AstraZeneca / Pozen

Collaboration and License Agreement

August 1, 2006

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Execution Copy

COLLABORATION AND LICENSE AGREEMENT

by and between

POZEN INC.

and

ASTRAZENECA AB

August 1, 2006

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EXHIBITS AND SCHEDULES

COLLABORATION AND LICENSE AGREEMENT

THIS COLLABORATION AND LICENSE AGREEMENT (**"Agreement"**) is made and entered into effective as of August 1, 2006 (the **"Execution Date"**), by and between **POZEN INC.**, a Delaware corporation having offices at 1414 Raleigh Road, Suite 400, Chapel Hill, North Carolina (**"POZEN"**), and ASTRAZENECA AB, a Swedish corporation having an office at SE-431 83, Mölndal, Sweden (**"AstraZeneca"**). POZEN and AstraZeneca each may be referred to herein individually as a **"Party,"** or collectively as the **"Parties."**

RECITALS

A. POZEN controls certain patents and other intellectual property pertaining to pharmaceutical products having gastroprotective agents in single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs.

B. AstraZeneca desires to obtain a license to POZEN's intellectual property and to enter into a collaboration with POZEN for the purpose of developing and commercializing certain pharmaceutical products.

C. POZEN desires to grant AstraZeneca such a license and to enter into such a collaboration on the terms and conditions set forth in this Agreement.

In consideration of the foregoing premises, the mutual promises and covenants set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, POZEN and AstraZeneca hereby agree as follows:

AGREEMENT

1. DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. All financial and accounting terms not otherwise defined in this Agreement, whether capitalized or not, shall have the meanings assigned to them in accordance with generally accepted accounting principles based on International Accounting Standards/International Financial Reporting Standards as in effect from time to time (**"IFRS"**).

1.1 "ADA Budget" has the meaning set forth in Section 3.3.3 (Expenses).

1.2 "Additional Development Activities" means any activities related to the Development of the Initial POZEN Product that are not Core Development Activities. Additional Development Activities agreed upon as of the Execution Date are included in the Initial U.S. Development Plan and Initial ROW Development Plan.

1.3 "Adverse Event" means any adverse medical occurrence in a patient or clinical investigation subject that is administered a pharmaceutical product, as designated under 21 CFR

§ 312.32 and any other Applicable Law in the Territory.

1.4 "Affiliate" means a legal entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with an entity. For purposes of this definition only, "control" and, with correlative 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; provided, that if local law restricts foreign ownership, control will be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests.

1.5 "Applicable Law" means the laws, rules, and regulations, including any statutes, rules, regulations, guidelines, or other requirements that may be in effect from time to time and apply to the activities contemplated by this Agreement in the Territory.

1.6 "AstraZeneca House Marks" means any trademarks, trade names, domain names, or other names or marks used or registered by AstraZeneca or its Affiliates at any time during the Term to identify itself.

1.7 "AstraZeneca Invention" means any Invention that is conceived solely by one or more employees, agents, or independent contractors of AstraZeneca or its Affiliate(s).

1.8 "Blocking Patent" means a Patent owned or controlled by a Third Party, one or more Valid Claims of which, in the absence of a license thereunder, would be infringed by the making, use, sale, offering for sale, or importation of a POZEN Product.

1.9 "Budgeted Development Activities" means the Additional Development Activities described in the first ADA Budget approved by the GPT pursuant to Section 3.3.3 (Expenses) and the first U.S. Development Plan and first ROW Development Plan approved by the GPT pursuant to Section 3.1 (Development Plans), in each case consistent with the Initial U.S. Development Plan and Initial ROW Development Plan.

1.10 "Business Combination" means any merger, consolidation, sale of stock, sale or transfer of all or substantially all of the assets, or other similar transaction to which POZEN is a party, other than any merger, consolidation, or similar transaction following which the individuals and entities who were the beneficial owners of the outstanding voting securities of POZEN immediately prior to such transaction still beneficially own, directly or indirectly, more than fifty percent (50%) of the voting power of the surviving entity immediately after such transaction.

1.11 "Business Day" means any day other than (i) Saturday or Sunday or (ii) any other day on which banks in New York, New York, United States, the United Kingdom or Sweden are permitted or required to be closed.

1.12 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.13 "cGCP" means current good clinical practices as defined in U.S. Regulations 21 CFR §§ 50, 54, 56, 312 and 314, (or in the case of foreign jurisdictions, comparable regulatory standards), the International Conference of Harmonization (ICH) E6 "Good Clinical Practice: Consolidated Guidance," and in any successor regulation or any official guidance documents issued by an applicable Regulatory Authority.

1.14 "cGLP" means current good laboratory practice standards as defined by the FDA pursuant to 21 CFR Part 58 (or in the case of foreign jurisdictions, comparable regulatory standards), and in any successor regulation or any official guidance documents issued by a Regulatory Authority.

1.15 "cGMP" means current good manufacturing practices as contained in 21 CFR Parts 210 and 211 as amended from time to time and any equivalents contained in regulations in countries outside the U.S.

1.16 "Change of Corporate Control" means the occurrence of either of the following:

(a) a Business Combination involving POZEN; or

(b) the acquisition (whether in a single transaction or series of related transactions) after the Effective Date by a Third Party or Group of beneficial ownership of [redacted] of POZEN's voting securities.

1.17 "Clinical Trial Materials" means the Initial POZEN Product formulated in accordance with the specifications of Schedule 6.1, matching placebo and matching individual ingredients and comparators, each packaged and labeled for use in the applicable clinical trial.

1.18 "Combination Product" means a Product that includes one or more pharmaceutically active ingredients (in addition to a single Gastroprotective Agent and a single NSAID) and is sold in final form either in a single fixed combination oral solid dosage or as separate doses in a single package and priced as one item.

1.19 "Commercial Launch" means the nationwide commercial sale, promotion and distribution of POZEN Product in a particular country of the Territory following receipt of Marketing Approval in such country.

1.20 "Commercialization" means all activities relating to the manufacture, marketing, promotion, advertising, selling and distribution of Product in any country of the Territory, including pre-Commercial Launch market development activities conducted in anticipation of Marketing Approval of Product, including, without limitation, seeking pricing and reimbursement approvals for Product, preparing advertising and promotional materials, sales force training, and all interactions and activities (*e.g.*, dossier preparations and filings) associated with Regulatory Authorities regarding the commercialization of Product and the maintenance of Marketing Approvals. The term "Commercialize" has a correlative meaning.

1.21 "Commercialization Plan" has the meaning set forth in Section 5.4.1.

1.22 "Commercialized POZEN Product" has the meaning set forth in Section 12.6.4(b)(ii).

1.23 "Competing Product" means, with respect to a particular Product being Commercialized by AstraZeneca or any of its Affiliates or Sublicensees in any country of the Territory, a product being marketed by or on behalf of a Third Party (other than a Sublicensee) in the same country containing at least [redacted]

1.24 "Controlled" means, with respect to any Know-How, Patent, or other intellectual property right, the possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Know-How, Patent or right as provided for herein without violating the terms of any agreement or other arrangements with any Third Party.

1.25 "Core Development Activities" means any activities identified on Exhibit B as being paid for by POZEN.

1.26 "DDMAC" means the FDA's Division of Drug Marketing, Advertising, and Communications.

1.27 "Develop" or "Development" means all activities relating to pre-clinical and clinical development of a Product and all development activities relating to the preparation and filing of NDAs and obtaining of Marketing Approvals, price and reimbursement approvals, including, without limitation, preparing and conducting pre-clinical testing, toxicology testing, human clinical studies, regulatory affairs.

1.28 "Development Program" means the program of Development described in the U.S. Development Plan and ROW Development Plan, each as amended from time to time.

1.29 "Diligent Efforts" means, (A) with respect to the Development, Manufacture or Commercialization by AstraZeneca of a product, at any given time as the case may be, efforts and resources reasonably used by AstraZeneca or its Affiliates (giving due consideration to relevant industry standards) for AstraZeneca's own products (including internally developed, acquired and in-licensed products) with similar commercial potential at a similar stage in their lifecycle (assuming continuing development of such product), taking into consideration their safety, tolerability and efficacy, the profitability (taking into account any payments payable under this Agreement), the extent of market exclusivity, patent protection, cost to develop the product, promotable claims, and health economic claims, and (B) with respect to the Development by POZEN of a product, at any given time as the case may be, efforts and resources reasonably used by an entity in the pharmaceutical industry of similar resources and expertise as POZEN, for such similar entity's own products (including internally developed, acquired and in-licensed products) with similar commercial potential at a similar stage in their lifecycle (assuming continuing development of such product), taking into consideration their safety, tolerability and efficacy, the profitability (taking into account any payments payable

under this Agreement), the extent of market exclusivity, patent protection, cost to develop the product, promotable claims, and health economic claims.

1.30 "Direct Costs" means all amounts which POZEN disburses to vendors for services rendered or product supplied in conducting studies pursuant to this Agreement. For clarification, no POZEN employee compensation, internally consumed supplies, utility charges, recoverable Indirect Taxes or other indirect costs will be included in Direct Costs.

1.31 "Effective Date" has the meaning as defined in Section 12.1 (HSR Act).

1.32 "**EMEA**" means the European Medicines Agency, or any successor agency thereto.

1.33 "Esomeprazole" means that certain pharmaceutical compound with the name (5-methoxy-2-{(S)-[(4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfinyl}-1H-benzimidazole), including any [redacted]

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

1.35 "Field of Use" means the treatment of human diseases and conditions by means of a pharmaceutical product.

1.36 "First Commercial Sale" means, with respect to a Product and on a country-by-country basis, the date on which AstraZeneca or its Affiliate or Sublicensee first sells the Product intended for commercial distribution to any Third Party after receipt of NDA Approval of such Product in such country (including, without limitation, sale in an individual state, province or similar sub-national political subdivision in which Marketing Approval may be received). Sale of a Product for clinical studies, compassionate use, named patient programs, under a treatment IND, test marketing, any clinical studies, or any similar instance where the Product is supplied with or without charge will not constitute a First Commercial Sale.

1.37 "Formulation Budget" has the meaning set forth in Section 6.1.4 (Expenses).

1.38 "Formulation Development Activities" has the meaning set forth in Section 6.1.4 (Expenses).

1.39 "Formulation Technology" means any Know-How Controlled by AstraZeneca in the AstraZeneca Inventions that are used by AstraZeneca in the manufacture, use, sale or import of the formulation of a Commercialized POZEN Product, and any Patents Controlled by AstraZeneca claiming such AstraZeneca Inventions; provided, that Formulation Technology will not include any Patents or Know-How to the extent directed to a Gastroprotective Agent, non-steroidal anti-inflammatory, or other drug or chemical agent, or any methods of manufacture or use thereof.

1.40 "FTE Costs" means an amount equal to [redacted] multiplied by the total number of hours spent by POZEN development personnel [redacted] conducting Additional Development Activities for the Development of Initial POZEN Products pursuant to

this Agreement in accordance with a Development plan and budget approved by the GPT.

1.41 "Gastroprotective Agent" means proton pump inhibitors and H2 receptor antagonists for the treatment, prevention or amelioration of injury to the gastrointestinal tract.

1.42 "GPT" means AstraZeneca's global product team operating pursuant to AstraZeneca's instructions for global product teams for the Initial POZEN Product with representatives of AstraZeneca having expertise in the areas of research & development, marketing, regulatory, intellectual property, finance, toxicology, and other areas.

1.43 "GPT Chair" will have the meaning set forth in Section 2.2.1 (GPT) .

1.44 "Group" means a group of related persons or entities deemed a "person" for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended.

1.45 "IND" means an Investigational New Drug Application filed with the FDA pursuant to 21 CFR § 312.20, or the corresponding filing in any country or regulatory jurisdiction other than the United States required for the clinical testing in humans of a pharmaceutical product.

1.46 "Indirect Tax" means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.47 "Initial POZEN Product" means the POZEN Product containing non-enteric coated Esomeprazole and enteric-coated Naproxen that is the subject of the Initial U.S. Development Plan and Initial ROW Development Plan, subject to substitution (either throughout the Territory or in any one or more countries of the Territory) in accordance with Section 3.4.2 (Substitution) hereof.

1.48 "Initial ROW Development Plan" means the outline for the ROW Development Plan, as set forth in Exhibit D as of the Effective Date.

1.49 "Initial ROW Development Plan Timeline" means the ROW Development Plan Timeline attached to this Agreement as Exhibit E as of the Effective Date.

1.50 "Initial U.S. Development Plan" means the outline for the U.S. Development Plan, as set forth in Exhibit B as of the Effective Date.

1.51 "Initial U.S. Development Plan Timeline" means the U.S. Development Plan Timeline attached to this Agreement as Exhibit C as of the Effective Date.

1.52 "Invention" means any invention, discovery or Know-How that is conceived during the Term in the performance of activities undertaken pursuant to this Agreement by employees, agents, or independent contractors of either Party, its Affiliates or Sublicensees and is Controlled by such Party, Affiliates or Sublicensees.

1.53 "Joint Invention" means any Invention that is conceived jointly by one or more employees, agents, or independent contractors of AstraZeneca or its Affiliate(s) and one or more

employees, agents, or independent contractors of POZEN or its Affiliate(s).

1.54 "Joint Patent" means a Patent claiming a Joint Invention.

1.55 "JSC" has the meaning set forth in Section 2.1.2 (Joint Steering Committee).

1.56 "Know-How" means any non-public, documented or otherwise recorded or memorialized knowledge, experience, know-how, technology, information, and data, including formulas and formulations, processes, techniques, unpatented inventions, discoveries, ideas, and developments, test procedures, and results, together with all documents and files embodying the foregoing.

1.57 "Licensed Know-How" means any Know-How that is necessary or useful for the Development, Manufacture or Commercialization of Product in the Field of Use and that is Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term.

1.58 "Licensed Patents" means: (a) the Patents set forth on Schedule 1.58, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, or extensions of such Patents, (b) any Patents Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that claim Inventions (including without limitation POZEN's interest in Joint Inventions), (c) all other Patents Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term that are necessary or useful for the Development, Manufacture or Commercialization of a Product; and any foreign counterparts of any of the foregoing.

1.59 "Licensed Technology" means the Licensed Patents and the Licensed Know-How.

1.60 "Major Ex-U.S. Market" means the following countries: [redacted] or any country substituted for one of the foregoing countries pursuant to Section 4.1.2 (Outside the U.S.).

1.61 "Manufacture" means all activities related to the manufacturing of a Product, or any ingredient thereof, including but not limited to formulation development and process development for the manufacture of a Product, manufacturing supplies for Development, manufacturing for commercial sale, packaging, in-process and finished product testing, release of product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of product, ongoing stability tests and regulatory activities related to any of the foregoing. "Manufacture" shall not include any of the above activities with respect to Esomeprazole as an active ingredient.

1.62 "Market Reduction" has the meaning set forth in Section 8.4.3 (Rate Step Down for Competing Product Entrants).

1.63 "Marketing Approval" means all approvals (including NDA Approvals and, where available under Applicable Law, pricing and reimbursement approvals in accordance with Applicable Law) of any Regulatory Authority in a country, that are necessary or useful to be obtained prior to the manufacture or Commercialization of a Product in that country. For

purposes of clarification, "Marketing Approval" in the U.S. shall have the same meaning as NDA Approval in the U.S.

1.64 "Milestone Events" means the events listed under the heading "Milestone Events" in the table in Section 8.2 (Development Milestone Payments).

