.**	**Filing date**	**Expiry**	**Status**	**SPC**
Exclusive Territory					
CA	CA 2343148	10.09.1999	10.09.2019	Pending	-
US	US 9786864	10.09.1999	10.09.2019	Pending	-
Limited Territory					
AT	EP 1109534	10.09.1999	10.09.2019	Granted	-
BE	EP 1109534	10.09.1999	10.09.2019	Granted	-
CH/LI	EP 1109534	10.09.1999	10.09.2019	Granted	-
DE	EP 1109534	10.09.1999	10.09.2019	Granted	-
DK	EP 1109534	10.09.1999	10.09.2019	Granted	-
FI	EP 1109534	10.09.1999	10.09.2019	Granted	-
FR	EP 1109534	10.09.1999	10.09.2019	Granted	-
GB	EP 1109534	10.09.1999	10.09.2019	Granted	-
GR	EP 1109534	10.09.1999	10.09.2019	Granted	-
IE	EP 1109534	10.09.1999	10.09.2019	Granted	-
NL	EP 1109534	10.09.1999	10.09.2019	Granted	-
SE	EP 1109534	10.09.1999	10.09.2019	Granted	-
LT	EP 1109534	10.09.1999	10.09.2019	Granted	-
LV	EP 1109534	10.09.1999	10.09.2019	Granted	-
EA*	EA 200100331	10.09.1999	10.09.2019	Pending	-

* In the EA applications the following relevant states are designated: AM, AZ, BY, KG, KZ, MD, RU, TJ, and TM.

Lornoxicam for injection					
Country	**Pat./appl. No.**	**Filing date**	**Expiry**	**Status**	**SPC**
Exclusive Territory					
CA	CA 2264626	01.09.1997	01.09.2017	Pending	-
Limited Territory					
AT	EP 934079	01.09.1997	01.09.2017	Granted	-
BE	EP 934079	01.09.1997	01.09.2017	Granted	-
CH/LI	EP 934079	01.09.1997	01.09.2017	Granted	-
DK	EP 934079	01.09.1997	01.09.2017	Granted	-
FI	EP 934079	01.09.1997	01.09.2017	Granted	-
FR	EP 934079	01.09.1997	01.09.2017	Granted	-
GB	EP 934079	01.09.1997	01.09.2017	Granted	-
IE	EP 934079	01.09.1997	01.09.2017	Granted	-
LU	EP 934079	01.09.1997	01.09.2017	Granted	-
NO	NO 19990909	01.09.1997	01.09.2017	Pending	-
SE	EP 934079	01.09.1997	01.09.2017	Granted	-

EXHIBIT H

DISCLOSURE OF PATENT APPLICATIONS AND COMMUNICATION

Lornoxicam QR (US)	
Supplemental amendment transmittal	January 9, 2003
Supplemental amendment	January 9, 2003
Amendment transmittal	December 23, 2002
Amendment incl. translation of prior art and declaration	December 23, 2002
Office action incl. cited prior art	September 20, 2002
Notice of recordation of assignment document	November 05, 2001
Filing receipt	September 20, 2001
Certificate of mailing by "express mail"	July 10, 2001
Transmittal letter to the US/RO	July 10, 2001
Declaration	July 10, 2001
Assignment Recordation cover sheet	July 10, 2001
Assignment	July 10, 2001
Transmittal of information disclosure statement	June 19, 2001
Transmittal letter to the US elected office	March 10, 2001
Amendment	
Lornoxicam QR (CA)	
Request for examination	August 1, 2001
Registration	July 25, 2001
Courtesy letter	May 22, 2001
Notice of national entry	May 15, 2001
Form for request of entry into national phase undet PCT	
Lornoxicam QR (EA)	
Notification about submission of additional materials	December 26, 2002
Notification of necessity to present additional materials incl comments	June 27, 2002
The application as filed	September 04, 2001

Lornoxicam INJ. (CA)	
Canadian patent application assignment	December 30, 2002
Acknowledgement of request for examination	October 16, 2002
Registration	April 14, 1999
Notice of national entry	April 14. 1999
Verification	February 20, 1999
Form for request of entry into national phase under PCT	February 04, 1999
WO publication	March 12, 1998
Demand	
Information concerning elected offices notified of their election	April 07, 1998
Notice informing the applicant of communication to designated offices	March 12, 1998
Notification of receipt of record copy	October 29, 1997
Notification concerning submission of priority documents	October 29, 1997
Notification of IPER	May 18, 1998
Notification of delivery of international search report	January 30, 1998
International search report incl. prior art	January 30, 1998
Notification of receipt of search copy	November 11, 1997
Notification of international filing number	October 21, 1997
Form 101	September 01, 1997
Lornoxicam INJ. (NO)	
Declaration of assignment	December 30, 2002
Power of attorney	December 20, 2002
Application text in Norwegian	February 25, 1999
Power of attorney	February 5, 1999
PCT documents (as above)	

EXHIBIT I

LIST OF COUNTRIES EXCLUDED FROM MANUFACTURING LICENSE

ITALY

JAPAN

TURKEY

EGYPT

KOREA

SAUDI ARABIA

ECUADOR

Exhibit J

FORM SUPPLY AGREEMENT FOR SUBLICENSEES

As set forth in Schedule J – 1 attached hereto and hereby incorporated by reference.

EXHIBIT K

DEFINITION OF CHANGES

The terms "Major Change", "Moderate Change" and "Minor Change" used in Section 9.6 of the Agreement will have the meanings set forth in the FDA's November 1999 Guidance for Industry Change to an Approved NDA or ANDA and the FDA's February 2001 Guidance for Industry BACPAC I: Intermediates in Drug Substance Synthesis (Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation), each as amended, and any successor regulations thereto. The term "Change" means either a Major Change, a Moderate Change or a Minor Change.

SCHEDULE J-1

TABLE OF CONTENTS

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

TABLE OF CONTENTS
(CONTINUED)

PAGE

SCHEDULE J-1

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "***Agreement***") is entered into as of the _____ day of _____, _____ (the "***Effective Date***"), by and between **NYCOMED DANMARK APS**, a Danish corporation, located at Langebjerg 1, DK-4000 Roskilde, Denmark, on behalf of itself and its Affiliates (collectively, "***Nycomed***"), and _____, a _____ corporation, located at _____, on behalf of itself and its Affiliates (collectively, "***Buyer***"). Nycomed and the Buyer are referred to in this Agreement individually as a ***"Party"*** and collectively as ***"Parties"***.

RECITALS

A. By the License Agreement (as hereinafter defined) Nycomed Danmark ApS granted to POZEN (as hereinafter defined) certain rights and licenses to develop, market and commercialize certain pharmaceutical products in certain countries, including POZEN's right to grant and authorize the grant of up to one level of further sublicenses.

B. By the Sublicense Agreement (as hereinafter defined) the Buyer was granted a sublicense under the licenses granted by Nycomed Danmark ApS to POZEN in the License Agreement.

C. The License Agreement provides for the execution of a supply agreement between Nycomed Danmark ApS and the Buyer for LX Bulk Drug Substance (as hereinafter defined).