1.65 "Naproxen" means that certain pharmaceutical compound with the chemical name (S)-6-methoxy-(alpha)-methyl-2-naphthaleneacetic acid, including any [redacted].

1.66 "NDA" means a New Drug Application filed with the FDA as described in 21 CFR § 314, or any corresponding application for Regulatory Authority approval (not including pricing and reimbursement approval) in any country or regulatory jurisdiction other than the U.S.

1.67 "NDA Approval" means receipt of a letter from the FDA, or equivalent Regulatory Authority in jurisdictions outside the U.S., approving an NDA.

1.68 "Net Sales" means with respect to any Product, the gross amounts recognized by AstraZeneca, its Sublicensees or its Affiliates from Third Party customers for sales of a Product in the Territory, less the following deductions made by AstraZeneca (to the extent not already taken by AstraZeneca in the Product invoice or in amounts recognized), its Sublicensees or its Affiliates in arriving at net sales as reported in the AstraZeneca statutory accounts prepared in accordance with IFRS:

(a) actual credited allowances to such Third Party customers for spoiled, damaged, rejected, recalled, outdated and returned Product and for retroactive price reductions;

(b) the amounts of trade and cash discounts actually granted to Third Party customers, to the extent such trade and cash discounts are specifically allowed on account of the purchase of such Product;

(c) sales taxes, excise taxes and import/export duties actually due or incurred in connection with the sales of a Product to any Third Party customer;

(d) allowances, adjustments, reimbursements, discounts, chargebacks and rebates actually granted to Third Party customers (not in excess of the selling price per unit of such Product);

(e) other deductions from gross sales made in arriving at net sales as reported in the AstraZeneca statutory accounts; and

(f) allowance for transportation costs, distribution expenses, special packaging and related insurance charges in the amount [redacted] of the Net Sales calculated after applying the deductions of items (a)-(e) above.

Net Sales shall be calculated using AstraZeneca's internal audited systems used to report such sales as adjusted for any of items (a)-(f) above not taken into account in such systems.

Notwithstanding the foregoing, if Product is sold as a Combination Product, the Net Sales used for the calculation of the royalties under Section 8.4 (Royalties) shall be determined as follows:

$\frac{A}{A+B}$ x Net Sales of the Combination Product, where:

A = Standard Sales Price of the ready-for-sale form of the Product if sold separately from the Combination Product in question, in the given country.

B = Standard Sales Price of the ready-for-sale form of a product containing the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the given country.

If, in a specific country, (a) the other therapeutically active ingredient(s) in such Combination Product are not sold separately in such country, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A/C, where C is the Standard Sales Price in such country of such Combination Product, and (b) if a Product contained in the Combination Product is not sold separately, Net Sales shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction (C-B)/C, where B is the Standard Sales Price in such country of the other therapeutically active ingredient(s) in the Combination Product and C is the Standard Sales Price in such country of the Combination Product. If, in a specific country, both a Product in a Combination Product and a product containing the other active ingredients in such Combination Product are not sold separately, a market price for such Product and such other active ingredients shall be negotiated by the Parties in good faith based upon the market price of products that are comparable to such Product or such other active ingredients, as applicable. In each country where the Product in the Combination Product is marketed, the Standard Sales Price of the Product in such Combination Product for purposes of calculating the royalty payable to POZEN will be no less than [redacted] of the Standard Sales Price of the Product sold outside of such Combination Product in such country.

In addition, and notwithstanding the foregoing, if a Product is sold together with other goods with or without a separate price for such Product (such group of products including the Product a **"Product Set"**), then the Net Sales applicable to the quantity of such Product included in any such transaction will be calculated as follows:

$\frac{A}{A+B}$ x Net Sales of the Product Set, where:

A = Standard Sales Price of the Product if sold separately from the Product set in question, in the given country.

B = The total of the Standard Sales Prices of all products in the Product Set other than the Product, in the given country.

1.69 "Nexium" means AstraZeneca's products containing Esomeprazole as the sole active ingredient in any presentation form.

1.70 "Nexium Business" means AstraZeneca's development and commercialization activities pertaining to Esomeprazole and Esomeprazole based products.

1.71 "NSAID" means any non-steroidal anti-inflammatory drug, the primary mechanism of action of which is inhibition of cyclooxygenase, but excluding acetyl salicylic acid (including salts and derivatives thereof).

1.72 "Patent Challenge" has the meaning set forth in Section 9.9.

1.73 "Patents" 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, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such patents or patent applications.

1.74 [redacted] has the meaning set forth in Section 6.1.3.

1.75 "PDUFA Date" means the date identified in an official communication from the FDA as the target date by which the FDA expects to issue an action letter, as required under the Prescription Drug User Free Act of 1992 (P.L. 102-571), as amended and in effect from time to time.

1.76 [redacted] study described in the Initial U.S. Development Plan.

1.77 [redacted] studies described in the U.S. Development Plan.

1.78 "Post-Approval Failure" means: (a) a mandatory withdrawal or recall of a Product by a Regulatory Authority in any country in the Territory, or (b) any voluntary withdrawal or recall of a Product in the U.S. or a Major Ex-U.S. Market country that arises from risks associated with a serious adverse health consequence or death reported to a Regulatory Authority anywhere in the world. Notwithstanding the foregoing, any such recall that results primarily from AstraZeneca's or its Affiliate's or Sublicensee's gross negligence, willful misconduct, or failure to comply with Applicable Law in the Development, Manufacture or Commercialization of a Product shall not be considered a Post-Approval Failure for purposes of this Agreement.

1.79 "POZEN House Marks" means any trademarks, trade names, domain names, or other names or marks used or registered by POZEN or its Affiliates at any time during the Term to identify itself.

1.80 "POZEN Invention" means any Invention that is conceived solely by one or more employees, agents, or independent contractors of POZEN or its Affiliate(s).

1.81 "POZEN Product" means any product that combines a Gastroprotective Agent and any NSAID in a single fixed combination dosage form, that would, if made, used, sold, offered for sale, had made, imported or exported without a license from POZEN of the Licensed Patents, infringe one or more Valid Claims of the Licensed Patents.

1.82 "Pre-Approval Failure" means any of the following:

(a) POZEN's failure to deliver the formulation, manufacturing process, data and materials for the Initial POZEN Product in accordance with the terms of Section 6.1.1 (Initial POZEN Product) or Section 6.1.2 (ROW POZEN Products);

(b) the receipt of notice from the FDA, EMEA or other Regulatory Authority in the EU that successful completion of the Budgeted Development Activities and Core Development Activities would be insufficient to achieve NDA Approval of the Initial POZEN Product without the performance of Additional Development Activities that are not included in the Budgeted Development Activities and that would be reasonably expected, in the aggregate, to either (i) delay the anticipated date of NDA Approval of the Initial POZEN Product by more than [redacted] past the dates set forth in the Initial U.S. Development Plan Timeline or for any country of the EU set forth in the Initial ROW Development Plan Timeline, or (ii) require AstraZeneca to spend more than an aggregate of [redacted] to perform; provided that, the cost of any such Additional Development Activities conducted pursuant to the [redacted] Studies shall not be counted toward such [redacted] limit;

(c) either (i) the failure of [redacted] Study described in the Initial U.S. Development Plan to satisfy its primary endpoint for all doses of the Initial POZEN Product, or (ii) the failure of [redacted] Study described in the Initial U.S. Development Plan to satisfy its primary endpoint, [redacted]

(d) receipt of results of a clinical trial of the Initial POZEN Product that show that such Initial POZEN Product is unsafe;

(e) TPP Failure;

(f) the receipt of notice from the FDA, the EMEA or a Regulatory Authority in a country in the Major Ex-U.S. Market that the NDA for the Initial POZEN Product in such country is not approvable;

(g) after the submission of an NDA for the Initial POZEN Product, receipt of notice from the FDA, EMEA or other Regulatory Authority in the EU that such NDA will not be approved without the performance of Additional Development Activities that would be reasonably expected, in the aggregate, to either (i) delay the anticipated date of NDA Approval of the Initial POZEN Product by more than [redacted] past the date set forth in the Initial U.S. Development Plan Timeline or for any country of the EU set forth in the Initial ROW Development Plan Timeline, or (ii) require AstraZeneca to spend more than an aggregate of [redacted] to perform; or

(h) subject to the terms of Sections 2.3.5 (Interim Results of [redacted]

[redacted]) and 4.3.3 (Label Negotiations and Approval), delay in Development activities not caused by AstraZeneca's failure to comply with its obligations under this Agreement that, in the aggregate, will delay NDA Approval for the Initial POZEN Product in either the U.S. or the EU at least [redacted] beyond the date for such NDA Approval set forth in the Initial U.S. Development Plan Timeline and the Initial ROW Development Plan Timeline.

1.83 "Product" means: (a) any POZEN Product, and (b) any other product that combines a Gastroprotective Agent and any NSAID in a single fixed combination oral solid dosage form (with or without one or more additional therapeutically active agents), which product is developed or commercialized by or for, invented or acquired by, or comes under the Control of AstraZeneca or its Affiliates during the Term. For the avoidance of doubt, "Product" does not include any product containing acetyl salicylic acid (including salts and derivatives thereof).

1.84 "Product Labeling" means (a) the full prescribing information for a POZEN Product approved by the applicable Regulatory Authority, and (b) all labels and other written, printed or graphic information included in or placed upon any container, wrapper or package insert used with or for the POZEN Product.

1.85 "Product Trademarks" means any trademarks, trade dress (including packaging design), logos, slogans, domain names and designs, whether or not registered in a country or territory, selected and owned by AstraZeneca and used to identify or promote a POZEN Product, but excluding any POZEN House Marks and AstraZeneca House Marks.

1.86 "Promotional Materials" means all sales representative training materials and all written, printed, graphic, electronic, audio or video presentations of information, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items) intended for use or used by AstraZeneca or its Affiliates in connection with any promotion of the Initial POZEN Product hereunder, but excluding Product Labeling.

1.87 "Proof of Concept Study" means the [redacted] Study and [redacted] Study described in the Initial U.S. Development Plan.

1.88 "Regulatory Authority" means, in a particular country or jurisdiction, any applicable government regulatory authorities involved in granting approval to market or sell a Product, including any pricing and reimbursement approvals, in such country or jurisdiction, including, (a) in the United States, the FDA, and any successor government authority having substantially the same function, (b) any non-United States equivalent thereof, and (c) in the EU, the EMEA and any national regulatory authority in any EU country.

1.89 "Regulatory Materials" means regulatory applications, submissions, notifications, registrations, Marketing Approvals or other submissions made to or with a Regulatory Authority that are necessary or reasonably desirable in order to develop, manufacture, market, sell or otherwise Commercialize the Initial POZEN Product in a particular country, territory or possession. Regulatory Materials include, without limitation, INDs and

NDAs, and amendments and supplements for any of the foregoing, and applications for pricing and reimbursement approvals.

1.90 "ROW Development Plan" means the plan for the Development of the Initial POZEN Product for Marketing Approval in the Territory outside the U.S. as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.91 "ROW Development Plan Timeline" means the estimated timeline for completion of the ROW Development Plan, as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.92 "Royalty Term" has the meaning set forth in Section 8.4.2 (Royalty Term).

1.93 "Specifications" has the meaning set forth in Section 6.1.1 (Manufacturing Development; Initial POZEN Product).

1.94 "Standard Sales Price" means, as reported by IMS (or ACNielsen in the case of over-the-counter products) in the relevant country, the average sales price for the preceding Calendar Quarter for the Product or, in the case of a Combination Product, the average sales price for the applicable presentation and dosage strength of all marketed brands of the other therapeutically active ingredient(s). As used herein, "presentation" means the method of administration of a pharmaceutical substance into the human body, including, but not limited to, solid oral (including tablets, capsules, gelcaps, sachets and caplets), other oral (including suspension and solution), parenteral (including intramuscular, subcutaneous and intravenous), transdermal, suppository and intranasal.

1.95 "Sublicense Agreement" means any agreement under which AstraZeneca grants a Third Party a sublicense, option or other right under the Licensed Technology to make, use, have made, sell, offer for sale, import and export Products in the Field of Use in the Territory.

1.96 "Sublicensee" means any Third Party that has entered into a Sublicense Agreement.

1.97 "Term" has the meaning assigned to it in Section 12.2 (Term).

1.98 "Territory" means all countries of the world, excluding Japan, unless and until AstraZeneca exercises the option under Section 7.6 (Japan Option), whereupon the Territory shall be all countries of the world.

1.99 "Third Party" means any entity other than POZEN, AstraZeneca, or any of their respective Affiliates.

1.100 "Third Party Royalties" means upfront, commercialization milestone, royalty and any other similar payments paid by AstraZeneca or any AstraZeneca Affiliate to any Third Party in consideration for a license to a Blocking Patent for the Development or Commercialization of POZEN Products.

1.101 "TPP" shall mean the target product profile of the Initial POZEN Product as

described in Exhibit F.

1.102 "TPP Endpoints" means the endpoints of the TPP Studies as described in Exhibit F.

1.103 "TPP Failure" means the failure of any TPP Study to achieve TPP Endpoint Success, as defined in Exhibit F.

1.104 "TPP Studies" means the studies entitled [redacted] in the Initial U.S. Development Plan.

1.105 "U.S." means the United States of America and its possessions and territories.

1.106 "U.S. Development Plan" means the plan for the Development of the Initial POZEN Product for Marketing Approval in the U.S. as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.107 "U.S. Development Plan Timeline" means the estimated timeline for completion of the U.S. Development Plan, as may be updated and amended from time to time by the GPT in accordance with this Agreement.

1.108 "Valid Claim" means any claim of any issued and unexpired patent or a patent application that has not been disclaimed or held invalid or unenforceable by judgment or decree entered in any judicial proceeding that is not further reviewable through the exhaustion of all permissible applications for rehearing or review by a superior tribunal, or through the expiration of the time permitted for such applications; provided, that any claim in a pending Patent application that does not issue as a patent claim within [redacted] after the earliest priority date of such application will not be a "Valid Claim" until such claim issues as a patent claim.

2. COLLABORATION GOVERNANCE

2.1 Establishment.

2.1.1 Global Product Team. Within twenty (20) days after the Effective Date, the Parties will appoint representatives to the GPT in accordance with the terms of this Section 2.1 and convene the first GPT meeting. The GPT will coordinate and oversee the Development and Commercialization of the Initial POZEN Product hereunder. The purposes of the GPT will be, with respect to the Initial POZEN Product only, (a) to coordinate the management and implementation of the Parties' Development activities hereunder, (b) to update the U.S. Development Plan in a manner consistent with the Initial U.S. Development Plan by providing additional detail regarding the activities described therein and to amend the U.S. Development Plan from time to time, (c) to update the ROW Development Plan in a manner consistent with the Initial ROW Development Plan by providing additional detail regarding the activities described therein and to amend the ROW Development Plan from time to time, (d) to propose, approve, amend and allocate responsibility for performing any Additional Development Activities, and (e) to develop AstraZeneca's Commercial Launch and marketing plans for the Initial POZEN Product. The GPT will have the membership and will operate by the procedures set forth in Section 2.2 (Membership and Procedures).

2.1.2 Joint Steering Committee Promptly following the Effective Date, the Parties will create a joint steering committee (the **"JSC"**) to provide strategic guidance to the GPT in decisions pertaining to the Initial POZEN Product. The purposes of the JSC will be (a) to review and make recommendations to the GPT regarding the U.S. Development Plan, and (b) to resolve disputes of the GPT. The JSC will have the membership and will operate by the procedures set forth in Section 2.2 (Membership and Procedures).