AGREEMENT

In consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

The capitalized terms used in this Agreement will have the meanings given to them in this Section 1 and throughout this Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

1.1 "**Affiliate**" means with respect to ....., any corporation or other business entity which (i) is an affiliate of ..... pursuant to the Sublicense Agreement as hereinafter defined) and (ii) has, either directly or indirectly, any requirements of LX Bulk Drug Substance (as hereinafter defined) or Lornoxicam (as hereinafter defined) (or any salts, solvates or polymorphs thereof) for the purposes provided for under Section 2.1 of this Agreement, and with respect to Nycomed Danmark ApS, any corporation or other business entity which (i) is an affiliate of Nycomed Danmark ApS pursuant to the License Agreement (as hereinafter defined) and (ii) Nycomed Danmark ApS desires to involve in the performance of this Agreement. Each of ..... and Nycomed Danmark Aps will notify the

other in writing if and as soon as any such corporation or other busniess entity becomes an Affiliate under this Agreement and Nycomed Danmark Aps hereby notifies ..... that such is the case in respect to Nycomed Austria GmbH, St. Peter-Straße 25, A-4020 Linz, Austria.

1.2 "***cGMP***" means current good manufacturing practices for medicinal products established by regulations in the United States (including 21 CFR §§ 210 and 211, as amended, and any successor regulations thereto), and the corresponding rules, regulations, or guidelines in the European Union and Canada.

1.3 "**Commercially reasonable efforts**" means, with respect to a Party, those efforts, consistent with the exercise of prudent scientific and business judgment, to conduct a particular activity hereunder that would be applied to a similar activity by other companies in the pharmaceutical industry.

1.4 "***DMF***" means a drug master file filed in accordance with 21 CFR § 314.420 and maintained with the FDA or the equivalent thereof, as applicable, in jurisdictions outside the United States.

1.5 "***Exclusive Manufacturing Period***" means: [(a) with respect to ***[Insert countries in Buyer's Territory that are in Exclusive Territory]***, the period commencing on the Effective Date and continuing until the date five years after: [either (i) the date of first commercial sale of the first POZEN Product sold in the United States by Buyer, if Buyer's territory to commercialize such POZEN Product includes both the United States and

Canada, or (ii) otherwise, the date of first commercial sale of the first POZEN Product sold anywhere in the Exclusive Territory (as defined in the License Agreement) by Buyer]; and (b) with respect to ***[Insert countries in Buyer's Territory that are in Limited Territory]***, the period commencing on the Effective Date and continuing until the date five years after: [either (i) the date of first commercial sale of the first POZEN Product sold in the United Kingdom, France or Germany by Buyer, if Buyer's territory to commercialize such POZEN Product includes one or more of those three countries; or (ii) otherwise, the date of first commercial sale of the first POZEN Product sold anywhere in the Limited Territory (as defined in the License Agreement) by Buyer; provided, however, that the Parties may extend any Exclusive Manufacturing Period for successive one-year terms, upon terms to be agreed upon at such time by the Parties].] **[TO BE REVISED BASED ON SPECIFIC SUBLICENSEE]**

1.6 "***FDA***" means the United States Food and Drug Administration, or any successor agency.

1.7 "***Latent Defect***" means any failure of a shipment of LX Bulk Drug Substance or portion thereof to conform at the date of delivery to the Product Warranty (as defined in Section 3.1 of this Agreement) that would not be discoverable prior to the deadline for notice of rejection under Section 3.5 of this Agreement upon reasonable physical inspection or standard testing of such LX Bulk Drug Substance in accordance with standards in the pharmaceutical industry, including in any event testing for purity and assay according to the methods included in the Specifications.

1.8 "***License Agreement***" means the Development, Option and License Agreement entered into as of the ____ day of May, 2003 by and between POZEN (as hereinafter defined) and Nycomed relating to the active drug substance known as Lornoxicam, as amended from time to time.

1.9 **"Licensed Technology"** has the meaning provided in the License Agreement.

1.10 "***Lornoxicam***" means the active drug substance known as lornoxicam, having the chemical structure set forth in **Exhibit A** to this Agreement (attached hereto and hereby incorporated in this Agreement by reference).

1.11 "***LX Bulk Drug Substance***" means Lornoxicam in bulk form, conforming to the Specifications (as hereinafter defined).

1.12 ***"Manufacturing Approval"*** means all filings, applications, licenses, permits, and other authorizations which are required for the manufacture of LX Bulk Drug Substance in compliance with applicable laws and regulations of the country of manufacture.

1.13 ***"NDA"*** means a new drug application submitted to the FDA to obtain FDA approval for the marketing of a pharmaceutical product in the United States.

1.14 "***POZEN***" means POZEN Inc., a Delaware corporation located at 1414 Raleigh Road, Suite 400, Chapel Hill, NC 27517, and its Affiliates (as defined in the License Agreement), if any.

1.15 "***POZEN Product***" means any pharmaceutical product sublicensed to Buyer from POZEN or its sublicensee under the Sublicense Agreement (as hereinafter defined) that contains LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof) as an active drug substance.

1.16 "***Process***" has the meaning provided in the License Agreement.

1.17 "***Specifications***" means the specific chemical and physical properties pertaining to LX Bulk Drug Substance set forth on **Exhibit B**, subject to change by Nycomed from time to time in accordance with Section 9.6 of the License Agreement. ***[At time of signing, the then-current specifications will be attached as Exhibit B.]***

1.18 "***Sublicense Agreement***" means the sublicense agreement entered into as of the _____ day of _____, ____, by and between Buyer and _____ in which Buyer was granted a sublicense under the licenses granted by Nycomed to POZEN under the License Agreement.

1.19 "***Territory***" means ***[insert countries in Buyer's licensed territory]***.

2. SUPPLY OF LX BULK DRUG SUBSTANCE

2.1 Exclusivity. During the Exclusive Manufacturing Period(s), and subject to Section 2.3 of this Agreement, Buyer will purchase from Nycomed and Nycomed will use commercially reasonable efforts to provide to Buyer, 100% of Buyer's requirements of LX Bulk Drug Substance or Lornoxicam (or any salts, solvates or polymorphs thereof), to be provided by Nycomed in the form of LX Bulk Drug Substance, for use in the manufacture of POZEN Products, except to the extent that Buyer obtains from POZEN all or any portion of such requirements that POZEN has purchased from Nycomed. For purposes of clarification, for any POZEN Product manufactured by or for Buyer for distribution in a particular country of the Territory after the Exclusive Manufacturing Period applicable to such country, Buyer will have the right to source LX Bulk Drug Substance or Lornoxicam (or any salt, solvate or polymorph thereof) from any entity.

2.2 Supply Diligence.

(a) Nycomed will use commercially reasonable efforts to maintain a reasonable inventory of LX Bulk Drug Substance, at Nycomed's expense, for use in filling orders of LX Bulk Drug Substance conforming to the Specifications and as forecasted in the binding portion of a forecast by Buyer in accordance with this Agreement, at Nycomed. Similarly, Buyer will use commercially reasonable efforts to maintain a reasonable inventory of LX Bulk Drug Substance supplied by Nycomed, at Buyer's expense.

(b) If Nycomed has reason to believe that it will be unable to manufacture and fill a particular order made in accordance with this Agreement of LX Bulk Drug Substance conforming to the Specifications despite the safeguards described in Section 2.2(a) above, then Nycomed will promptly notify Buyer of the cause for such projected shortfall and Buyer will have the right pursuant to Section 2.3 of this Agreement to use an alternate source to supply the actual shortfall.