2.2 Membership and Procedures.

2.2.1 GPT.

(a) Membership. In addition to members designated by AstraZeneca, the GPT shall have up to three (3) representatives designated by POZEN, attending, observing and participating in meetings of the GPT at POZEN's expense, such representatives having the relevant experience and skill appropriate for service on such team. Such representatives shall be regular working members of the GPT. AstraZeneca shall be entitled to have as many representatives serve as members of the GPT as it desires. POZEN may replace its representatives on the GPT at any time upon written notice to AstraZeneca. AstraZeneca shall provide POZEN office space at its facilities for such representatives to facilitate such participation; provided, that such representatives shall comply with all policies and reasonable restrictions imposed by AstraZeneca and provided to POZEN in writing. Upon prior written consent of AstraZeneca, which consent will not be unreasonably withheld, a reasonable number of employees, consultants, representatives or advisors of POZEN who are not POZEN's GPT representatives may attend GPT meetings as observers; provided, that such persons shall comply with all policies and reasonable restrictions imposed by AstraZeneca and provided to POZEN in writing.

(b) Chairpersons. The global product director for the Initial POZEN Product designated by AstraZeneca will chair the GPT (**"GPT Chair"**).

(c) Meetings. The GPT will hold meetings when called by the GPT Chair but, in any event, at least once every Calendar Quarter. Meetings may be held in person at AstraZeneca's facilities or by means of telecommunication (telephone, video, or web conferences). Following any GPT meeting, the GPT Chair will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. Such minutes will not be finalized until a representative of the GPT designated by each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement.

2.2.2 JSC.

(a) Membership. Each Party will designate an equal number of representatives, but in no event less than three (3) each, with appropriate expertise to serve as members of the JSC. Each Party may replace its representatives on the JSC at any time upon written notice to the other Party.

(b) Co-Chairpersons. One of each Party's representatives to the JSC will be designated as a co-chairperson. The co-chairpersons will be responsible for calling

meetings and preparing and circulating an agenda in advance of each meeting, and preparing minutes of each meeting.

(c) Meetings. The JSC will hold meetings at least once every Calendar Quarter, or more frequently as the Parties may agree with at least two meetings held in person annually. Subject to the preceding sentence, meetings may be held in person at locations to be determined by the mutual agreement of the Parties (a majority of which must be outside the United States) or by means of telecommunication (telephone, video, or web conferences). Following any JSC meeting, the co-chairpersons will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. Such minutes will not be finalized until a representative of each Party has reviewed and confirmed the accuracy of such minutes in writing. If a disagreement regarding the accuracy of such minutes cannot be resolved, the minutes will reflect such disagreement.

2.2.3 Limitations of Powers. The GPT and JSC will have only such powers as are specifically delegated to them hereunder and will not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, the GPT and JSC will not have any power to amend this Agreement (except amendments to the U.S. Development Plan or ROW Development Plan). Any amendment to the terms and conditions of this Agreement may only be implemented pursuant to Section 15.6 (Entire Agreement; Modifications) below.

2.2.4 Expenses. Each Party will be responsible for all of its own expenses of participating in the GPT and JSC.

2.3 Decision-Making.

2.3.1 GPT Decisions. Subject to the terms of this Section 2.3 (Decision-Making), the GPT will act by decision of the GPT Chair. If a POZEN representative objects to any decision, then such dispute will be referred to the JSC.

2.3.2 JSC Decisions. Subject to the terms of this Section 2.3 (Decision-Making), the JSC will take action by unanimous vote with each Party having a single vote, irrespective of the number of representatives actually in attendance at a meeting, or by a written resolution signed by the designated representatives of each of the Parties. If the JSC fails to reach unanimous consent on a particular matter within [redacted] of POZEN having requested a formal vote on such matter (or any earlier period mutually agreed to by the Parties if a delay may reasonably be anticipated to have an adverse effect on the Development or Commercialization of the Initial POZEN Product), then such dispute will be subject to the resolution procedures described in Section 2.3.3 (Dispute Resolution) below.

2.3.3 Dispute Resolution. In the event of any dispute in the JSC that is not resolved pursuant to the terms of Section 2.3.2 (JSC Decisions), either Party may provide written notice of such failure (a **"Notice of Disagreement"**) to the Chief Executive Officer of the other Party (or his or her designee). The Chief Executive Officers or designees of each of the Parties will meet at least once in person or by means of live telecommunication (telephone, video, or web conferences) to discuss the matter on which the JSC failed to reach unanimous consent and use their good faith efforts to resolve the matter within [redacted] after receipt of the

Notice of Disagreement by the applicable Chief Executive Officer of a Party. If any such disagreement is not resolved by the Chief Executive Officers or designees within such [redacted] period, then (A) the Chief Executive Officer or designee of POZEN will have the final decision-making authority with respect to any such disagreement arising out of either (i) Core Development Activities (other than [redacted]) or (ii) subject to Section 3.3.3 (Expenses), Additional Development Activities but only to the extent that such activities are required by the FDA to obtain NDA Approval in the U.S. of the Initial POZEN Product, and (B) the Chief Executive Officer or designee of AstraZeneca will have the final decision-making authority with respect to disagreement relating to all other matters. Notwithstanding anything to the contrary in this Section 2.3.3 (Dispute Resolution):

(a) POZEN'S Chief Executive Officer or designee will not make a final determination that would [redacted] without AstraZeneca's prior written consent;

(b) POZEN'S Chief Executive Officer or designee will not make a final determination [redacted] without the prior written consent of AstraZeneca; provided, that AstraZeneca will not unreasonably withhold, condition or delay its consent;

(c) Neither Party's Chief Executive Officer or designee [redacted]

(d) Neither Party's Chief Executive Officer or designee may make any decision without the prior written consent of the other Party that would [redacted] by the Parties through the [redacted] will not be [redacted]; provided, that the foregoing will [redacted] set forth in this Agreement [redacted] in this Agreement;

(e) AstraZeneca's Chief Executive Officer or designee will not, without POZEN's prior written consent, [redacted]

2.3.4 Extension of Pre-Approval Failure Time Limits. [redacted] if AstraZeneca proposes to change either the U.S. Development Plan or the ROW Development Plan so as to add Development activities that are reasonably expected to delay the NDA Approval of the Initial POZEN Product in the U.S. or any Major Ex-U.S. Market country (other than in a manner required by a Regulatory Authority to obtain NDA Approval in the U.S. or any Major Ex-U.S. Market country) beyond the dates for NDA Approval set forth in the Initial U.S. Development Plan Timeline and the Initial ROW Development Plan Timeline, then if the plan is so amended, the Parties will determine in good faith negotiations whether to adjust the periods referred to in paragraphs [redacted] of the definition of Pre-Approval Failure in Section 1.82 (Pre-Approval Failure) to take account of such delay; provided, that in no event will either period be extended longer than [redacted]

2.3.5 Interim Results of [redacted] If the interim results of the [redacted] described in the Initial U.S. Development Plan lead either Party to reasonably believe that there is a substantial likelihood that the [redacted] will not [redacted] then such Party will provide written notice to the other Party of such determination and the Parties will discuss in good faith, through the GPT, whether to postpone commencement of some or all of the future Core Development Activities or Additional Development Activities pending the receipt of [redacted] (it being understood that ongoing activities will continue).

(a) If, following such GPT discussion, AstraZeneca elects to postpone commencement of some or all new Additional Development Activities, then POZEN shall not commence such new Additional Development Activities. If AstraZeneca elects to postpone commencement of new Additional Development Activities in a way that would be reasonably likely to delay Development of the Initial POZEN Product, POZEN may postpone commencement of some or all of the new Core Development Activities for the same period that AstraZeneca postpones commencement of such new Additional Development Activities, subject to POZEN's using Diligent Efforts to commence such new Core Development Activities as soon as reasonably practicable at the end of such suspension period. Notwithstanding anything to the contrary herein, any delays in obtaining NDA Approval of the Initial POZEN Product resulting from such postponement of Additional Development Activities or Core Development Activities shall not be counted in determining whether the time period in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) has been exceeded

(b) If, following such GPT discussion, AstraZeneca desires to postpone commencement of new Additional Development Activities and POZEN does not agree to such postponement, then POZEN in its sole discretion may continue performing the applicable Additional Development Activities at its own expense.

(c) In any event, if [redacted] indicates that [redacted] then unless AstraZeneca terminates this Agreement on account of a Pre-Approval Failure described in Section 1.82(c), (i) the Parties will commence the performance of the postponed Additional Development Activities and Core Development Activities in accordance with the applicable development plans, and (ii) with respect to any Additional Development Activities performed by POZEN pursuant to the preceding clause (b) during the interim period, AstraZeneca will reimburse POZEN for all costs of performing such activities under the terms of Section 3.3.3 (Expenses). In any event, AstraZeneca will reimburse POZEN for any reasonable cancellation or suspension fees paid by POZEN in connection with the postponement of Additional Development Activities contemplated by this Section 2.3.5.

2.3.6 Limitation. Notwithstanding this Section 2.3 (Decision-Making), any dispute regarding the interpretation of this Agreement, the performance or alleged nonperformance of a Party's obligations under this Agreement, or any alleged breach of this Agreement will be resolved in accordance with the terms of Section 15.4 (Governing Law; Dispute Resolution).

3. PRODUCT DEVELOPMENT

3.1 Development Plans.

3.1.1 U.S. Development Plan. The Development of Initial POZEN Product under this Agreement for U.S. Marketing Approval will be governed by the U.S. Development Plan and the U.S. Development Plan Timeline. As promptly as practicable following the Effective Date, the GPT will update the U.S. Development Plan in a manner that is consistent with the Initial U.S. Development Plan and the Initial U.S. Development Plan Timeline. Subject to Section 2.3.3 (Dispute Resolution), from time to time during the Term, the GPT will update the U.S. Development Plan as it deems necessary and appropriate. The U.S. Development Plan will be part of this Agreement and incorporated herein by reference.

3.1.2 ROW Development Plan. The Development of Initial POZEN Product under this Agreement for Marketing Approval outside the U.S. will be governed by the ROW Development Plan and the ROW Development Plan Timeline. As promptly as practicable following the Effective Date, the GPT will update the ROW Development Plan in a manner that is consistent with the Initial ROW Development Plan and the Initial ROW Development Plan Timeline. The ROW Development Plan will be part of this Agreement and incorporated herein by reference. Subject to Section 2.3.3 (Dispute Resolution), from time to time during the Term, the GPT will update the ROW Development Plan as it deems necessary and appropriate.

3.1.3 TPP Endpoints. The Parties acknowledge that a primary goal of Development efforts under this Agreement is to generate data that will enable AstraZeneca to promote the Initial POZEN Product on the basis of the TPP Endpoints. Accordingly, the Parties agree, subject to Section 3.3 (Additional Development Activities), to use Diligent Efforts to conduct Additional Development Activities directed to achievement of the TPP Endpoints, to include the data from the TPP Studies in the NDA (subject to the terms of Section 4.1.1 (In the U.S.)), and to obtain approval of such Product Labeling as may be necessary for the promotion of the Initial POZEN Product in the U.S. on the basis of the TPP Endpoints (subject to the terms of Section 4.3.3 (Label Negotiations and Approval)).

3.2 Core Development Activities.

3.2.1 Performance. POZEN will use Diligent Efforts to perform the Core Development Activities.

3.2.2 Records and Reports. POZEN will retain all records required by Applicable Law to be maintained in connection with its obligations under Section 3.2.1 (Performance) pursuant to the U.S. Development Plan. POZEN will provide written reports to the GPT on its activities in conjunction with regularly scheduled meetings of the GPT, at a level of detail reasonably sufficient to enable AstraZeneca to monitor POZEN's compliance with its obligation pursuant to this Agreement. Moreover, AstraZeneca shall have the right to audit the facility and records of POZEN and each contract research organization and other vendors employed by POZEN to conduct Development of the Initial POZEN Product in accordance with the terms of Section 3.7 (Audits and Inspections).

3.2.3 Expenses. POZEN will bear the expenses for the Core Development Activities.

3.2.4 Diligence. POZEN will use Diligent Efforts to conduct all Development activities under this Section 3.2 (Core Development Activities) in a good scientific manner and in compliance in all material respects with all Applicable Laws (including cGCP, cGLP and cGMP) and to adhere to the Initial Development Plan Timeline. All efforts of POZEN's Affiliates, Third Party contractors and sublicensees will be considered efforts of POZEN for the purpose of determining compliance with its obligations under this Section 3.2.4 (Diligence).

3.3 Additional Development Activities.

3.3.1 Performance. POZEN shall perform all Additional Development Activities that are identified in Exhibit B and Exhibit D as being POZEN's responsibility and all Additional Development Activities required to obtain NDA Approval of the Initial POZEN Product in the U.S. and EU, at AstraZeneca's expense, subject to Section 3.3.3 (Expenses) below. The GPT will allocate between the Parties the responsibility for the performance of other Additional Development Activities; provided, that each Party will have the right to consent to such activities as may be allocated to it. Each Party hereby agrees to perform such Additional Development Activities as may be allocated to such Party by the GPT.

3.3.2 Records and Reports. Each Party will retain all records required by Applicable Law to be maintained in connection with such Party's performance of Development Activities. Each Party will provide written reports to the GPT on such activities with the Initial POZEN Product, in conjunction with regularly scheduled meetings of the GPT, at a level of detail reasonably sufficient to enable the other Party to determine the reporting Party's compliance with its obligations pursuant to this Agreement, including Section 3.3.1 (Performance) and 3.3.4 (Diligence).

3.3.3 Expenses. Within [redacted] after the Effective Date, POZEN shall develop a schedule of expected activities and related costs for Additional Development Activities to be conducted by POZEN. This schedule will describe in reasonable detail the expected activities to be performed and will contain sufficient detail on both Direct Costs to be incurred with Third Parties and FTE Costs to be incurred by POZEN, as well as estimated timings of such costs. The GPT will review this schedule and approve a budget for the Additional Development Activities conducted by POZEN after the Execution Date (the **"ADA Budget"**). By [redacted] of each calendar year, beginning 2007, POZEN shall provide the GPT with an update of the ADA Budget for the subsequent calendar year for the review and approval of the GPT, such update to take effect once approved, beginning [redacted] of such subsequent year. The GPT will reasonably consider each such proposed ADA Budget and may withhold its approval of any proposed ADA Budget (including all updates thereof) only if the budget is not reasonable in light of prevalent market conditions for similar work or is not consistent with POZEN's expenditures on Core Development Activities to the extent the activities are comparable. In addition to this annual process, the GPT may also periodically review and amend the ADA Budget as appropriate in light of approved changes to the Additional Development Activities allocated to POZEN (including upon finalization of the scope of [redacted]) consistent with the above principles. POZEN will calculate and maintain records of all Direct Costs and FTE Costs incurred by POZEN in performing Additional Development Activities, in accordance with POZEN's internal accounting policies. Within [redacted] after the end of each calendar month during which POZEN incurs Direct Costs or FTE Costs in performing the

Additional Development Activities, POZEN will submit to AstraZeneca a written invoice setting forth in reasonable detail the Direct Costs and FTE Costs it has incurred in performing the Additional Development Activities. AstraZeneca will pay POZEN within [redacted] following the receipt of the invoice for Direct Costs and FTE Costs that do not exceed the then-current ADA Budget by more than [redacted] provided, that the GPT will approve variances above [redacted] if and to the extent the variances are (a) reasonable in light of prevalent market conditions for similar work and consistent with POZEN's expenditures on Core Development Activities to the extent the activities are comparable, or (b) beyond POZEN's reasonable control. Any payments made pursuant to this Section 3.3.3 (Expenses) will be subject to the general payment procedures set forth in Sections 8.5 through 8.7, inclusive. POZEN will inform the GPT at least [redacted] prior to incurring any Direct Costs or FTE Costs that exceed the then-current ADA Budget by more than [redacted] AstraZeneca shall not be held responsible for any expenditure relating to the Additional Development Activities incurred by POZEN that exceeds the then-current ADA Budget by more than [redacted] unless such expenditure has been specifically approved by the GPT as an exception to the ADA Budget in accordance with this Section 3.3.3 (Expenses). For clarity, the terms of this Section 3.3.3 will apply with respect to any Additional Development Activities commenced by POZEN after the Execution Date.