(c) If Nycomed has reason to believe that it will be unable, on an ongoing basis, to manufacture and fill orders by Buyer of LX Bulk Drug Substance conforming to the Specifications forecasted in accordance with this Agreement, then Nycomed will notify Buyer of the cause for such projected shortfall, and use commercially reasonable efforts to establish a contract manufacturer to manufacture such shortfall for Nycomed for supply to Buyer. Nycomed will not retain any contract manufacturer that Nycomed has reason to believe would be unable to manufacture LX Bulk Drug Substance in accordance with the Product Warranty (as defined in Section 3.1 of this Agreement). If Nycomed has reason to believe that it will be unable to establish, or establish in due time, such a contract manufacturer and to have manufactured such projected shortfall, then Nycomed will promptly notify Buyer thereof and Buyer will then have the right pursuant to Section 2.3 of this Agreement to use an alternate source to supply the greater of: (i) any quantities that Nycomed will be unable to supply of LX Bulk Drug Substance conforming to the Specifications forecasted by Buyer, and (ii) the minimum total order quantity of LX Bulk Drug Substance required by Buyer's alternate source, provided that Buyer shall use

commercially reasonable efforts to negotiate the lowest possible minimum total order quantity available at a commercially reasonable price from such alternate source.

2.3 **Establishment of Alternate Source.**

(a) During the Exclusive Manufacturing Period(s), Buyer will have the right to manufacture or have manufactured and supplied to it LX Bulk Drug Substance for further processing into a POZEN Product by an alternate source to the extent Nycomed fails to supply Buyer's requirement of LX Bulk Drug Substance as described in Section 2.2.

(b) If Buyer purchases from an alternate source a quantity of LX Bulk Drug Substance that Nycomed failed to supply as described above and if such failure is related to Nycomed's gross negligence or willful misconduct or Nycomed's material breach of this Agreement, then, if the price paid by Buyer to such alternate source for such quantity of LX Bulk Drug Substance is greater than the applicable supply price under this Agreement for such quantity of LX Bulk Drug Substance, Nycomed will reimburse Buyer the amount of the difference between the supply price per kilogram paid to the alternate source and the supply price per kilogram that would have been applicable hereunder, up to a maximum amount corresponding to 50% of the applicable supply price under this Agreement for such quantity, multiplied by the number of kilograms purchased from such alternate source.

2.4 **Supply Price.** All supply of LX Bulk Drug Substance by Nycomed to Buyer for further processing into POZEN Products will be made at the prices set forth on the following table:

Quantity of LX Bulk Drug Substance ordered by Buyer for delivery during a calendar year:	Price per kg of LX Bulk Drug Substance:
Up to 100 kg	[€4000 per kg, plus any increases] ***[Insert POZEN's current price at time of execution]***
More than 100 kg, up to 200 kg	[€3900 per kg, plus any increases] ***[Insert POZEN's current price at time of execution]***
More than 200 kg, up to 300 kg	[€3800 per kg, plus any increases] ***[Insert POZEN's current price at time of execution]***
More than 300 kg	[€3600 per kg, plus any increases] ***[Insert POZEN's current price at time of execution]***

By way of example (and assuming no price increases have occurred under the License Agreement or this Agreement), if Buyer orders, in one or more orders during a calendar year, 320 kg of LX Bulk Drug Substance for delivery, the price for the first 100 kg is [€ 400,000]; for the second 100 kg, [€ 390,000]; for the third 100 kg, [€ 380,000]; and for the remaining 20 kg,

[€ 72,000]. ***[Revise Euro amounts in example based on prices in table above.]***

2.5 **Price Increases**. If any changes to cGMP or any changes to applicable laws or regulations are adopted after the Effective Date, and if Nycomed's compliance with such changed cGMP, laws or regulations will result in an increase in the direct manufacturing costs of Nycomed for LX Bulk Drug Substance, then Nycomed will promptly inform Buyer and may reasonably increase the prices set forth in Section 2.4 of this Agreement; *provided, however,* if any such price increase would lead to an increase of the prices set forth in Section 2.4 of this Agreement of more than 15% of the prices set forth in **Exhibit C** to this Agreement, then Buyer will have the right to terminate this Agreement within 30 days from receipt of Nycomed's notification of such price increase. Buyer's notice of termination shall become effective between 180 and 360 days from receipt by Nycomed as specified in such termination notice (unless Nycomed reduces the price increase exceeding such 15% to 15%, and such price change and the effective date thereof are communicated to Buyer within 30 days of receipt of Buyer's notice), provided that Buyer will continue to purchase LX Bulk Drug Substance during such period at the increased price and such increased price will be subject to any further price increases that result from additional changes to cGMP, laws or regulations during such period.

2.6 **Forecasts**. No later than one calendar quarter prior to the beginning of the calendar quarter in which Buyer desires the first delivery of LX Bulk Drug Substance from Nycomed under this Agreement (the "***Initial***

Quarter"), Buyer will provide Nycomed with a forecast setting forth Buyer's requirements of LX Bulk Drug Substance for the 6 calendar quarters comprising the Initial Quarter and the 5 subsequent calendar quarters. Thereafter, on or before the first business day of each calendar quarter following the calendar quarter in which the first forecast was provided by Buyer to Nycomed, Buyer will provide Nycomed with an updated rolling 6-calendar-quarter forecast. The quantities of LX Bulk Drug Substance set forth for the first 2 calendar quarters set forth in any forecast will be binding on the Parties; *provided, however,* that the quantity of LX Bulk Drug Substance set forth in the second calendar quarter in any forecast will be greater than 85%, and less than 115%, of the quantity of LX Bulk Drug Substance forecast for such calendar quarter in the previous forecast submitted by Buyer under this Section 2.6. All quantities of LX Bulk Drug Substance set forth for the fourth through sixth calendar quarters in any forecast provided under this Section 2.6 are to be considered non-binding good faith estimates, and are provided to Nycomed only for preliminary planning purposes. The following table provides an example of the forecasts described by this Section 2.6:

	Forecast submitted on first business day, 1Q2005	Forecast submitted on first business day, 2Q2005
Quantity for delivery during 2Q2005	100kg (binding)	---
Quantity for delivery during 3Q2005	200kg (binding)	200kg (binding)
Quantity for delivery during 4Q2005	300kg (non-binding)	300kg ± 15% binding)
Quantity for delivery during 1Q2006	350kg (non-binding)	400kg (non-binding)
Quantity for delivery during 2Q2006	400kg (non-binding)	200kg (non-binding)
Quantity for delivery during 3Q2006	400kg (non-binding)	700kg (non-binding)
Quantity for delivery during 4Q2006	---	500 kg (non-binding)

2.7 **Order Process**. Together with each forecast provided by Buyer pursuant to Section 2.6 above, Buyer will submit a purchase order to Nycomed for the quantities of LX Bulk Drug Substance in any binding

forecasts that are not covered by a previous purchase order, specifying such quantities of LX Bulk Drug Substance and the delivery dates thereof. Except with the prior agreement of Nycomed, Buyer will not designate in a purchase order less than 20 kg of LX Bulk Drug Substance for delivery on any particular delivery date. Nycomed will use commercially reasonable efforts to supply to Buyer the quantities of LX Bulk Drug Substance ordered on the delivery dates set forth in a purchase order.

2.8 **Shipping**. Nycomed will package and label the LX Bulk Drug Substance for shipment in accordance with applicable law and in accordance with Nycomed's standard practices. Nycomed will ship the LX Bulk Drug Substance on the relevant purchase order FCA (ICC Incoterms 2000) either Nycomed's facility in Linz, Austria or any other place named by Nycomed and by a carrier designated by Buyer in the applicable purchase order. Each shipment will be made according to the schedule and in the amounts specified in the applicable purchase order and under the terms and conditions set forth in this Agreement. Each batch of LX Bulk Drug Substance will be tested and Nycomed will enclose with each shipment of LX Bulk Drug Substance a material safety data sheet and a certificate of analysis in accordance with Section 3.3 of this Agreement. Nycomed will enclose any other required shipping documentation with each shipment of LX Bulk Drug Substance. Should Nycomed at any time during the term of this Agreement have reason to believe that it will be unable to meet a delivery date of a shipment, Nycomed will promptly notify Buyer of the cause for such delay and the steps undertaken by Nycomed to avoid or minimize such delay.