3.3.4 Diligence. Each Party will use Diligent Efforts to conduct the Additional Development Activities allocated to it in a good scientific manner and in compliance in all material respects with all Applicable Laws (including cGCP, cGLP and cGMP) and to adhere to the Initial U.S. Development Plan Timeline. All efforts of a Party's Affiliates and Third Party contractors will be considered efforts of such Party for the purpose of determining compliance with its obligations under this Section 3.3.4 (Diligence). Without limiting the foregoing general obligation, each Party will use Diligent Efforts to perform the Additional Development Activities in accordance with the U.S. Development Plan Timeline and the ROW Development Plan Timeline.

3.4 Development of Products by AstraZeneca.

3.4.1 General Principles. In addition to the Development of the Initial POZEN Product pursuant to Section 3.3 (Additional Development Activities) above, AstraZeneca will have the right to Develop and Commercialize other Products during the Term in each country of the Territory, for so long as AstraZeneca is using Diligent Efforts to Develop and Commercialize at least one POZEN Product in accordance with the terms and conditions of this Agreement, it being understood that the Parties intend for AstraZeneca to focus its initial efforts on the Development and Commercialization of the Initial POZEN Product.

3.4.2 Substitution.

(a) Upon Certain Pre-Approval Failures. If a Pre-Approval Failure of the Initial POZEN Product described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs in the U.S. (it being understood that the failure described in paragraph [redacted] will not be deemed to have occurred until expiration of the nine [redacted] period described in Section [redacted]) and AstraZeneca provides POZEN with a written notice of its election to discontinue the Development of such product and to substitute another POZEN Product, without prejudicing

AstraZeneca's right to terminate this Agreement under Section 12.4.1, then AstraZeneca will have the option, in its sole discretion, to identify a POZEN Product as a replacement for the Initial POZEN Product within [redacted] of the occurrence of such Pre-Approval Failure. If AstraZeneca elects to make such a replacement, then AstraZeneca will consult in good faith with POZEN regarding the identification of such substitute POZEN Product and shall designate such substitute in writing to POZEN; provided, that as of the time of such election, [redacted] of such [redacted] must be [redacted]. Such substitution shall be effective immediately upon AstraZeneca's designation of the replacement POZEN Product.

(b) Otherwise. If circumstances occur which [redacted] and AstraZeneca wishes to discontinue the Development of the Initial POZEN Product, then AstraZeneca may identify a different POZEN Product to replace the Initial POZEN Product, either throughout the Territory or in one or more countries of the Territory, by written notice to POZEN of such election; provided, that as of the time of such election [redacted] AstraZeneca will consult in good faith with POZEN regarding the identification of such proposed substitute POZEN Product, and POZEN shall either approve or disapprove the identification of such proposed substitute Initial POZEN Product within [redacted] of AstraZeneca's providing POZEN with such notice, such approval not to be unreasonably withheld, conditioned or delayed. If POZEN approves the identification of the substitute Initial POZEN Product, then the Parties shall negotiate to agree upon the applicable development plan for such proposed substitute Initial POZEN Product in accordance with Section 3.4.2(c) (Effects of Election), and such substitution shall not become effective until the Parties have agreed upon such revised development plan pursuant to Section 3.4.2(c).

(c) Effects of Election. In the event of any proposed Product substitution pursuant to this Section 3.4.2, AstraZeneca will prepare and submit to POZEN a new U.S. Development Plan and ROW Development Plan, as applicable, for the applicable replacement Initial POZEN Product within [redacted] following the election of such replacement, and the Parties will use good faith efforts to agree upon such plan.

(i) If the Parties, despite the use of good faith efforts, fail to agree upon a new U.S. Development Plan and/or ROW Development Plan, as applicable, for a substitute Initial POZEN Product, then (1) if such substitution was made pursuant to Section 3.4.2(a) above, then such failure will be subject to the applicable dispute resolution procedures set forth in this Agreement, or (2) if such substitution was made pursuant to Section 3.4.2(b) above, then, notwithstanding anything to the contrary herein, the proposed substitution shall not be effective and AstraZeneca may not proceed with the Development of the substitute Initial POZEN Product.

(ii) If the Parties agree upon a new U.S. Development Plan and/or ROW Development Plan, as applicable, for a substitute Initial POZEN Product, any such development plan must provide for a proof of concept study with mutually agreed endpoints. Furthermore, any such U.S. Development Plan and/or ROW Development Plan shall provide that

if such proof of concept study fails to meet its mutually agreed endpoints, then AstraZeneca shall have the right, at its option, to terminate this Agreement without penalty either in its entirety or with respect to the territory of such substitute Initial POZEN Product; provided, that written notice of termination must be delivered to POZEN within [redacted] following the receipt of the final clinical study report for such proof of concept study. For the purposes of this Section 3.4.2(c)(ii), a "proof of concept" study is a study that provides clinical confirmation that the substitute Initial POZEN Product possesses a desired pharmacological effect in patients, and is typically a positive placebo-controlled study or dose-response study using a validated surrogate variable or the final clinical outcome variable.

(d) Effects of Substitution. Upon the effectiveness of a substitution pursuant to this Section 3.4.2, the applicable replacement POZEN Product shall be deemed the "Initial POZEN Product" in the Territory or such country(ies), as applicable, for all purposes under this Agreement; provided, however if the market opportunity and timing of NDA Approval for the POZEN Product that is substituted for the original Initial POZEN Product is not substantially equivalent, the Parties shall meet and negotiate in good faith to adjust milestone payments that would be due with respect to such replacement Initial POZEN Product under Section 8.2 (Development Milestone Payments) in a manner that reflects the commercial opportunity for such replacement Initial POZEN Product and the Parties' relative contribution to the Development of the replacement POZEN Product.

3.5 Oversight of Proof of Concept Studies. Without limiting the generality of POZEN's obligations with respect to Additional Development Activities generally, POZEN shall conduct the Proof of Concept Studies, including design, execution and analysis to AstraZeneca's reasonable satisfaction. Without limiting the foregoing, POZEN will consult with AstraZeneca with respect to the foregoing activities and will give reasonable consideration to and use Diligent Efforts to give effect to AstraZeneca's comments with respect thereto. POZEN will provide AstraZeneca with copies of all data from the Proof of Concept Studies and all draft reports for such studies as the data and draft reports become available. The clinical study reports for the Proof of Concept Studies are subject to review and comment by AstraZeneca; provided, that [redacted] such study reports will not affect either Party's rights under this Agreement. AstraZeneca shall be permitted to reasonably participate in POZEN's study team meetings and receive communications from the POZEN study team as reasonably necessary to keep AstraZeneca informed regarding the conduct of the Proof of Concept Studies.

3.6 Exchange of Know-How. In addition to the periodic reports provided to the other Party pursuant to Section 3.2.2 (Records and Reports), each Party will provide to the other Party copies of any Know-How in its possession relating to the Initial POZEN Product, including, without limitation, procedures, formulations, manufacturing reports, pre-clinical and clinical protocols and data, regulatory filings, and toxicology reports with respect to the Initial POZEN Product, including any final versions of any study reports and any drafts then-outstanding of any study reports, all to the extent reasonably required for the requesting Party to perform its obligations under this Agreement.

3.7 Audits and Inspections.

3.7.1 Audits. At all times that POZEN is participating in the Development of the Initial POZEN Product, a delegation consisting of a reasonable number of representatives of AstraZeneca (or its Third Party contractors reasonably acceptable to POZEN) will have the right to inspect and audit any POZEN facility and the facilities of Third Party contractors and Affiliates of POZEN where the Development is being conducted and the documentation generated in connection with the Development of the Initial POZEN Product. Such inspections will take place no more than [redacted] per site during any calendar year, and will be conducted during regular business hours and after at [redacted] prior notice to POZEN. However, any such inspections that are made for cause in response to a failure or deficiency at the applicable site will not count toward such annual limit. AstraZeneca will discuss the results of any inspection with POZEN. Any inspection by or on behalf of AstraZeneca, if it occurs, does not relieve POZEN of its obligation to comply with all Applicable Laws and does not constitute a waiver of any right otherwise available to AstraZeneca.

3.7.2 Inspections. POZEN will notify AstraZeneca promptly following notice from the FDA or any Regulatory Authority of a visit to any POZEN facility and the facilities of Third Party contractors and Affiliates of POZEN wherein the Development of the Initial POZEN Product is conducted. A representative of AstraZeneca (or its Third Party contractor reasonably acceptable to POZEN) will have the right to be present as a silent observer at any announced visits to POZEN's facility and the facilities of Third Party contractors (to the extent POZEN is entitled to attend such visits) and Affiliates of POZEN by any Regulatory Authority relating to the Development of the Initial POZEN Product. Furthermore, POZEN will inform AstraZeneca of the results of any inspection by a Regulatory Authority that does or could reasonably be expected to affect the Development of the Initial POZEN Product. POZEN will promptly provide AstraZeneca with copies of notifications from any Regulatory Authority (including, without limitation, any Form No. 483 notification, Enforcement Inspection Reports, Notice of Adverse Finding, etc.). AstraZeneca will treat all information subject to review under this Section 3.7.2 (Inspections) in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party auditor retained by AstraZeneca (and reasonably acceptable to POZEN) to enter into a reasonably acceptable confidentiality agreement with POZEN obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

4. REGULATORY MATTERS

4.1 Responsibilities; Diligence.

4.1.1 In the U.S. Subject to Section 2.3.3 (Dispute Resolution), POZEN will be responsible, at its sole expense, for preparing and filing the NDA and seeking NDA Approval for the Initial POZEN Product as outlined in the U.S. Development Plan, including preparing all reports and other documents necessary as part of any IND or NDA; provided, that each Party will be responsible for preparing reports for studies or activities for which it has responsibility in accordance with Articles 3 and 6. The initial NDA submission for the Initial POZEN Product shall [redacted], and POZEN shall not, without AstraZeneca's prior written consent (but subject in any event to Applicable Law), submit the initial NDA for the Initial POZEN Product [redacted] Such NDA will be filed in the name of POZEN. POZEN will provide all filings (including the NDA) to AstraZeneca for

review and comment prior to their submission to the FDA. Each Party will conduct the Development activities in accordance with the agreed U.S. Development Plan. Subject to Section 2.3.3 (Dispute Resolution), each Party will use Diligent Efforts to obtain NDA Approval of the Initial POZEN Product in the U.S. AstraZeneca shall have the right at its own expense to seek any Marketing Approval in the U.S. for claims not obtained in the initial U.S. NDA Approval for POZEN Products. Within [redacted] following receipt of NDA Approval for the Initial POZEN Product in the United States and POZEN's receipt of the milestone payment set forth in item 4 of the table in Section 8.2, POZEN will transfer and assign, without additional compensation, corresponding Regulatory Materials (including the relevant NDA) to AstraZeneca. During the period between [redacted] As owner of the NDA, AstraZeneca will be the sole owner of all data exclusivity protection related to the Initial POZEN Product as provided by Applicable Law. The GPT will allocate responsibility for preparing the "Chemistry and Manufacturing Controls" ("CMC") section for the NDA for the Initial POZEN Product, as commercially reasonable. POZEN's Direct Costs and FTE Costs of preparing the CMC section of such NDA shall be included in the Formulation Budget established pursuant to Section 6.1.4 (Expenses).

4.1.2 Outside the U.S. AstraZeneca will be responsible at AstraZeneca's expense, but other than as set forth in this Agreement, shall not be obligated to, prepare and file INDs and NDAs and seek NDA Approvals for the Initial POZEN Product in all countries in the Territory other than the U.S., including preparing all reports necessary as part of any such IND or NDA. All such INDs and NDAs will be filed in the name of AstraZeneca. AstraZeneca will use Diligent Efforts to obtain Marketing Approval of the Initial POZEN Product in each Major Ex-U.S. Market country. However, AstraZeneca shall not be required to Develop or Commercialize a POZEN Product in a particular Major Ex-U.S. Market country if it is not commercially reasonable to do so consistent with the exercise of Diligent Efforts and, upon POZEN's request, will provide POZEN data supporting such determination. AstraZeneca will have the right in its sole discretion, at any time upon [redacted] prior written notice to POZEN, to replace any country in the Major Ex-U.S. Market with any other country or group of countries having a market potential of at least [redacted] of the market potential of the relevant Major Ex-U.S. Market country based on the then-current IMS MAT (Moving Annual Total) Data for sales of [redacted] drugs in such Major Ex-U.S. Market country as compared to sales of [redacted] drugs in such other country or group of countries, and AstraZeneca's diligence requirements hereunder shall accordingly transfer from such initial Major Ex-U.S. Market country to the replacement country or countries. Schedule 4.1.2 sets forth IMS MAT Data that is current as of December 2005. Based on such data, by way of example, if AstraZeneca desired to elect one or more countries to replace [redacted] as a Major Ex-U.S. Market country (having [redacted] in sales), any of the following countries or combinations of countries would be acceptable substitutes: [redacted]

4.1.3 Core Development Activities Failure. Without limiting any right or remedy that AstraZeneca may have under this Agreement or otherwise, if a dispute arises regarding POZEN's cessation of Core Development Activities and pursuant to the dispute

resolution procedures described in Section 15.4 a court of competent jurisdiction makes a determination (whether in a preliminary or final order) that POZEN has materially breached its obligation to perform the Core Development Activities and that such material breach has not been cured within [redacted] of POZEN receiving notice of such breach, then, if requested by AstraZeneca in writing, POZEN shall do the following:

(a) to the extent permitted by Applicable Law, transfer and assign to AstraZeneca all Regulatory Materials, including any IND or NDA, for any POZEN Product that are Controlled by POZEN;

(b) transfer to AstraZeneca or its designee the management and continued performance of any clinical trials for any POZEN Product ongoing as of the effective date of such request, which clinical trials will be conducted at AstraZeneca's expense after such transfer; and

(c) for a reasonable period of time, provide such assistance, at AstraZeneca's cost, to transfer or transition to AstraZeneca all then-existing Third Party contracts (to the extent transferable in accordance with the terms and conditions thereof) as may be reasonably necessary or useful for AstraZeneca to conduct the Core Development Activities and Additional Development Activities, to the extent POZEN is then performing or having performed such activities (including without limitation transferring, upon request of AstraZeneca, any relevant agreements with Third Party contractors, to the extent such agreements are transferable in accordance with their terms and conditions). POZEN shall use Diligent Efforts to cause all contracts that it enters into after the Execution Date related to the Development of the Initial POZEN Product to be assignable to AstraZeneca as contemplated by this paragraph.