2.9 **Invoices**. Nycomed will send an invoice to Buyer via facsimile upon transferring a shipment of LX Bulk Drug Substance under this Agreement to the carrier designated by Buyer, and will enclose such invoice with each shipment of LX Bulk Drug Substance under this Agreement. Each such invoice will set forth a detailed account of the quantities and price of LX Bulk Drug Substance included in such shipment. All invoices submitted to Buyer by Nycomed under this Agreement will be payable within 30 days of invoice date.

3. WARRANTIES; ACCEPTANCE AND REJECTION OF LX BULK DRUG SUBSTANCE

3.1 **Product Warranty**. Nycomed hereby warrants that at the date of delivery, any LX Bulk Drug Substance supplied by Nycomed under this Agreement will (i) conform to the Specifications, (ii) be manufactured in compliance with cGMP and the applicable laws of the country of manufacture, (iii) not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended ("***FD&C Act***"), (iv) conform to the applicable DMF, (v) be manufactured in accordance with the Process, and (vi) comply with current USP and EP monographs and ICH guidelines (collectively, the "***Product Warranty***"). Failure of a delivery of LX Bulk Drug Substance to comply with clause (ii) of this Section 3.1 will not be deemed a breach of the Product Warranty to the extent that such LX Bulk Drug Substance may, in accordance with applicable law, be used for the manufacture of POZEN Products for development, testing or commercial sale, as applicable.

3.2 ***[Subject to confirmation by Nycomed at time of signing]*** **Process Warranty**. Nycomed hereby warrants that, as of the Effective Date, it has not been served with any interference action, litigation or other notice alleging that (i) the Process infringes the intellectual property rights of any person or entity or (ii) that the Process constitutes a misappropriation of the trade secrets or other intellectual property rights of any person or entity within the Territory.

3.3 **Certificates of Analysis**. Nycomed will enclose a certificate of analysis with each shipment of LX Bulk Drug Substance supplied hereunder. Such certificate of analysis will contain the results of the analysis of such LX Bulk Drug Substance conducted as required in the Specifications, and will certify with respect to each shipment and lot (identified by lot number): (i) the quantity of the shipment, and (ii) that such LX Bulk Drug Substance conforms to the Product Warranty.

3.4 **Acceptance Testing**. If a shipment of a lot of LX Bulk Drug Substance or any portion thereof fails to conform to the Product Warranty, then Buyer will have the right to either reject such nonconforming shipment of LX Bulk Drug Substance or the nonconforming portion thereof, as the case may be, in accordance with the terms set forth in this Section 3.

3.5 **Notice Period**.

(a) Within 45 days (or, in the case of the first shipment of LX Bulk Drug Substance under this Agreement, 90 days) after delivery by Nycomed to Buyer of any shipment of any LX Bulk Drug Substance that

does not conform, in whole or in part, with the Product Warranty, Buyer may give written notice to Nycomed of its rejection of either such shipment or portion thereof, as the case may be, specifying the grounds for such rejection, and deliver to Nycomed samples of the rejected LX Bulk Drug Substance. If Buyer fails to give the aforesaid notice to Nycomed within the applicable period set forth above, then Buyer will be deemed to have unconditionally accepted the applicable LX Bulk Drug Substance as in conformity with the Product Warranty, except as to Latent Defects.

(b) Within 20 days after Buyer's discovery that a shipment of any LX Bulk Drug Substance or portion thereof contains a Latent Defect, Buyer may give written notice to Nycomed of its rejection of either such shipment or portion thereof, as the case may be, specifying the grounds for such rejection, and deliver to Nycomed samples of the rejected LX Bulk Drug Substance. If Buyer fails to give the aforesaid notice to Nycomed within the applicable period set forth above, Buyer will be deemed to have unconditionally accepted the applicable LX Bulk Drug Substance as free of the identified Latent Defect.

3.6 **Disputes Regarding Conformity**. After receipt of a rejection notice and samples from Buyer pursuant to the preceding Section 3.5, Nycomed will be permitted, for a period of 30 business days, to analyze the LX Bulk Drug Substance rejected by Buyer for nonconformity to the Product Warranty, and to present its findings with respect to such LX Bulk Drug Substance to Buyer. If the Parties cannot agree on whether such LX Bulk Drug Substance conforms to the Product Warranty within 40 business

days of Nycomed's receipt of Buyer's written notice of rejection and samples, then, as soon as reasonably practicable, each Party will deliver samples of the LX Bulk Drug Substance in question to an independent laboratory selected by Nycomed as soon as reasonably practicable and reasonably acceptable to Buyer, and the independent laboratory will analyze such samples according to the methods included in the Specifications and determine whether or not such LX Bulk Drug Substance conforms to the Product Warranty. Nycomed will use commercially reasonable efforts to cause the independent laboratory to complete such analysis as soon as reasonably practicable. The definitive result of such analysis by the independent laboratory will be binding on the Parties. The cost of such analysis will be borne by the Party whose assessment was incorrect.

3.7 **Remedies**. If Buyer rejects a shipment of LX Bulk Drug Substance and Buyer and Nycomed agree, or the independent laboratory determines, that such shipment of LX Bulk Drug Substance does not conform to the Product Warranty, such nonconforming LX Bulk Drug Substance will be held for Nycomed's disposition, or will be returned to Nycomed (unless prohibited by applicable laws or regulations), in each case at Nycomed's expense, as directed by Nycomed. Nycomed will use commercially reasonable efforts to replace each nonconforming shipment of LX Bulk Drug Substance, or the nonconforming portion thereof on a batch-by-batch basis, with conforming LX Bulk Drug Substance as soon as reasonably practicable or will promptly provide Buyer with a credit therefor, at Buyer's election.

3.8 **Notice of Latent Defects.** If Nycomed becomes aware of a Latent Defect in any shipment of LX Bulk Drug Substance or portion thereof, Nycomed will immediately notify Buyer as to the shipment involved, and, at Buyer's election (to be communicated to Nycomed within 10 days), either such shipment or portion thereof, as the case may be, will be deemed rejected as of the date of Buyer's communication, and such nonconforming LX Bulk Drug Substance will be held for Nycomed's disposition, or will be returned to Nycomed (unless prohibited by applicable laws or regulations), in each case at Nycomed's expense, as directed by Nycomed. Nycomed will use commercially reasonable efforts to replace each nonconforming shipment, or the nonconforming portion thereof, with conforming LX Bulk Drug Substance as soon as reasonably practicable, or will promptly provide Buyer with a credit therefor, at Buyer's election.

3.9 **Recalls.** If a Party believes it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any POZEN Product (a "***Recall***"), Nycomed and Buyer will consult with each other as to how best to proceed, it being understood and agreed that the final decision as to any such Recall with respect to a POZEN Product will be made by Buyer and the final decision as to any such Recall with respect to LX Bulk Drug Substance that has not yet been processed into a POZEN Product will be made by Nycomed.