4.2 Access to Filings. Each Party will permit the other Party access to, and the right to reference and use (including by providing a letter of authorization to the applicable Regulatory Authorities), all data, regulatory filings and regulatory communications associated with any submissions for NDA Approval of the Initial POZEN Product for the purpose of seeking NDA Approval of the Initial POZEN Product, in accordance with Section 4.1 (Responsibilities; Diligence). AstraZeneca and its Affiliates will have the right of cross-reference to all NDAs or other filings made by or on behalf of POZEN for the purpose of prosecuting Marketing Approval applications for Products, and POZEN and its Affiliates will, or will use reasonable efforts to cause their licensees to, take all such reasonable actions to allow such cross-reference.

4.3 Interactions with Regulatory Authorities.

4.3.1 Consultation. Each Party will consult with the other Party regarding (and provide copies of materials prior to any submission to a Regulatory Authority and materials after receipt from a Regulatory Authority), and keep such other Party reasonably and regularly informed of, the status of the preparation of all Regulatory Materials, review of such materials by the relevant Regulatory Authority, and Marketing Approvals received for the Initial POZEN Product.

4.3.2 Communications. Except as may be required by Applicable Law and

subject to Section 2.3.3 (Dispute Resolution), only the Party responsible for the preparation of Regulatory Materials in a particular country or territory will communicate regarding the Initial POZEN Product with any Regulatory Authority having jurisdiction in such country or territory; provided, that if POZEN is required by Applicable Law to provide to a Regulatory Authority any communication that relates to [redacted] provided, that this sentence shall not be construed to obligate POZEN to take any action or make any omission in violation of Applicable Law. If POZEN is required to make such a communication by a Regulatory Authority, then POZEN [redacted] During the period which the Regulatory Materials for the Initial POZEN Product are under POZEN's name, AstraZeneca will provide copies of all ex-US correspondence regarding such Initial POZEN Product with Regulatory Authorities to POZEN, and POZEN will provide copies of all U.S. correspondence regarding such Initial POZEN Product to AstraZeneca. In addition, during such period, POZEN shall not submit any substantive correspondence or communication to the FDA that is material to the NDA of the Initial POZEN Product without prior review by and consultation with AstraZeneca, and POZEN shall provide AstraZeneca with copies of all other correspondence.

4.3.3 Label Negotiations and Approval. Notwithstanding anything in this Agreement to the contrary, POZEN shall not submit to the FDA any draft label, revised draft label, or correspondence regarding the label of the Initial POZEN Product without AstraZeneca's prior written review and consent, which shall not be unreasonably withheld, conditioned or delayed. AstraZeneca will review and provide POZEN with a response on all draft labels and revised draft labels proposed for submission to the FDA, and on draft correspondence with the FDA, as promptly as reasonably practicable and in any event will use Diligent Efforts to approve labeling proposed by the FDA for the Initial POZEN Product within [redacted] after the PDUFA Date. In the event that the U.S. label for the Initial POZEN Product is not approved by AstraZeneca within [redacted] period shall not be counted in determining whether the time period in paragraph [redacted] of Section 1.82 (the definition of Pre-Approval Failure) has been exceeded.

4.3.4 Meetings. Prior to the first NDA Approval, each Party responsible for the preparation of Regulatory Materials for the Initial POZEN Product in a particular country will request the applicable Regulatory Authority in such country to allow a reasonable number of the other Party's representatives to attend and, to the extent permitted under Applicable Law, participate in all meetings and telephone conferences between the responsible Party and such Regulatory Authority in respect of any Regulatory Materials. The responsible Party shall inform the other Party of any such meetings and telephone conferences scheduled with any such Regulatory Authority in respect of any Regulatory Materials as soon as practically possible. Each Party will bear its own expenses in attending or otherwise participating in any meetings and conferences pursuant to this Section.

4.4 Information Sharing. Each Party will provide the other Party, in a timely manner, with copies of, and all information received by it pertaining to, notices, questions, actions and requests from or by Regulatory Authorities with respect to the Initial POZEN

Product, or the testing, Manufacture, packaging, distribution or facilities in relation thereto, including any notices of non-compliance with laws in connection with the Initial POZEN Product (*e.g.*, warning letters or other notices of alleged non-compliance), audit notices, notices of initiation by Regulatory Authorities of investigations, inspections, detentions, seizures or injunctions concerning the Initial POZEN Product (or its manufacture, distribution, or facilities connected thereto), notice of violation letters (*i.e.*, an untitled letter), warning letters, service of process or other inquiries. Except as otherwise set forth in this Agreement or as reasonably necessary for POZEN to perform its Development obligations hereunder or to comply with Applicable Law, [redacted]

4.5 Regulatory Audits. If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility, or a facility under contract with a Party, with regard to a POZEN Product, then such Party will promptly notify the other Party and permit and cooperate with such inspection or audit, and will cause the contract facility to permit and cooperate with such Regulatory Authority and such other Party during such inspection or audit. Such other Party will have the right upon request (which request shall not be unreasonably withheld) to have a representative observe such inspection or audit; provided, that POZEN'S rights of observance under this Section will end upon the transfer of the U.S. NDA for the Initial POZEN Product to AstraZeneca. Following receipt of the inspection or audit observations of such Regulatory Authority (a copy of which the audited Party will immediately provide to the other Party), the audited Party will prepare the response to any such observations, and will provide a copy of such response to the other Party. The audited Party agrees to conform its activities under this Agreement to any commitments made in such a response, except to the extent it believes in good faith that such commitments violate Applicable Laws.

4.6 Adverse Event Reporting. Within [redacted] after the Effective Date, the Parties will enter into an Adverse Event Reporting Agreement, which upon such execution will be attached as an exhibit hereto and hereby incorporated into this Agreement by reference (the **"AE Agreement"**), governing the Parties' respective adverse event reporting and global safety database maintenance obligations. Without limiting the generality of the AE Agreement, the Parties hereby agree as follows:

4.6.1 Until POZEN transfers the approved US NDA to AstraZeneca, POZEN will be solely responsible for reporting all Adverse Events (AEs) and Serious Adverse Events (SAEs) associated with the Initial POZEN Product from any source (including AEs and SAEs from AstraZeneca sponsored studies) to the FDA and any other Regulatory Authority outside the U.S. as required by Applicable Laws. In addition, prior to such transfer of the U.S. NDA, POZEN shall report to AstraZeneca all AEs and SAEs of which POZEN becomes aware within the timelines specified in the AE Agreement to the extent necessary to enable AstraZeneca to comply with its reporting obligations outside the U.S., and AstraZeneca shall report to POZEN all AEs and SAEs of which AstraZeneca becomes aware within the timelines specified in the AE Agreement to the extent necessary to enable POZEN to comply with its reporting obligations in the U.S., each as more fully described in the AE Agreement. Notwithstanding the foregoing, if [redacted]

[redacted]

4.6.2 All AE and SAE reports will be exchanged using either approved study forms, electronic, or computer generated reports agreed upon by both parties (*e.g.*, CIOMS I form).

4.6.3 Subject to Section 4.6.1, AstraZeneca will maintain and will be the recognized holder of a global safety database for AE and SAE reports related to POZEN Products received by either Party. Direct access to this database will not be granted to POZEN. Upon request, all reasonable assistance will be provided by either Party in responding to safety inquiries.

4.6.4 Each Party shall keep the other Party informed of notification of any action by, or notification or other information which it receives (directly or indirectly) from any Regulatory Authority which: (i) raises any material concerns regarding the safety or efficacy of the Initial POZEN Product; (ii) indicates or suggests a potential material liability for either Party to Third Parties arising in connection with the Initial POZEN Product; (iii) is reasonably likely to lead to a "Dear Doctor" letter, recall or market withdrawal of the Initial POZEN Product; (iv) relates to the Initial POZEN Product, Regulatory Materials, Promotional Materials, samples, package inserts, the indications, labeling, expedited and periodic Adverse Event Reports, medical inquiries, Initial POZEN Product complaints, this Agreement, or (v) is otherwise important to the Development and/or Commercialization of the Initial POZEN Product.

5. COMMERCIALIZATION

5.1 Commercialization. As between the Parties, AstraZeneca will be solely responsible for the Commercialization of POZEN Products during the Term.

5.2 Regulatory Obligations during Commercialization. On a country-by-country basis, AstraZeneca will own and maintain all regulatory filings and Marketing Approvals for POZEN Products developed pursuant to this Agreement, including all INDs and NDAs for the Initial POZEN Product following POZEN's transfer of such filings and approvals subsequent to NDA Approval of the Initial POZEN Product in the U.S. As between the Parties, but subject to [redacted], AstraZeneca will be solely responsible for all activities in connection with maintaining Marketing Approvals required for the Commercialization and manufacture of POZEN Products, including communicating and preparing and filing all reports (including Adverse Event reports) with the applicable Regulatory Authorities.

5.3 Performance; Diligence.

5.3.1 Level of Efforts. Upon the grant of Marketing Approval for a POZEN Product in the U.S. or a country of the Major Ex-U.S. Market, AstraZeneca will use Diligent Efforts to Commercialize a POZEN Product in such country. The foregoing Diligent Efforts requirement will apply only to one POZEN Product in each of the U.S. and the Major Ex-U.S. Market countries, irrespective of the number of POZEN Products AstraZeneca elects to Develop and Commercialize, and AstraZeneca may elect to fulfill its Diligent Efforts obligation in such

countries in respect to any POZEN Product of its choice in the exercise of its reasonable and good faith judgment.

5.3.2 Specific Timelines. AstraZeneca will use Diligent Efforts in the U.S. and in each country of the Major Ex-U.S. Market to achieve Commercial Launch within [redacted] after the date on which Marketing Approval is granted for such Initial POZEN Product in such country; provided, that for any country in which Marketing Approval is granted by Regulatory Authorities [redacted], then the obligations set forth in this Section 5.3.2 will apply only to [redacted] and provided, further, that if AstraZeneca elects to launch the Initial POZEN Product in a particular country or territory following NDA Approval in such country or territory, but before or without obtaining pricing or reimbursement approval therein, then the [redacted] period set forth in this Section 5.3.2 will commence as of the date of such NDA Approval.

5.4 Commercialization Plan.

5.4.1 AstraZeneca shall prepare and update from time to time an initial commercialization plan summarizing the plan for Commercializing the Initial POZEN Product in the U.S. and the Major Ex-U.S. Markets (the "**Commercialization Plan**") within [redacted] after U.S. NDA filing for the Initial POZEN Product and the first filing of a Marketing Approval application for the Initial POZEN Product in a country of the Major Ex-U.S. Markets, respectively. The Commercialization Plan as reviewed by the GPT shall describe the overall plan for Commercializing the Initial POZEN Product during the first three years after First Commercial Sale of the Initial POZEN Product in the U.S. and the Major Ex-U.S. Market.

5.4.2 The Commercialization Plan will be in a format consistent with the format of similar plans prepared by AstraZeneca for its other products.

5.5 Threatened Removal. In the event that any governmental authority threatens or initiates any action to remove any POZEN Product from the market in a country or territory, AstraZeneca will promptly notify POZEN of such communication. Any voluntary recall or withdrawal of any POZEN Product will be at AstraZeneca's sole discretion and expense. Before AstraZeneca initiates a recall or withdrawal, the Parties will promptly and in good faith discuss the reasons therefor; provided, that such discussions do not delay the recall or withdrawal. In the event of any recall or withdrawal for any POZEN Product, AstraZeneca will implement any necessary action, with assistance from POZEN as reasonably requested by AstraZeneca.

5.6 Compliance. Each Party will comply with all Applicable Laws relating to activities performed or to be performed by such Party (or its Affiliates or contractors) under or in relation to the Commercialization of the Initial POZEN Product pursuant to this Agreement. Each Party represents, warrants and covenants to the other Party that, as of the Effective Date and during the Term, such Party and its Affiliates have adequate policies and procedures in place: (i) to ensure their compliance with such laws; (ii) to bring any non-compliance therewith by any of the foregoing entities to its attention; and (iii) to promptly remedy any such non-compliance.

5.7 Branding; Trademarks; Domain Names; Trade Dress; Logos.

5.7.1 Responsibilities. AstraZeneca will select all Product Trademarks for use on or in connection with POZEN Products, will be the sole owner of the Product Trademarks, will be responsible for the filing, prosecution, maintenance and defense of all registrations of the Product Trademarks, and will be responsible for the payment of any costs relating to filing, prosecution, maintenance and defense of the Product Trademarks.

5.7.2 Use. AstraZeneca will use the Product Trademarks in connection with the Commercialization of POZEN Products hereunder. The packaging, Promotional Materials and Product Labeling for POZEN Products will carry the POZEN House Marks only if and to the extent required by Applicable Law in a country or territory.

5.7.3 AstraZeneca Marks. AstraZeneca reserves all rights in the Product Trademarks and AstraZeneca House Marks. POZEN acknowledges AstraZeneca's exclusive right, title and interest in and to such trademarks and acknowledges that nothing herein will be construed to accord to POZEN any rights in such trademarks. POZEN agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any Product Trademarks or AstraZeneca House Mark.

5.7.4 POZEN Marks. POZEN reserves all rights in the POZEN House Marks not expressly granted to AstraZeneca in this Agreement. AstraZeneca acknowledges POZEN's exclusive right, title and interest in and to the POZEN House Marks and acknowledges that nothing herein will be construed to accord to AstraZeneca any rights in such trademarks except as expressly provided herein. AstraZeneca further acknowledges that its use of the POZEN House Marks will not create in AstraZeneca any right, title or interest in such trademarks, and that all use of such trademarks and the goodwill generated thereby will inure solely to the benefit of POZEN. AstraZeneca agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any POZEN House Mark.

5.7.5 Promotional Materials. AstraZeneca will own all right, title and interest in and to any Promotional Materials created by or on behalf of AstraZeneca (or its Affiliates) relating to POZEN Product, but excluding the POZEN House Marks. The GPT will approve a standard template for use of the POZEN House Marks in Promotional Materials, and AstraZeneca will use the POZEN House Marks in accordance with approved template.

6. MANUFACTURE OF POZEN PRODUCTS

6.1 Manufacturing Development.

6.1.1 Initial POZEN Product. POZEN has developed formulations for [redacted] and Manufacturing processes for bulk and finished supplies, itself and through one or more Third Party contract manufacturers. [redacted] after the Effective Date, AstraZeneca will provide the Esomeprazole Materials (as defined below) to POZEN. POZEN shall, no later than [redacted] after the date that POZEN receives the Esomeprazole Materials (as defined below), develop (itself and through one or more Third Party contract manufacturers) a formulation and a manufacturing process (and related testing procedures) for the Initial POZEN Product meeting the specifications set forth in

Schedule 6.1 (the "**Specifications**") and sufficient quantities of the Initial POZEN Product meeting the Specifications as reasonably necessary to conduct the [redacted] studies described in the Initial U.S. Development Plan. However, AstraZeneca will be responsible for supplying to POZEN or its designee [redacted] as a separate component that will be used for the [redacted] described in the Initial U.S. Development Plan, and POZEN will supply [redacted] for such study. As used herein, **"Esomeprazole Materials"** means sufficient quantities of Esomeprazole substance for POZEN to perform the activities described in Sections 6.1.1 and 6.1.2 as well as the [redacted] studies designated as [redacted], including a certificate of analysis, ID test method for esomeprazole, reference standard for esomeprazole, cleaning method for esomeprazole, current drug product methods for esomeprazole for assay, related substances and dissolution (*i.e.*, chromatographic conditions), and esomeprazole solubility data and associated technical information.