3.10 **Adverse Drug Events.** Any adverse drug event or reaction complaint reports or any other reports or information received by Buyer indicating that any POZEN Product has any toxicity, sensitivity reaction, or

is otherwise alleged to cause illness or injury of any kind or is adulterated or misbranded, which toxicity, sensitivity reaction, illness or injury is caused or alleged to be caused by the LX Bulk Drug Substance contained therein, will be reported promptly by Buyer to Nycomed, or as otherwise may be required under any applicable laws, rules or regulations, with copies of any such written reports, and Nycomed will thereafter expeditiously investigate the information contained in such reports and communicate such results promptly to Buyer upon conclusion of such investigation. Buyer will copy Nycomed on all correspondence with regulatory authorities relating to adverse drug events in relation to the LX Bulk Drug Substance supplied by Nycomed or any POZEN Products.

4. QUALITY REGULATIONS

4.1 **Documentation and Record Keeping**. Nycomed will keep complete, accurate and authentic accounts, notes, data and resources of all of work performed by Nycomed related to LX Bulk Drug Substance under this Agreement, including, but not limited to, complete and adequate records pertaining to the methods and facilities used for the manufacture in accordance with master production records, batch production records, product related documents (e.g., master formulae, validation packages, specifications, clinical trial batch related documents, batch specific deviation reports, certificates of analysis) and standard operating procedures ("SOPs"). ***[Include only if sublicensee's territory includes the U.S.:]*** [As soon as reasonably practicable following receipt of NDA approval for any POZEN Product, Buyer shall provide Nycomed with

written notice of the date of such NDA approval, which notice shall identify by lot number the lots of LX Bulk Drug Substance that correspond to such NDA approval, and Nycomed shall maintain such records with respect to such lots of LX Bulk Drug Substance for a minimum of 2 years after NDA approval.] With respect to each lot of LX Bulk Drug Substance supplied by Nycomed under this Agreement, Nycomed shall maintain such records for 2 years after the expiration date of any POZEN Product that contains such lot of LX Bulk Drug Substance. Buyer will notify Nycomed in writing of the expiration date of any POZEN Product and of any changes thereto. An SOP will be maintained for 5 years after it is superseded or deleted.

4.2 Inspections and Audits.

(a) During the term of this Agreement, Buyer shall have the right to participate in inspections and audits of Nycomed's facilities solely through POZEN in accordance with Section 9.2.1 of the License Agreement.

(b) Nycomed will inform Buyer of the results of any inspection of Nycomed's manufacturing facilities by a regulatory authority that could adversely affect the manufacture and supply of the LX Bulk Drug Substance by Nycomed, regardless of whether or not such inspection was conducted in connection with the LX Bulk Drug Substance manufacture, at the conclusion of each calendar year (or earlier as expressly provided in this Agreement). If such an inspection is in connection with the LX Bulk Drug Substance manufacture, Nycomed will additionally provide Buyer with

a summary of the regulatory authority final report within 5 business days of Nycomed's receipt of such report.

(c) During any period in which Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed will provide Buyer within 5 business days of receipt with copies of any Form No. 483 notification, Notice of Adverse Finding, or their analogous forms from any regulatory authorities, as well as any subsequent responses by Nycomed or the regulatory authorities relating to the manufacture of LX Bulk Drug Substance or Nycomed's manufacturing facilities used for such manufacture. Nycomed will have the right to redact from any documentation provided to Buyer under this Section 4.2(c) any information that is specific to products other than the LX Bulk Drug Substance or that is related to the Process.

(d) During any period in which Nycomed is supplying LX Bulk Drug Substance hereunder, Nycomed agrees to inform Buyer within 10 business days of receipt of any notice of inquiry or inspection with respect to a facility where LX Bulk Drug Substance is manufactured by any regulatory authority from a country in which Buyer plans to submit (as notified to Nycomed) or has submitted dossiers for regulatory approval for POZEN Products containing LX Bulk Drug Substance (as notified to Nycomed) if such notice could adversely affect the manufacture or use of LX Bulk Drug Substance, and Nycomed will provide Buyer with copies of any written communications received from regulatory authorities related to the manufacture of LX Bulk Drug Substance, and Nycomed may at its

discretion redact any proprietary information relating to the Process or to products other than POZEN Products.

4.3 **Personnel**. Neither Party will use in any capacity, in connection with any manufacturing or other services to be performed under this Agreement, any individual who has been debarred pursuant to the FD&C Act or who is subject to an action, suit, claim, investigation or legal or administrative proceeding that could reasonably be expected to lead to a debarment of Nycomed, Buyer or any person performing manufacturing or other services hereunder. Either Party will, if so requested by the other Party, prepare and submit a certification statement as necessary to satisfy the requirements of the FD&C Act. Either Party agrees to immediately inform the other Party in writing if any person who is performing services hereunder is debarred or if such person becomes subject to an action, suit, claim, investigation or legal or administrative proceeding that could lead to a debarment of such person.

4.4 **DMFs and Manufacturing Approvals**. Nycomed will be responsible for filing and maintaining at its expense, and will use commercially reasonable efforts to file and maintain, in such country(ies) of the Territory coordinated by Nycomed and POZEN pursuant to the License Agreement, all DMFs necessary for the manufacture of LX Bulk Drug Substance supplied by Nycomed under this Agreement for clinical trials performed by Buyer and the commercial sale of POZEN Products by Buyer after marketing approvals have been obtained for such POZEN Products. Nycomed will be responsible for filing and maintaining at its expense, and

will use commercially reasonable efforts to file and maintain, the Manufacturing Approval for LX Bulk Drug Substance supplied by Nycomed under this Agreement.

4.5 **Records.** Nycomed will notify Buyer that Nycomed has submitted to regulatory authorities in the Territory as required by applicable law any annual reports or updates in connection with the maintenance of DMFs under this Agreement within 30 days of the filing of such reports or updates with any regulatory authority in the Territory.

4.6 **Changes.** Buyer acknowledges that Nycomed may make changes in manufacturing materials, equipment, processes, procedures, or site, or to the Specifications or to the Process, for LX Bulk Drug Substance provided to Buyer under this Agreement in accordance with Section 9.6 of the License Agreement.

5. NO INFORMATION, NO LICENSE

Except as expressly provided for in this Agreement, Nycomed shall have no obligation to provide any information, data, documentation or know-how to Buyer. Nothing in this Agreement shall be construed as granting the Buyer a license or right to use any information, data, documentation or know-how which Nycomed was not obligated to provide to Buyer (but nevertheless provided to Buyer) or any of Nycomed's patents or intellectual property rights other than patents.

6. REPRESENTATIONS AND WARRANTIES; LIMITATION OF WARRANTY

6.1 **Mutual Representations and Warranties**. Each of the Parties hereby represents and warrants to the other Party as follows:

(a) such Party is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated;

(b) this Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms, subject to applicable bankruptcy, reorganization, insolvency, moratorium and other laws affecting creditors' rights generally from time to time in effect and to general principles of equity and the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it;

(c) it has the full power and authority to enter into this Agreement and to carry out the obligations contemplated hereby; and

(d) it has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement.

6.2 **Representation of Buyer**. Buyer hereby represents and warrants to Nycomed that:

(a) Buyer is aware of all provisions of the License Agreement that are relevant to the Parties' rights and obligations under this Agreement; and

(b) Under the Sublicense Agreement, Buyer has the right to receive from POZEN copies, whether or not redacted, of amendments to the License Agreement that are relevant to the Parties' rights and obligations under this Agreement.

6.3 **DISCLAIMER**. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF ANY THIRD PARTY'S PATENTS, OTHER INTELLECTUAL PROPERTY, KNOW-HOW OR TRADE SECRETS, WITH RESPECT TO ANY MATERIALS (INCLUDING LX BULK DRUG SUBSTANCE), INFORMATION, OR DOCUMENTATION OR DATA PROVIDED TO THE OTHER PARTY IN CONNECTION WITH THIS AGREEMENT.

7. INDEMNIFICATION

7.1 **Indemnification by Buyer**. Buyer will indemnify, defend and hold Nycomed and its directors, officers and employees (each a "***Nycomed Indemnitee***") harmless from and against any damages, costs or expenses, including reasonable attorneys' fees and expenses (collectively, "***Losses***") incurred by a Nycomed Indemnitee in connection with any claim, lawsuit or

other action by a third party ("***Third Party Claim***") to the extent such Losses arise out of, relate to or result from: (a) the breach by Buyer of any of its representations, warranties, covenants or obligations contained within this Agreement; or (b) the gross negligence or willful misconduct of Buyer, its directors, officers or employees in connection with this Agreement. Notwithstanding the foregoing, Buyer will have no obligation under this Section 7.1 with respect to any Losses for which a Buyer Indemnitee is entitled to indemnification pursuant to Section 7.2 of this Agreement.

7.2 **Indemnification by Nycomed.** Nycomed will indemnify, defend and hold Buyer and its directors, officers and employees, (each a "***Buyer Indemnitee***") harmless from and against any Losses incurred by a Buyer Indemnitee in connection with any Third Party Claim to the extent such Losses arise out of, relate to or result from: (a) the breach by Nycomed of any of its representations, warranties, covenants or obligations contained within this Agreement, including the supply by Nycomed of LX Bulk Drug Substance that do not conform to the Product Warranty (except to the extent Buyer did not perform reasonable physical inspection or standard testing of such LX Bulk Drug Substance in accordance with standards in the pharmaceutical industry, including in any event testing for purity and assay according to the methods included in the applicable Specifications); or (b) the gross negligence or willful misconduct of Nycomed, its directors, officers or employees in connection with this Agreement. Notwithstanding the foregoing, Nycomed will have no obligation under this Section 7.2 with respect to any Losses for which a

Nycomed Indemnitee is entitled to indemnification pursuant to Section 7.1 of this Agreement.

7.3 **Indemnification Procedures**. A Party which or whose officers, directors or employees intend to claim indemnification under Section 7.1 or 7.2 of this Agreement (the "***Indemnitee***") will promptly notify the other Party (the "***Indemnitor***") in writing of any claim, lawsuit or other action in respect of which the Indemnitee or any of its directors, officers or employees intend to claim such indemnification as soon as reasonably practicable after the assertion of such claim; *provided, however,* that the failure to provide written notice of such claim as soon as reasonably practicable will not relieve the Indemnitor of any of its obligations hereunder, except to the extent that the Indemnitor is prejudiced by such failure to provide prompt notice. For purposes of clarification, an officer, director or employee of a Party will not have the right to claim indemnification directly from the other Party under this Section 7 and shall instead make any such claim solely through the Party employing such officer, director or employee; *provided, however,* that the foregoing shall not be construed to limit any right to indemnification that any officer, director or employee of a Party may have other than under this Agreement (e.g., under applicable laws or regulations). The Indemnitor will have the right to assume the complete control of the defense, compromise or settlement of any such claim with the prior written consent of such Indemnitee, which such consent will not be unreasonably withheld or restricted, or withdrawn or restricted at a later stage; *provided, however,* that Indemnitee will have the right to withhold consent to any compromise or settlement in its sole discretion if such

compromise or settlement includes any admission of wrongdoing on the part of an Indemnitee, or limits the scope of any claims in or enforceability of any Patents owned by or licensed to the Indemnitee. Subject to the aforesaid, the Indemnitor may at its own expense, employ legal counsel to defend the claim at issue and at any time after Indemnitor has assumed defense of a claim, the Indemnitor may exercise, on behalf of the Indemnitee, any rights which may mitigate the extent or amount of such claim; *provided, however,* the Indemnitee: (a) may, in its sole discretion and at its own expense, employ legal counsel to represent it (in addition to the legal counsel employed by the Indemnitor) in any such matter, and in such event legal counsels selected by the Indemnitee and the Indemnitor will be required to confer and cooperate with each other in such defense, compromise or settlement for the purpose of informing and sharing information; (b) will, at its own expense, make available to Indemnitor those employees, officers and directors of Indemnitee whose assistance, testimony or presence is necessary, useful or appropriate to assist the Indemnitor in evaluating and in defending any such claim; *provided, however,* that any such access will be conducted in such a manner as not to interfere unreasonably with the operations of the businesses of Indemnitee; and (c) will otherwise reasonably cooperate with the Indemnitor and its legal counsel in the investigation and defense of such claim. Notwithstanding any other provision of this Agreement to the contrary, to the extent that a Party has indemnification rights under this Agreement as well as under the License Agreement or the Sublicense Agreement, as applicable, with respect to a particular item of Losses, such

Party shall in no event be entitled to recover more than 100% of the amount of such Losses in the aggregate under both such agreements.

7.4 **Insurance**. During the term of this Agreement and for 5 years thereafter, each Party will maintain commercially reasonable insurance coverage commensurate with its obligations under this Agreement.

8. LIABILITY

8.1 **LIMITATION**. IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATING IN ANY WAY TO THIS AGREEMENT (EXCEPT WITH RESPECT TO THE PROVISIONS SET FORTH IN SECTIONS 7 AND 12 OF THIS AGREEMENT), INCLUDING, BUT NOT LIMITED TO, ANY CLAIM FOR DAMAGES BASED UPON LOST PROFITS.

8.2 **Affiliates**. Each of ..... and Nycomed Danmark ApS will be responsible and liable to each other for any of its Affiliates', contractors' or consultants' acts, performances, omissions or failures to perform in connection with this Agreement, as if such acts, performances, omissions or failures were made by themselves.

9. TERM AND TERMINATION

9.1 **Term.** The term of this Agreement shall commence on the Effective Date and end upon the first to occur of: (i) the expiration of all Exclusive Manufacturing Periods (including any extension thereof), or (ii)

the termination of this Agreement as otherwise provided for in this Section 9.

9.2 **Optional Termination**. On or after January 1, 2014, either Party may provide the other Party with written notice of its intention to terminate this Agreement, in which case this Agreement will terminate on the date 24 months after the date such notice is received by such other Party.

9.3 **Termination for Material Breach**. In the event of a material breach of this Agreement by either Party, the non-breaching Party will have the right to terminate this Agreement by written notification to the other Party, effective immediately upon receipt, if such breach is not cured within 60 days after receipt of written notice of such breach from the non-breaching Party.

9.4 **Failure to Supply**. Buyer will have the right to terminate this Agreement, effective immediately upon receipt of written notice of termination:

(a) upon the failure of Nycomed to supply for any reason, excluding force majeure, at least 90% of Buyer's requirement of LX Bulk Drug Substance conforming to the Specifications forecasted and ordered in accordance with this Agreement for any 2 consecutive orders, or for 3 orders in any 8 consecutive orders, in each case, unless Nycomed remedies such shortfall either (i) within 30 days of the scheduled delivery date in the case of failure to deliver at least 90% of ordered quantities of LX

Bulk Drug Substance, or (ii) in accordance with either Section 3.7 or Section 3.8 (as applicable) in the case of failure of at least 90% of such LX Bulk Drug Substance delivered to conform to the Specifications. The termination right set forth in this subsection (a) will expire with respect to a particular failure described above if not exercised within 30 days of the expiration of Nycomed's rights to remedy such failure; or

(b) upon the failure of Nycomed to supply for any reason, excluding force majeure, at least 90% of Buyer's requirement of LX Bulk Drug Substance conforming to the Specifications forecasted and ordered in accordance with this Agreement during any calendar year, unless Nycomed remedies such shortfall either (i) within 30 days of the scheduled delivery date in the case of failure to deliver at least 90% of ordered quantities of LX Bulk Drug Substance, or (ii) in accordance with Section 3.7 or Section 3.8 (as applicable) in the case of failure of at least 90% of such LX Bulk Drug Substance delivered to conform to the Specifications. The termination right set forth in this subsection (b) will expire with respect to a particular failure described above if not exercised within 30 days of the expiration of Nycomed's rights to remedy such failure.