6.1.2 ROW POZEN Products. POZEN shall develop (itself and through one or more Third Party contract manufacturers) a formulation and a manufacturing process (and related testing procedures) for each Initial POZEN Product contemplated to be developed under the Initial ROW Development Plan meeting the Specifications and shall deliver to AstraZeneca sufficient quantities of such Initial POZEN Products as reasonably necessary to conduct the [redacted] described in the Initial ROW Development Plan within the timeline for such studies set forth in the Initial ROW Development Plan Timeline.

6.1.3 Manufacturing, Cooperation, and Assistance. The manufacturing processes developed by POZEN shall be designed to be scalable for commercial manufacture of the Initial POZEN Product under the Initial U.S. Development Plan and Initial ROW Development Plan and to enable the manufacture of the Initial POZEN Product routinely and predictably in conformance with the Specification and in compliance with Applicable Law. POZEN will consult with AstraZeneca on a regular basis with respect to the development described in this Section 6.1 (Manufacturing Development) and will give reasonable consideration to AstraZeneca's suggestions. AstraZeneca will provide all reasonable assistance requested by POZEN. AstraZeneca hereby consents to POZEN's using [redacted] to perform the process development activities described in this Section 6.1 (Manufacturing Development). In furtherance of the forgoing, if POZEN does use [redacted] to perform such activities, POZEN shall enter into an agreement with [redacted] that, as between POZEN and [redacted] requires [redacted] to transfer to POZEN and gives POZEN ownership of all formulation and Manufacturing Know-How developed by [redacted] related to the Initial POZEN Product and all intellectual property rights therein.

6.1.4 Expenses. Promptly following the Execution Date and not later than the Effective Date, the Parties will agree on a schedule of expected activities and related costs for activities to be conducted by or on behalf of POZEN pursuant to Sections 6.1 and 6.2 after the Execution Date (including the Direct Costs of any inventory used in connection with such activities whether or not purchased by POZEN prior to the Execution Date) (**"Formulation Development Activities"**) and a budget for the Formulation Development Activities including both Direct Costs to be incurred with Third Parties and FTE Costs to be incurred by POZEN, as well as estimated timings of such costs (the **"Formulation Budget"**), which will be attached to

this Agreement as Exhibit A. POZEN will calculate and maintain records of all Direct Costs and FTE Costs incurred by POZEN in performing the Formulation Development Activities, in accordance with POZEN's internal accounting policies. Within [redacted] after POZEN incurs Direct Costs or FTE Costs in performing the Formulation Development Activities, POZEN will submit to AstraZeneca a written invoice setting forth in reasonable detail the Direct Costs and FTE Costs it has incurred in performing the Formulation Development Activities. AstraZeneca will pay POZEN within [redacted] following the receipt of the invoice for Direct Costs and FTE Costs that do not exceed the then-current Formulation Budget by more than [redacted] Any payments made pursuant to this Section 6.1.4 (Expenses) will be subject to the general payment procedures set forth in Section 8.5 through 8.7, inclusive. POZEN will inform the GPT at leas[redacted] prior to incurring any Direct Costs or FTE Costs that exceed the then-current Formulation Budget by more than [redacted] and the GPT will meet to consider the adjustment of such budget or approval of such variance; provided, that the GPT will approve variances above [redacted] if and to the extent the variances are (a) reasonable in light of prevalent market conditions for similar work, or (b) beyond POZEN's reasonable control. AstraZeneca shall not be held responsible for any expenditure relating to the Formulation Development Activities incurred by POZEN that exceeds the then-current Formulation Budget by more than [redacted] unless such expenditure has been specifically approved by the GPT as an exception to the Formulation Budget.

6.1.5 AstraZeneca Development of Formulation. If POZEN fails to perform its obligations under Section 6.1.1 (Initial POZEN Product) or 6.1.2 (ROW POZEN Products), within the time periods required thereby, without limiting any other rights and remedies available to AstraZeneca, unless AstraZeneca has selected a substitute Initial POZEN Product pursuant to Section 3.4.2 (Substitution) or has terminated the Agreement, then AstraZeneca shall use Diligent Efforts to develop (itself and through one or more Third Party contract manufacturers) a formulation and a manufacturing process for the Initial POZEN Product meeting the Specifications and to deliver to POZEN sufficient quantities of the Initial POZEN Product meeting the Specifications within[redacted] after AstraZeneca receives from POZEN all formulation Know-How in POZEN's possession. In such event, POZEN will provide all reasonable assistance requested by AstraZeneca in connection with such efforts. POZEN hereby consents to AstraZeneca's using [redacted] to perform the activities described in this Section 6.1.5 (AstraZeneca Development of Formulation) and consents to AstraZeneca's granting to [redacted] a sublicense of rights under the Licensed Technology to the extent reasonably necessary for [redacted] to perform such work.

6.1.6 POZEN Warranties. POZEN hereby warrants that the Initial POZEN Product provided by POZEN (itself or through one or more Third Party contractors) for use in clinical studies pursuant to Sections 6.1.1 or 6.1.2, at the time of delivery will have been manufactured and shipped in accordance with cGMP and cGLP, the IND for the Initial POZEN Product and other Applicable Law; and will not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended.

6.2 Process Transfer. Following the completion of the activities described in Section 6.1.1, POZEN will transfer all formulation and Manufacturing Know-How necessary to establish the applicable Manufacturing processes at commercial scale at a site designated by AstraZeneca (including such formulation and Manufacturing Know-How possessed by its Third

Party contractors), and will use Diligent Efforts to cause such Third Party manufacturers to allow AstraZeneca employees or agents to reasonably observe the Manufacture of the Initial POZEN Product at POZEN's subcontractor's or agent's premises and subject to any reasonable rules imposed by such Third Party. Thereafter, (i) POZEN will continue to be reasonably available, and will use reasonable efforts to cause its subcontractors and agents to be reasonably available, to AstraZeneca and will provide all reasonable assistance requested by AstraZeneca in connection with the establishment and implementation of such Manufacturing process, and (ii) AstraZeneca will use Diligent Efforts to establish commercial-scale Manufacturing processes for bulk and finished supplies of the Initial POZEN Product.

6.3 Terms for Clinical Supply.

6.3.1 Responsibility. AstraZeneca will use Diligent Efforts to conclude a supply agreement for the Initial POZEN Product with a Third Party contract manufacturer [redacted] within [redacted] after the Effective Date, under which such Third Party contract manufacturer will supply AstraZeneca Initial POZEN Product in quantities for all clinical studies [redacted] Commercial Launch, and post-launch supply until such time as AstraZeneca has, itself or through its designated contract manufacturer, successfully manufactured at commercial scale a product that meets such specifications as may be required by Applicable Law and that is bioequivalent to the Initial POZEN Product Clinical Trial Material used in the Phase III clinical studies for such Initial POZEN Product. Once POZEN has established a qualified source of Initial POZEN Product supply for the [redacted] contemplated by the Initial U.S. Development Plan and transferred the necessary formulation and Manufacturing Know-How pursuant to Section 6.2 (Process Transfer)), AstraZeneca will Manufacture and supply the Parties' entire requirements of Initial POZEN Product for the Development of the Initial POZEN Product under the U.S. Development Plan sufficient for the Parties to conduct the applicable clinical activities in accordance with the time periods set forth in U.S. Development Plan Timeline. Likewise, once POZEN has established a qualified source of the Initial POZEN Product for the [redacted] contemplated by the ROW Development Plan and transferred the necessary formulation and manufacturing Know-How pursuant to Section 6.2 (Process Transfer), AstraZeneca will Manufacture and supply (itself or through one or more Third Party contractors) the Parties' entire requirements of Initial POZEN Product for the Development of the Initial POZEN Product under the ROW Development Plan sufficient for the Parties to conduct the applicable clinical activities in accordance with the time periods set forth in ROW Development Plan Timeline. [redacted] will bear all costs and expenses incurred for any such Manufacture and supply. POZEN hereby consents to AstraZeneca's using [redacted] to Manufacture clinical supplies and commercial quantities of POZEN Products if AstraZeneca should so desire and consents to AstraZeneca's granting to [redacted] a sublicense of rights under the Licensed Technology to the extent reasonably necessary for [redacted] to perform such work.

6.3.2 Clinical Supply. Except as provided in Section 6.1 (Manufacturing Development), AstraZeneca will supply POZEN at [redacted] with Clinical Trial Materials in order for POZEN to perform clinical studies pursuant to Section 3.2 (Core Development Activities) and 3.3 (Additional Development Activities), as applicable, in accordance with a reasonable delivery schedule as the Parties may jointly agree in writing (which such schedule, in any event, will enable the completion of the applicable clinical trials in

accordance with the timelines set forth in the applicable development plan).

6.3.3 Packaging, Shipping and Delivery. AstraZeneca will fill, release, package and label such Clinical Trial Materials to be used in clinical trials conducted by POZEN pursuant to this Agreement in final bottles or blisters (or such other dose per package as agreed by the GPT) using due care and in accordance with Applicable Laws and any specifications as the Parties may agree in writing. POZEN will be responsible for identification testing, randomization and clinical patient labeling of Clinical Trial Materials supplied to POZEN by AstraZeneca in the final packaging. POZEN at [redacted] will complete such identification testing, randomization, and clinical patient labeling of Clinical Trial Materials as soon as practicable following receipt of the Clinical Trial Materials from AstraZeneca. AstraZeneca will ship the Clinical Trial Materials DDU (Incoterms 2000) to the facility in the U.S. as POZEN may designate to AstraZeneca by a common carrier designated by AstraZeneca. Each shipment will be made generally in accordance with an agreed timeline and under the terms and conditions set forth in this Section 6 (Manufacture of POZEN Product) and the U.S. Development Plan or ROW Development Plan, as applicable. Each shipment will include a certificate of analysis and any other release data customarily transferred by AstraZeneca in accordance with its usual practice. There will be a remaining shelf life for Clinical Trial Materials upon delivery that is appropriate in light of the expected schedule and duration of the clinical trial(s) in which such Clinical Trial Materials are to be used. AstraZeneca will notify POZEN of the results of ongoing stability testing of the Clinical Trial Materials by AstraZeneca.

6.3.4 Warranties. AstraZeneca hereby warrants that any Clinical Trial Materials provided by AstraZeneca to POZEN under this Agreement, at the time of delivery pursuant to Section 6.3.3 (Packaging, Shipping and Delivery): (i) will conform to the specifications for such Clinical Trial Materials, within applicable regulatory requirements, as agreed by the Parties in writing; (ii) will have been manufactured and shipped to POZEN (or its designee) in accordance with cGMP, cGLP, the IND for POZEN Product and other Applicable Laws; and (iii) will not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, as amended (collectively, the **"CTM Warranties"**).

6.3.5 Remedies for Non-Conforming Clinical Trial Materials. In the event that a shipment of Clinical Trial Materials does not conform with the CTM Warranties, in whole or in part, then AstraZeneca will promptly produce (at its cost) for POZEN sufficient quantities of Clinical Trial Materials to replace the non-conforming portion of such shipment of Clinical Trial Materials, in accordance with the provisions of this Agreement. In the event that the Clinical Trial Materials are rendered non-conforming to the CTM Warranties by the action of POZEN or its agent following delivery as provided in Section 6.3.3 (Packaging, Shipping and Delivery), then AstraZeneca will produce (at POZEN's cost) for POZEN sufficient quantities of Clinical Trial Materials to replace the non-conforming portion of such shipment of Clinical Trial Materials, in accordance with the provisions of this Agreement.

6.4 Commercial Supply. AstraZeneca will be solely responsible, [redacted] for the Manufacture and supply of AstraZeneca's entire requirements of supplies of POZEN Product for Commercialization.

6.5 Audits and Inspections.

6.5.1 Audits. At all times that AstraZeneca is supplying Clinical Trial Material to POZEN, a delegation consisting of a reasonable number of representatives of POZEN (or its Third Party contractors reasonably acceptable to AstraZeneca), no more than [redacted] per calendar year, will have the right to inspect and audit any AstraZeneca facility where the Clinical Trial Material, including their active pharmaceutical ingredients [redacted] are Manufactured, and the documentation generated in connection with the Manufacture and testing of Initial POZEN Product. However, any such inspections that are made for cause in response to a failure or deficiency at the applicable site will not count toward such annual limit. Such inspections will take place during regular business hours and after at least thirty (30) days prior notice to AstraZeneca. POZEN will discuss the results of any inspection with AstraZeneca. Any inspection by or on behalf of POZEN, if it occurs, does not relieve AstraZeneca of its obligation to comply with all Applicable Laws and does not constitute a waiver of any right otherwise available to POZEN.

6.5.2 Inspections. AstraZeneca will notify POZEN promptly following notice from the FDA or any other Regulatory Authority of a visit to any AstraZeneca facility where the Clinical Trial Material [redacted] is Manufactured. A representative of POZEN (or its Third Party contractor reasonably acceptable to AstraZeneca) may request to be present as a silent observer at any announced visits to AstraZeneca by any Regulatory Authority relating to the Manufacture of Clinical Trial Material, such request not to be unreasonably refused. Furthermore, AstraZeneca will inform POZEN of the results of any inspection by a Regulatory Authority that does or could reasonably be expected to affect the Manufacture of Clinical Trial Material [redacted] AstraZeneca will promptly provide POZEN with copies of notifications from any Regulatory Authority (including, without limitation, any Form No. 483 notification, Enforcement Inspection Reports, Notice of Adverse Finding, etc.). POZEN will treat all information subject to review under this Section 6.5.1 (Audits and Inspections) in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party auditor retained by POZEN (and reasonably acceptable to AstraZeneca) to enter into a reasonably acceptable confidentiality agreement with AstraZeneca obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

6.6 Reference Rights; Support. In connection with any supply or transfer of Clinical Trial Materials under this Section 6 (Manufacture of POZEN Product) and for so long as AstraZeneca supplies any of the foregoing to POZEN, or POZEN is using such Clinical Trial Materials pursuant to this Agreement, AstraZeneca will grant to POZEN rights of reference (including by providing a letter of authorization to the applicable Regulatory Authorities) to any AstraZeneca IND or NDA pertaining to Esomeprazole. Upon the expiration of such right, POZEN will send written notice to such effect to the applicable Regulatory Authority.

7. LICENSES

7.1 Licensed Technology. Subject to the terms and conditions of this Agreement, POZEN hereby grants to AstraZeneca an exclusive (including with regard to POZEN and its Affiliates), royalty-bearing license, with the right to grant sublicenses as described in Section 7.3 (Sublicenses), under the Licensed Technology to make, use, have made, sell, offer for sale, import, and export Products in the Field of Use in the Territory. For the avoidance of doubt, AstraZeneca shall have no license or other right under the Licensed Technology to make, use,

have made, sell, offer for sale, import, and export any product containing acetyl salicylic acid (including salts and derivatives thereof).

7.2 Trademarks. Subject to the terms and conditions set forth in this Agreement, POZEN hereby grants to AstraZeneca a license to use the POZEN House Marks in connection with the Commercialization of POZEN Products in the Field of Use in the Territory.