9.5 **Termination Of Sublicense Agreement Or License Agreement.** This Agreement shall automatically terminate on the effective date of any expiration or termination of the Sublicense Agreement (and the Buyer shall promptly notify such effective date to Nycomed), whether expired or terminated in its entirety or only with respect to the Licensed Technology, or the License Agreement.

9.6 **Force Majeure.** The Party not subject to force majeure will have the right to terminate this Agreement pursuant to Section 13.8 of this Agreement, effective immediately upon receipt of written notice of termination.

9.7 **Severability.** This Agreement may be terminated in accordance with Section 13.6 of this Agreement.

9.8 **Insolvency.** If either .....or Nycomed Danmark ApS commences as a debtor any proceedings under any bankruptcy, insolvency, reorganization, dissolution or liquidation law or if any such proceedings are commenced against either .....or Nycomed Danmark ApS, the other Party will have the right to terminate this Agreement, effective immediately upon receipt of written notice of termination.

9.9 **Price Increases.** Buyer may terminate this Agreement in accordance with Section 2.5 of this Agreement.

10. CONSEQUENCES OF EXPIRATION OR TERMINATION

10.1 **Accrued Claims.** No expiration or termination of this Agreement will relieve any Party hereto from any liability which, at the time of such expiration or termination, has already accrued to such Party prior to such expiration or termination or which is attributable to a period prior to such expiration or termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which

accrued or are based upon any event occurring prior to such expiration or termination.

10.2 **Survival**. In the event of expiration or termination of this Agreement, the following provisions will survive, together with the definitions of the defined terms used therein Sections 3.1, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 4.1, 5, 6.3, 7, 8, 10, 11, 12 and 13. All other provisions, including all rights and obligations thereunder, will terminate and be of no further force and effect (except to the extent necessary with respect to liabilities accrued prior to expiration or termination as described in Section 10.1 above).

10.3 **Cancellation of Right of Reference.** If this Agreement expires or terminates for whatsoever reason, Nycomed will be entitled to promptly cancel with any regulatory authority (including the FDA) any Buyer right of reference to Nycomed's DMFs.

11. DISPUTE RESOLUTION

11.1 The Parties will try to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement ("***Dispute***"), a Party may notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within 20 days of receipt of the written notice by the other Party, such dispute will be resolved according to the procedures set forth elsewhere in this Agreement, or,

absent such procedures, referred to the Chief Executive Officers of each of the Parties (or their respective designees) who will use their good faith efforts to resolve the Dispute within 15 days after such referral. Notwithstanding the aforesaid, a Party will not be obligated to comply with the procedures as provided in this Section 11.1 and may immediately invoke the procedures set forth in Section 11.2 if such compliance might result in such Party's claims becoming statute barred.

11.2 Any Dispute that is not resolved as provided in the preceding Section 11.1 will be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with such Rules. The language of any such arbitration proceeding will be English, and any such arbitration proceeding will take place in Copenhagen, Denmark. Notwithstanding the foregoing, either Party shall have the right to pursue an action in a court of competent jurisdiction to obtain injunctive or other equitable remedy, in order to preserve the status quo during the resolution of any Dispute under this provision.

12. CONFIDENTIALITY

12.1 **Confidential Information**. Any information or materials communicated by one Party to the other Party, or as to which one Party provides the other Party with access, pursuant to this Agreement will be deemed "Confidential Information" of the disclosing Party if either (a) marked "confidential" or with a similar legend, or (b) if disclosed orally or visually, if identified as being confidential at the time of such oral or visual

disclosure, and thereafter reduced to writing, marked "confidential" or with a similar legend, and sent to the other Party within 30 days of such oral or visual disclosure, or (c) if the nature of such information or materials or circumstances of disclosure would suggest to a reasonable person that such disclosure was confidential, which will in any event apply to any information or materials that Buyer accesses at Nycomed's facilities. Notwithstanding the preceding sentence, "Confidential Information" will not be deemed to include information or materials that the receiving Party can demonstrate, by competent written proof:

(a) At the time of disclosure is published or is publicly known or otherwise in the public domain, other than through any act or omission by the receiving Party;

(b) Was already known to the receiving Party, other than under an obligation of confidentiality or non-use, prior to the time of disclosure by the disclosing Party;

(c) Is disclosed to the receiving Party in good faith, without an obligation of confidentiality, by a third party not under any obligation of confidence with respect to such information, after the time of disclosure by the disclosing Party; or

(d) Is independently developed by employees of the receiving Party who had no access to the disclosing Party's Confidential Information.

12.2 **Treatment of Confidential Information**. The Parties agree that during the term of this Agreement and for 10 years after the expiration

or termination of this Agreement for any reason whatsoever, a Party receiving Confidential Information of the other Party will: (a) treat any such Confidential Information disclosed to it by the other Party as strictly confidential; (b) not disclose such Confidential Information to third parties without the prior written consent of the other Party, other than to the extent necessary in the performance of this Agreement to its contractors or any consultants, provided that such disclosure be under confidentiality agreements with provisions substantially similar to those contained in this Agreement and further provided that the Party so disclosing Confidential Information shall be fully responsible and liable for any breach of any such confidentiality agreement by any contractor or consultant; (c) not use such Confidential Information for purposes other than those authorized expressly herein; and (d) use reasonable efforts to prevent unauthorized access to such Confidential Information.

12.3 **Access**. Access to Confidential Information will be limited to those employees of the Party receiving Confidential Information who reasonably require such Confidential Information in order to carry out activities authorized pursuant to this Agreement, provided that such access be under confidentiality agreements with provisions substantially similar to those contained in this Agreement and further provided that such Party shall be fully responsible and liable for any breach of any such confidentiality agreement by any such employee.

12.4 **Permitted Disclosures**. Notwithstanding any other provision in this Agreement, a receiving Party may disclose Confidential Information

of the disclosing Party to the extent such disclosure is required by law or court order, provided that the receiving Party gives the disclosing Party prompt written notice of the requirement to disclose and reasonably cooperates with the disclosing Party to seek a protective order or other restrictions on the disclosure of such Confidential Information of the disclosing Party. Any such required disclosure will be limited only to that Confidential Information that is required to be disclosed and such disclosed Confidential Information will remain Confidential Information hereunder despite the required disclosure.

12.5 **Return of Confidential Information.** Upon termination or expiration of this Agreement for any reason whatsoever, each Party hereto will return or destroy (and certify the destruction of), as instructed by the disclosing Party, all Confidential Information of the other Party in its possession to the other Party; *provided, however,* that each Party may retain: (a) a single archival copy of the Confidential Information of the other Party solely for the purpose of determining the extent of disclosure of Confidential Information hereunder and assuring compliance with the surviving provisions of this Agreement; and (b) subject to the non-use and non-disclosure provisions of this Section 12, any portion of the Confidential Information of the other Party which a Party is required by mandatory applicable law to retain.