7.3 Sublicenses. AstraZeneca may grant a sublicense, option to sublicense, or any other right relating to any Licensed Technology to any of its Affiliates without the right to grant further sublicense rights to any Third Party. AstraZeneca may grant a sublicense, option to sublicense, or any other right relating to any Licensed Technology to any Third Party solely as provided in this Section 7.3 (Sublicenses). AstraZeneca may enter into Sublicense Agreements only with POZEN's prior consent. In order for rights under Licensed Technology to be validly granted to a Sublicensee, the Sublicense Agreement with such Sublicensee must be consistent with the following terms and conditions of this Agreement, and will include provisions for the benefit of POZEN corresponding to [redacted] AstraZeneca will use Diligent Efforts to (i) procure the performance by any Sublicensee of the terms of each such Sublicense Agreement, and (ii) ensure that any Sublicensee will comply with the applicable terms and conditions of this Agreement. AstraZeneca hereby guarantees the performance of its Affiliates and Sublicensees that are sublicensed as permitted herein, and the grant of any such sublicense will not relieve AstraZeneca of its obligations under this Agreement, except to the extent they are satisfactorily performed by such Affiliate or Sublicensee. Notwithstanding the foregoing, AstraZeneca will have the right to sell POZEN Products through any distributors or sub-distributors of its choice, without the need to obtain prior consent from POZEN, in carrying out its Commercialization activities under this Agreement.

7.4 Reservation of Rights; No Implied Licenses. POZEN retains rights under the Licensed Technology to the extent necessary to perform its obligations under this Agreement. Except for the rights specifically granted in this Agreement, POZEN reserves all rights to the Licensed Technology. No implied licenses are granted under this Agreement. In particular POZEN is not by this Agreement, by implication or otherwise, granted any license or other right relating to Esomeprazole, Nexium or the Nexium Business or any Esomeprazole based products or any products containing acetyl salicylic acid (including salts and derivatives thereof) or any right in relation to any patent, trademark or other intellectual property right belonging to AstraZeneca or any of its Affiliates, and likewise AstraZeneca is not by this Agreement, by implication or otherwise, granted any license or other right under the Licensed Technology relating to any products containing acetyl salicylic acid (including salts and derivatives thereof) or any right in relation to any patent, trademark or other intellectual property right belonging to POZEN or any of its Affiliates, in each case, except as expressly set forth in this Agreement.

7.5 Restrictive Covenant. AstraZeneca hereby covenants and agrees not to use any Licensed Technology, nor grant any Third Party any license or right under any Licensed Technology, other than as expressly permitted in this Agreement. The Parties agree that nothing in this Agreement restricts or prohibits AstraZeneca from by itself or with Third Parties exploiting any products, including without limitation any products containing non-steroidal anti-inflammatory drugs (*e.g.*, acetyl salicylic acid and esters and derivatives thereof); provided, that

AstraZeneca shall not use or practice Licensed Technology in connection with the development, manufacture or commercialization of any product that is not a Product, and nothing requires AstraZeneca to compensate POZEN if AstraZeneca so exploits such products.

7.6 Japan Option. POZEN hereby grants AstraZeneca an option for a period of twenty-four (24) months (the **"Japan Option Period"**) after the Effective Date to include Japan in the Territory at no additional cost to AstraZeneca. The option will be exclusive to AstraZeneca during [redacted] of the Japan Option Period, and during such exclusive period POZEN will not solicit or enter into discussions with any Third Party regarding the availability or exploitation of Licensed Know-How or Licensed Patents in Japan. Thereafter, the option will be non-exclusive, and POZEN may, prior to exercise of the option by AstraZeneca, grant rights in Japan to any Third Party. AstraZeneca may exercise the option at any time prior to the expiration of the Japan Option Period by providing written notice to POZEN and a Development plan for a Product AstraZeneca intends to Commercialize in Japan, whereupon Japan shall immediately be included in the Territory.

8. FINANCIAL TERMS

8.1 Upfront Fee. Within ten (10) Business Days following the Effective Date, AstraZeneca will pay to POZEN a non-creditable, non-refundable upfront fee of $40,000,000.

8.2 Development Milestone Payments. Subject to the terms and conditions of this Agreement, including without limitation the last paragraph of this Section 8.2 (Development Milestone Payments), AstraZeneca will pay to POZEN the following one-time, non-creditable, non-refundable payments with respect to the first achievement of the corresponding events with a POZEN Product.

	Milestone Event	Milestone Payment
1.	Receipt by the [redacted] as described in the Initial U.S. Development Plan and the final written [redacted] as described in the Initial U.S. Development Plan, and either (a) the [redacted] described in the Initial U.S. Development Plan.	[redacted]

	Milestone Event	Milestone Payment
2.	Notification by the FDA that it has accepted the first U.S. NDA submission for a POZEN Product in accordance with Section 4.1.1 (Regulatory Responsibilities Inside the U.S.).	[redacted]
3.	Submission of the first NDA in a Major Ex-U.S. Market country for a POZEN Product.	[redacted]
4.	Receipt of the first NDA Approval for a POZEN Product in the U.S.	[redacted]
5.	Receipt of the first NDA Approval for a POZEN Product in a Major Ex-U.S. Market country.	[redacted]
6.	[redacted]	[redacted]

POZEN shall notify AstraZeneca in writing upon the achievement of Milestones Events 2 and 4 above, and shall provide AstraZeneca with reasonable evidence that such Milestone Events have been achieved. The payments due with respect to achievement of each Milestone Event shall be due and payable within [redacted] after (i) AstraZeneca receives notification from POZEN of the achievement of Milestone Events #2 and 4, and (ii) the occurrence of the Milestone Events #1, 3, 5, and 6, it being understood that with respect to Milestone Event #1(b) the Milestone Event will not have occurred until the end of the [redacted] period referenced therein. The date on which any such milestone payment is due and payable in accordance with the preceding sentence is hereinafter referred to as the **"Milestone Due Date."**

Each milestone payment identified in this Section 8.2 (Development Milestone Payments) shall be payable one time only, irrespective of the number of POZEN Products that achieve the applicable Milestone Event. Notwithstanding the foregoing, if a Milestone Event for which a payment would be due under this Section 8.2 (Development Milestone Payments) is achieved, but AstraZeneca provides notice to POZEN that it is exercising its right to terminate this Agreement pursuant to Section 12.3 (Termination for Material Breach), 12.4 (Termination for Cause) or 12.5 (Termination at Will) prior to the applicable Milestone Due Date for such Milestone Event, then such milestone payment will not be payable; provided, that AstraZeneca

complies with its obligations under Section 12.6.3(b) (Effect of Termination for Cause or Material Breach) or 12.6.4 (Effect of Termination at Will) if applicable.

8.3 Sales Milestone Payments. Subject to the terms and conditions of this Agreement, AstraZeneca will pay to POZEN the following one-time, non-creditable, non-refundable payments within [redacted] following the achievement of the corresponding events described in the table below.

Milestone Event	Milestone Payment
1. End of first calendar year during which aggregate annual Net Sales of Products were at least [redacted]	[redacted]
2. End of first calendar year during which aggregate annual Net Sales of Products were at least [redacted]	[redacted]
3. End of first calendar year during which aggregate annual Net Sales of Products were at least [redacted]	[redacted]

Each milestone payment identified in this Section 8.3 (Sales Milestone Payments) shall be payable one time only, and not for each time that the "annual Net Sales" of Products exceeds a specified amount.

8.4 Royalties.

8.4.1 Royalty Rate. Subject to the terms and conditions of this Agreement, AstraZeneca will pay to POZEN royalties based on the aggregate annual Net Sales of Products sold by AstraZeneca, its Affiliates or Sublicensees, at the rates set forth below:

(a) For Net Sales [redacted]

(i) [redacted] of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than [redacted]

(ii) [redacted] of the portion of aggregate Net Sales of Products during a calendar year that is greater than [redacted] and

(iii) [redacted] of the portion of aggregate Net Sales of Products

during a calendar year that is greater than [redacted]

(b) For Net Sales [redacted]

(i) [redacted] of the portion of aggregate Net Sales of Products during a calendar year that is equal to or less than [redacted] and

(ii) [redacted] of the portion of aggregate Net Sales of Products during a calendar year that is greater than [redacted]

(c) Notwithstanding the foregoing provisions of this Section 8.4.1 (Royalty Rate), if a [redacted] is sold in one or more countries where [redacted], the total royalties owed for Products shall be determined on a segregated basis, according to the following calculations:

(i) [redacted] of the total Net Sales of the [redacted] sold in any country shall be added to the total Net Sales [redacted] (the resulting amount being the **"Segregated Net Sales"**), and the applicable royalty rates set forth in Section 8.4.1(a) and (b) shall be applied to the Segregated Product Net Sales (the resulting amount being the **"Segregated Royalty Amount"**);

(ii) the applicable royalty rates set forth in Section 8.4.1(a) and (b) shall be applied to the remaining [redacted] of the total Net Sales of [redacted] (the resulting amount being the **"Remaining Royalty Amount"**); and

(iii) the amount owed by AstraZeneca shall be equal to the Segregated Royalty Amount plus the Remaining Royalty Amount.

(iv) If [redacted] are also sold in a country where there are at least [redacted] being sold, then the calculations above shall be applied similarly to each such additional Product, such that [redacted] of the Net Sales of each additional Product shall be added to the Segregated Royalty Amount, and the remaining [redacted] of each additional Product shall be combined only with the remaining [redacted] of Net Sales of the other additional Products (*i.e.*, the [redacted]) that are being sold in other countries. The example set forth in Schedule 8.4.1 illustrates the application of this 8.4.1(c).

8.4.2 Royalty Term. AstraZeneca acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to AstraZeneca of certain elements of, the Licensed Technology pursuant to this Agreement (including the Licensed Know-How and the regulatory data to be provided to AstraZeneca pursuant to this Agreement) as well as from AstraZeneca's own development of technology derived from the practice of such license and AstraZeneca's use of such Licensed Technology, even after expiration of all Valid Claims of the Licensed Patents covering the composition of matter, manufacture, use or sale of POZEN Product in a country. Accordingly, subject to the terms of Section 8.4.3 (Rate Step Down for Competing Product Entrants), AstraZeneca's royalty payment obligations under this Section 8.4 (Royalties) will commence upon First Commercial Sale of a Product in a particular country and will expire on a country-by-country basis upon the later of: (i) expiration of the last-to-expire

Valid Claim of the Licensed Patents that, but for the licenses granted in this Agreement, would be infringed by the sale of such Product in such country, and (ii) ten (10) years after the First Commercial Sale of such Product in such country (such period ending at the later of the periods set forth in clause (i) and (ii) above, the **"Royalty Term"**).

8.4.3 Rate Step Down For Competing Product Entrants. With respect to any particular Product and country, if in any Calendar Quarter there is a Market Reduction of such Product (based on prescription market data published by IMS Health, Scott-Levin, or such other industry standard source as the Parties may agree), then the royalty rates which would otherwise apply to Net Sales of such Product in such country during such Calendar Quarter will be reduced to [redacted] of the rates set forth in Section 8.4.1 (Royalty Rate); provided, that in no event will [redacted] Such reduced royalty rates will continue in effect, on a Product-by-Product and country-by-country basis, until expiration of the applicable Royalty Term. As used in this Section 8.4.3, the term **"Market Reduction"** of a Product in a Calendar Quarter occurs when [redacted] The example set forth in Schedule 8.4.3 illustrates the application of this Section 8.4.3.

8.4.4 Third Party Payments. If AstraZeneca determines that a license to certain Third Party technology is reasonably necessary for the successful Development, Manufacture or Commercialization of a Product, then AstraZeneca will notify POZEN in writing of such determination. The Parties will consult in good faith regarding the need for such Third Party technology and, subject to POZEN's consent (not to be unreasonably withheld, conditioned or delayed), AstraZeneca will negotiate the terms on which such a Third Party license would be granted to AstraZeneca and will serve as the primary point of contact with the applicable Third Party licensor following the execution of the license agreement. The royalties required to be paid by AstraZeneca with respect to a Product in a particular country pursuant to Section 8.4 (Royalties) shall be subject to a reduction by AstraZeneca in an amount equal to [redacted] Notwithstanding anything to the contrary in this Agreement, AstraZeneca shall be solely responsible for any Third Party Payment obligations it may have to Merck & Co., Inc. or its affiliates, without any offset or deduction. Any amount of Third Party Royalties that may, pursuant to the preceding paragraph be used to reduce royalties due hereunder, in any Calendar

Quarter, but are not so used as a result of the limitation described in clause (i) of this paragraph may be carried over and used for further reduction in any succeeding royalty payment due for such Product.

8.4.5 [redacted]

8.5 Payments and Sales Reporting.

8.5.1 Sales Reporting. AstraZeneca will provide POZEN, within [redacted] of the end of each Calendar Quarter, with a report setting forth, on a country-by-country and Product-by-Product basis, the amount of gross sales of each Product in such country, a calculation of Net Sales, the currency conversion rate used and Dollar-equivalent of such Net Sales, and a calculation of the amount of royalty payment due on such Net Sales, provided that AstraZeneca shall use reasonable efforts to provide such report as soon as practicable to accommodate POZEN's SEC filing requirements and to provide such reports in a shorter time period than the periods specified above if AstraZeneca has such reports available for its own internal purposes. If any payment reduction is claimed by AstraZeneca under this Agreement from the full royalty rates set forth in Section 8.4 (Royalties), then the report will set forth in detail the claimed reduction and the related facts.

8.5.2 Payment Timing. AstraZeneca will make royalty payments to POZEN within [redacted] of the last day of each Calendar Quarter for which such payments are due under Section 8.4 (Royalties).

8.5.3 Payment Method. All amounts due hereunder will be paid in United States Dollars by wire transfer in immediately available funds to the following account, or such other account as may be designated in writing by POZEN:

Receiving bank name:	[redacted]
Receiving bank address:	[redacted]
ABA routing number (1):	[redacted]
SWIFT BIC address (2):	[redacted]
For credit to the account of:	POZEN Inc.
For credit to account number:	[redacted]

8.5.4 Currency Conversion. All payments required under this Article 8 shall be made in U.S. Dollars. For the purpose of computing the Net Sales of Licensed Products sold in a currency other than U.S. Dollars, such currency shall be converted from local currency to U.S. Dollars by AstraZeneca in accordance with the rates of exchange for the relevant month for converting such other currency into U.S. Dollars used by AstraZeneca's internal accounting systems, which are independently audited on an annual basis.

8.5.5 Late Payments. If a Party does not receive payment of any sum due to it on or before the due date, simple interest will thereafter accrue on the sum due to such Party until

the date of payment at the per annum rate of [redacted] quoted by Citibank in New York City, or the maximum rate allowable by Applicable Law, whichever is lower.

8.6 Records; Audit. AstraZeneca will maintain complete and accurate records in sufficient detail to permit POZEN to confirm the accuracy of the calculation of payments under this Agreement. Upon reasonable prior notice, such records will be available during regular business hours of AstraZeneca for a period of [redacted] following the year in which such records were created, for examination at POZEN's expense, and not more often than once each calendar year, by an independent certified public accountant selected by POZEN and reasonably acceptable to AstraZeneca, for the sole purpose of verifying the accuracy of the financial reports furnished by AstraZeneca pursuant to this Agreement. Any such auditor will not disclose AstraZeneca's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by AstraZeneca or the amount of payments due by AstraZeneca under this Agreement. Any amounts shown to be owed but unpaid will be paid within [redacted] from the accountant's report, plus interest (as set forth in Section 8.5.5 (Late Payments)) from the original due date. Any amounts determined to be overpaid will be refunded within [redacted] from the accountant's report. POZEN will bear the full cost of such audit unless such audit discloses an underpayment of the amount actually owed during the applicable calendar year of more than [redacted] in which case AstraZeneca will bear the full cost of such audit.