12.6 **Confidentiality of the Agreement Terms.** Neither Party will disclose the terms of this Agreement to any third party without the prior written consent of the other Party; *provided, however,* that either Party may

disclose the terms of this Agreement to actual or prospective investors and corporate partners, to a Party's accountants, attorneys, insurers and other professional advisors, and as required by applicable laws and regulations of the U.S. Securities and Exchange Commission and any stock exchange on which a Party's stock is traded.

13. MISCELLANEOUS

13.1 **Further Assurances**. At any time during the term of this Agreement, each Party will, at the request of the other Party, use reasonable efforts to: (a) deliver to the other Party such records, data or other documents consistent with the provisions of this Agreement, and (b) take or cause to be taken all such other actions, as a Party may reasonably deem necessary in order for such Party to obtain the full benefits of this Agreement and the transactions contemplated hereby.

13.2 **Assignment**. Neither ..... nor Nycomed Danmark ApS will assign its rights or obligations under this Agreement to any third party, without the prior written consent of the other, except that either ..... or Nycomed Danmark ApS may assign such rights and obligations to a third party in connection with a merger, consolidation, transfer or sale of all or substantially all of the assets (including those to which this Agreement relates) of the assignor. In addition, either ..... or Nycomed Danmark ApS may assign its rights and obligations under this Agreement to an Affiliate without the prior written consent of the other; *provided, however,* that in the case of assignment to an Affiliate, the assignor will be responsible and liable for the compliance of such Affiliate

with this Agreement. All permitted assignments by either ..... or Nycomed Danmark ApS of any of its rights under this Agreement will be subject to all of the terms and conditions of this Agreement. All successors, permitted assignees of either ..... or Nycomed Danmark ApS will be subject to, and will be bound by, all the terms and conditions of this Agreement. Any purported assignment not permitted under the terms of this Agreement will be null, void, and of no effect.

13.3 **Independent Contractors.** The Parties hereto are independent contractors. Nothing contained herein will constitute either Party the agent of the other Party for any purpose whatsoever, or constitute the Parties as partners or joint venturers. Employees of each Party remain employees of said Party and will be considered at no time agents of or owing a fiduciary duty to the other Party. Neither Party hereto will have any implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any third party.

13.4 **Waiver.** The failure of either Party to enforce any provision of this Agreement at any time will not be construed as a present or future waiver of such or any other provision of this Agreement. The express waiver by either Party of any provision or requirement hereunder will not operate as a future waiver of such or any other provision or requirement and will be effective only if set forth in a written instrument signed by a duly authorized representative of the Party waiving such provision or requirement.

13.5 **Amendment**. The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but such amendment, modification or alteration will be valid and binding on either Party only if made by a written instrument that explicitly refers to this Agreement and that is signed by a duly authorized representative of each Party.

13.6 **Severability**. In the event that any provision in this Agreement is held to be unlawful or invalid in any jurisdiction, the meaning of such provision will be construed to the greatest extent possible so as to render it enforceable. If no such construction can render such provision enforceable, it will be severed. The remainder of this Agreement will remain in full force and effect, and the Parties will negotiate in good faith a reasonable substitute provision that is valid and enforceable in such jurisdiction. If the Parties are unable to agree on a substitute provision, and if a Party reasonably and in good faith determines that the unlawful or invalid provision was an essential element of this Agreement without which such Party would not have entered into this Agreement, as evidenced by this Agreement as a whole, then such Party may terminate this Agreement by written notice to the other Party, effective immediately upon receipt.

13.7 **Notice**. All notices hereunder must be given in writing and will be deemed given if delivered personally or by facsimile transmission (receipt confirmed), mailed by registered or certified mail (return receipt requested) with postage prepaid, or sent by express courier service (FedEx or other reputable, internationally recognized courier service), to the Parties at the following addresses (or at such other address for a Party as will be

specified by like notice; provided that notices of a change of address will be effective only upon receipt thereof).

If to Buyer: _____

_____

_____

Attention: _____

Facsimile: _____

If to Nycomed: Nycomed Danmark ApS
Langebjerg 1
DK-4000 Roskilde
Denmark
Attention: Senior Vice President International Sales
Facsimile: +45 46 75 69 04

13.8 **Force Majeure.** Neither Party will be deemed to be in breach of this Agreement as a result of default, delay or failure to perform by such Party which is due to any cause beyond the reasonable control of such Party, including without limitation fire, earthquake, acts of God, severe weather, acts of war, strikes, lockouts or other labor disputes, riots, civil disturbances, actions or inactions of governmental authorities (except actions in response to a breach of applicable laws by such Party), or epidemics. In the event of any such force majeure, the Party affected will promptly notify the other Party, will use commercially reasonable efforts to overcome such force majeure, and will keep the other Party informed with

respect thereto. If such force majeure continues for a period of more than 180 days and concerns a material obligation of a Party, the Party not subject to such force majeure may terminate this Agreement by written notice to the other Party, effective immediately upon receipt.

13.9 **Counterparts**. This Agreement may be executed by the Parties in one or more identical counterparts, all of which together will constitute this Agreement. If this Agreement is executed in counterparts, no signatory hereto will be bound until both Parties have duly executed a counterpart of this Agreement.

13.10 **Governing Law**. This Agreement will be governed by, and construed and interpreted in accordance with, the laws of Denmark, with the exclusion of the United Nations Convention on Contracts for the International Sale of Goods, without giving effect to any choice of law rule that would cause the application of the laws of any jurisdiction other than the internal laws of Denmark to the right and duties of the Parties.

13.11 **Construction**. Unless used in combination with the word "either," the word "or" is used throughout this Agreement in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein will mean including, without limiting the generality of any description preceding such term. This Agreement has been drafted and negotiated jointly by the Parties and will not be construed against a Party by virtue of such Party having drafted this

Agreement or a particular provision hereof. Unless expressly provided herein to the contrary, all time limits, notice periods, deadlines or the like described herein will be governed by the following parameters: (i) all time periods that are 5 days in length or less will be deemed to be business days, and (ii) all time periods greater than 5 days in length will be deemed to be calendar days.

13.12 **English Language**. This Agreement, including any Exhibits attached hereto, has been written and executed in the English language. Any translation into any other language will not be an official version of this Agreement, and in the event of any conflict in interpretation between the English version and such translation, the English version will control.

13.13 **Entire Agreement**. This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof, and supersedes all prior and contemporaneous agreements, understandings and negotiations, whether oral or written, with respect to such subject matter.

13.14 **Purchase Orders**. Notwithstanding anything to the contrary in this Agreement, in the event of any conflict between the terms set forth in any purchase order submitted by Buyer hereunder and this Agreement, the terms of this Agreement shall prevail, and no purchase order that conflicts with the terms of this Agreement will be binding on Nycomed.

13.15 **V.A.T.** All amounts to be paid by Buyer to Nycomed under this Agreement will be paid plus V.A.T. (if applicable).

[Remainder of page intentionally left blank. Signature page follows.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by signature of their duly authorized representatives.

[BUYER]

By: _____

Name: _____

Title: _____

NYCOMED DANMARK A/S

By: _____

Name: _____

Title: _____

Exhibit A

Chemical Structure of Lornoxicam

Exhibit B

Specifications

[To be attached at time of signing.]

Exhibit C

Original Prices Per Kilogram of LX Bulk Drug Substance Under the License Agreement

Quantity of LX Bulk Drug Substance ordered for delivery during a calendar year:	Original price per kg of LX Bulk Drug Substance:
Up to 100 kg	€4000 per kg
More than 100 kg, up to 200 kg	€3900 per kg
More than 200 kg, up to 300 kg	€3800 per kg
More than 300 kg	€3600 per kg