8.7 Taxes.

8.7.1 General. The royalties, milestones and other amounts payable by one Party to the other Party pursuant to this Agreement ("**Payments**") shall not be reduced on account of any taxes unless required by Applicable Law. The Party receiving any Payment shall be responsible for paying any and all taxes (other than withholding taxes or deduction of tax at source required by Applicable Law to be paid by the paying Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The paying Party shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if the Party receiving payment is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to the paying Party or the appropriate governmental authority (with the assistance of the paying Party to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding tax or to relieve the paying Party of its obligation to withhold tax, and the paying Party shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that the paying Party has received evidence, in a form satisfactory to the paying Party, of the other Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [redacted] prior to the time that the Payments are due. If, in accordance with the foregoing, the paying Party withholds any amount, it shall pay to the other Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to the other Party proof of such payment within [redacted] following that payment.

8.7.2 Indirect Taxes. Notwithstanding anything contained in Section 8.7.1

(General), this Section 8.7.2 (Indirect Taxes) shall apply with respect to Indirect Taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, the paying Party shall pay the Indirect Taxes at the applicable rate in respect of any such Payments following the receipt of an Indirect Taxes invoice in the appropriate form issued by Party receiving Payments in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate.

9. INTELLECTUAL PROPERTY

9.1 Prosecution and Maintenance of Licensed Patents. POZEN will be responsible for the preparation, filing, prosecution and maintenance of the Licensed Patents (other than Joint Patents), at its own expense. Notwithstanding the foregoing, [redacted] POZEN will provide a copy of all proposed filings at least [redacted] in advance of the filing date and will consider in good faith the requests and suggestions of AstraZeneca with respect to filing and prosecuting the Licensed Patents and will keep AstraZeneca promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of Licensed Patents. In the event that POZEN desires to abandon any Licensed Patent, POZEN will provide reasonable prior written notice to AstraZeneca of such intention to abandon (which notice will, in any event, be given no later than [redacted] prior to the next deadline for any action that may be taken with respect to such Licensed Patent with the U.S. Patent & Trademark Office or any foreign patent office), and AstraZeneca will have the right to assume responsibility for such Licensed Patent.

9.2 Prosecution and Maintenance of Joint Patents. AstraZeneca will be responsible for the preparation, filing, prosecution and maintenance of Joint Patents, at its own expense. AstraZeneca will provide to POZEN a copy of all proposed filings at least [redacted] in advance of the filing date and will consider in good faith the requests and suggestions of POZEN with respect to filing and prosecuting the Joint Patents and will keep POZEN promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of Joint Patents. In the event that AstraZeneca desires to abandon any Joint Patent, AstraZeneca will provide reasonable prior written notice to POZEN of such intention to abandon (which notice will, in any event, be given no later than [redacted] prior to the next deadline for any action that may be taken with respect to such Joint Patent with the U.S. Patent & Trademark Office or any foreign patent office), and POZEN will have the right to assume responsibility for such Joint Patent.

9.3 Ownership of Inventions. Inventorship of Inventions will be determined in accordance with the rules of inventorship under United States patent laws. Subject to the licenses granted under this Agreement, as between the Parties, AstraZeneca will own all AstraZeneca Inventions, POZEN will own all POZEN Inventions, and Joint Inventions will be owned jointly by AstraZeneca and POZEN; provided, however, that during the Term of this Agreement: (i) neither POZEN nor AstraZeneca shall [redacted]

other than as expressly provided in this Agreement, including Section 7.1 (Licensed Technology), without the consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, and (ii) neither Party shall assign, pledge, encumber, license or otherwise transfer any of its rights in any Joint Invention or Joint Patent without the other Party's prior written consent, which consent shall not be unreasonably withheld, conditioned or delayed. Upon any expiration or termination of this Agreement, each Party will have the right to exploit, license and grant rights to sublicense each such Joint Invention and Joint Patent, without any duty of accounting to the other Party, and each Party hereby consents, and agrees to consent, without payment of any further consideration or royalty, to the Joint Party's exploitation and licensing of said Joint Party's interest in such Joint Invention or Joint Patent to Third Parties; provided, that nothing in this Section 9.3 gives either Party any right or license under any intellectual property rights Controlled by the other Party other than Joint Inventions and Joint Patents, regardless of whether such rights are necessary in order to exploit the Joint Inventions and Joint Patents pursuant to this Section 9.3.

9.4 Disclosure. Each Party will promptly disclose to the other Party in writing, and will cause its Affiliates, agents, and independent contractors to so disclose to the other Party, the conception and reduction to practice of any Invention.

9.5 Cooperation. Each Party acknowledges the importance of securing and maintaining effective patent protection for the Licensed Technology and Joint Patents throughout the Territory. Each Party agrees to cooperate fully in the preparation, filing, prosecution and maintenance of the Licensed Patents and Joint Patents and in the obtaining and maintenance of any patent extensions, supplementary protection certificates and the like with respect to the Licensed Patents and Joint Patents. Such cooperation includes, but is not limited to: (a) executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, so as to effectuate the ownership of Inventions set forth in Section 9.3 (Ownership of Inventions), and Patents claiming or disclosing such Inventions, and to enable the other Party to apply for and to prosecute patent applications in any country; and (b) promptly informing the other Party of any matters coming to such Party's attention that may affect the preparation, filing, prosecution or maintenance of any such patent applications.

9.6 Enforcement of Licensed Patents.

9.6.1 Infringement by Third Parties. AstraZeneca and POZEN will each, within [redacted] of learning of any alleged or threatened infringement of the Licensed Patents or Joint Patents, notify the other Party in writing. [redacted] will have the first right, but not the obligation, to prosecute any such infringement. If [redacted] does not commence an infringement action against the alleged or threatened infringement (i) within [redacted] following the detection of the of alleged infringement, or (ii) [redacted] before the time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then [redacted] will so notify [redacted] promptly, and [redacted] may commence litigation with respect to the alleged or threatened infringement at its own expense.

9.6.2 Challenge by Third Parties. AstraZeneca and POZEN will each notify the other Party in writing within [redacted] of learning of any alleged or threatened

opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability of the Licensed Patents or Joint Patents by a Third Party. [redacted] will have the first right, but not the obligation, to defend any such challenge. If [redacted] does not commence Diligent Efforts to defend against the alleged or threatened challenge (i) within [redacted] following the detection of the alleged challenge, or (ii) [redacted] before the time limit, if any, set forth in appropriate laws and regulations for making a filing in defense of such a challenge, whichever comes first, then [redacted] will so notify [redacted] promptly, and [redacted] may take action with respect to the alleged or threatened challenge at its own expense.

9.6.3 Cooperation. In the event a Party brings an infringement action pursuant to Section 9.6.1 (Infringement by Third Parties), the other Party will cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or to join such action as a necessary party, executing all papers and instruments, or requiring its employees or contractor, to execute such papers and instruments, so as to successfully prosecute any such actions. Neither Party will have the right to settle any patent infringement litigation under this Section 9.6.3 (Cooperation) in a manner that could be reasonably expected to diminish the rights or interest of the other Party, or adversely effect the validity or enforceability of such other Party's Patents, without the express written consent of such other Party. The Party commencing the litigation will provide the other Party with copies of all pleadings and other documents filed with the court and will consider reasonable input from the other Party during the course of the proceedings.

9.6.4 Recovery. Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of such litigation described in Section 9.6.1 (Infringement by Third Parties) (whether by way of settlement or otherwise) will be first allocated to reimbursement of unreimbursed legal fees and all litigation expenses incurred by the Party initiating the proceeding, then toward reimbursement of any of unreimbursed legal fees and all litigation expenses of the other Party, and then the remainder will be divided between the Parties as follows: (a) settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought by [redacted] and (b) settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought by [redacted] will be retained by [redacted]

9.7 Defense of Infringement Claims. If the manufacture, sale or use of a POZEN Product pursuant to this Agreement results in any claim, suit, or proceeding by a Third Party alleging that such activities infringe a Third Party patent, or if a Third Party threatens such a claim, suit or proceeding, each Party will promptly notify the other Party thereof. [redacted] will have the exclusive right to defend and control the defense of any such claim, suit or proceeding at its own expense, using counsel of its own choice; provided, that if any such proceedings involve matters relating to the validity or enforceability of the Licensed Patents or Joint Patents, then the provisions of Section 9.6.3 (Cooperation) above shall apply. In any claim, suit or proceeding under this Section 9.7, [redacted] will keep [redacted] reasonably informed of all material developments in connection with any such claim, suit, or proceeding; provided, that if [redacted] is named as a defendant in any such claim, suit or proceeding, that [redacted] shall have the right to participate in the defense using counsel of its choice at its own expense. In any claim, suit or proceeding under this Section 9.7, [redacted]

agrees to provide [redacted] with copies of all pleadings filed in such action and to allow [redacted] reasonable opportunity to participate in the defense of the claims.

9.8 Patent Term Extension and Supplementary Protection Certificate. Upon receiving Marketing Approval for a POZEN Product, the Parties agree to coordinate the application for any patent term extension or supplementary protection certificates that may be available. The primary responsibility of applying for any extension or supplementary protection certificate will be the Party having the right to make the application under the Applicable Law. The Party responsible for filing the application will keep the other Party fully informed of its efforts to obtain such extension or supplementary protection certificate. Each Party will provide prompt and reasonable assistance, without additional compensation, to obtain such patent extension or supplementary protection certificate. The Party filing such request will pay all expenses in regard to obtaining the extension or supplementary protection certificate.

9.9 Consequence of Patent Challenge. If AstraZeneca or its Affiliates challenge the validity or enforceability of any of the Licensed Patents by any opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof before any governmental agency, court or other similar adjudicative forum (any such proceeding, a **"Patent Challenge"**), such Patent Challenge shall give POZEN the right to terminate this Agreement as provided in Section 12.3 (Termination for Material Breach) or to terminate all licenses granted under any of the Licensed Patents subject to such Patent Challenge; provided, that the foregoing provisions of this Section 9.9 (Consequence of Patent Challenge) will not apply in the event that, prior to such Patent Challenge, POZEN or any of its licensees or assignees initiates or threatens litigation against, or makes claims or assertions against, AstraZeneca or its Affiliates, Sublicensees or Third Party contractors, that allege that any of such parties infringe a Licensed Patent.

9.10 Patent Certifications.

9.10.1 Orange Book Listings. To the extent required or permitted by Applicable Law, after the completion of the assignment and transfer of the U.S. Regulatory Materials (including the NDA) for the Initial POZEN Product to AstraZeneca as required by Section 4.1.1 (Regulatory Matters in the U.S.), AstraZeneca will use Diligent Efforts to promptly list and maintain with the applicable Regulatory Authorities during the Term correct and complete listings of applicable Licensed Patents for such POZEN Product, including all so called "Orange Book" listings required under the Hatch-Waxman Act. Prior to such assignment and transfer, to the extent required or permitted by Applicable Law, POZEN will use Diligent Efforts to promptly list and maintain with the applicable U.S. Regulatory Authorities correct and complete listings of the applicable Licensed Patents for such POZEN Product, including so-called Orange Book listings. Promptly after the Effective Date, POZEN and AstraZeneca will meet to discuss the Parties' efforts under this Section 9.10.1 (Patent Certification). [redacted]

[redacted]

9.10.2 Hatch-Waxman Act. Notwithstanding Section 9.6.1 (Infringement by Third Parties) above, each Party will immediately give notice to the other Party of any notice it receives of certification filed under the Hatch-Waxman Act claiming that any of the Licensed Patents is invalid, unenforceable or that any infringement will not arise from the manufacture, use or sale of the POZEN Product by a Third Party. If [redacted] decides not to bring infringement proceedings against the entity making such a certification with respect to any such Licensed Patents, [redacted] will give notice to [redacted] of its decision not to bring suit within [redacted] after receipt of notice of such certification (or, if the time period permitted by law is less than [redacted] within [redacted] permitted by law for [redacted] to commence such action). [redacted] may then, but is not required to, bring suit against the Third Party that filed the certification. Any suit by either Party may be in the name of either or both Parties, as may be required by law. For this purpose, the Party not bringing suit will execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

9.11 Patent Marking. Any POZEN Product marketed and sold by AstraZeneca under this Agreement will be marked with appropriate patent numbers or indicia as permitted or required by law. The Parties agree to cooperate to reach a decision on the marking requirements.

10. REPRESENTATIONS, WARRANTIES; COVENANTS

10.1 POZEN Representations and Warranties. POZEN hereby warrants and represents to AstraZeneca as of the Execution Date and the Effective Date that, except as set forth on Schedule 10.1 to this Agreement (as such schedule may be updated by POZEN pursuant to Section 10.2 (Notice of Developments)):

10.1.1 POZEN is the sole and exclusive owner of the Licensed Patents and has the right to perform its obligations hereunder and to grant to AstraZeneca the rights and licenses set forth in this Agreement in and to the Licensed Technology;

10.1.2 Each person who has contributed to the conception of an invention claimed in the Licensed Patents has been identified to the United States Patent & Trademark Office and the applicable patent offices in all other countries where such Licensed Patent is filed, registered, nationalized or validated and is named on such Licensed Patent. [redacted] is the sole inventor of U.S. Patent [redacted]. Each inventor of any invention claimed in any Licensed Patent has assigned all of that inventor's right, title and interest in and to the Licensed Patent to POZEN, and such assignment has been recorded at the United States Patent & Trademark Office and at the applicable patent offices in all other countries where such Licensed Patent is nationalized or validated;

10.1.3 To the knowledge of POZEN, each person associated with the invention, filing or prosecution of any Licensed Patent has complied with the obligation under Applicable Law to disclose to the relevant patent authority, during the pendency of any patent application included in the Licensed Patents, information known by any such person to be material to the

patentability of the pending claims in such application;

10.1.4 To the knowledge of POZEN, none of the Licensed Patents existing on the Execution Date is involved in any action for declaratory judgment, nullity action, reexamination, interference proceeding, or other attack upon its validity, title or enforceability, and POZEN has not received any written request, demand or notice from any Third Party or governmental authority threatening or disclosing any such action, proceeding or attack with respect to any of the Licensed Patents;

10.1.5 There is no action or proceeding pending or, to the knowledge of POZEN, threatened that relates to, affects or arises in connection with any Licensed Technology or POZEN Product; and POZEN is not subject to any order, ruling or judgment of any governmental or Regulatory Authority that could reasonably be expected to impair or delay the ability of POZEN to perform its obligations under this Agreement;

10.1.6 The Licensed Patents are not subject to any encumbrance, lien, license rights (including any covenant not to sue in respect thereto) or claim of ownership by any Third Party;

10.1.7 To the knowledge of POZEN, there are no activities by Third Parties that would constitute infringement of any Licensed Patents or misappropriation of Licensed Know-How existing on the Execution Date;

10.1.8 To the knowledge of POZEN, there are no Patents or trade secret rights owned or controlled by a Third Party, that would be infringed or misappropriated by the Development, Manufacture or Commercialization of POZEN Product(s), and POZEN has received no written claims relating to any such infringement or misappropriation. To the knowledge of POZEN, AstraZeneca's use and exploitation of the Regulatory Materials as contemplated by this Agreement will not misappropriate any confidential information or trade secret of any Third Party;

10.1.9 POZEN has made available to AstraZeneca all clinical study reports, formulation development study reports and Regulatory Materials in its possession or Control regarding or related to POZEN Products. All such clinical study reports, formulation development study reports and Regulatory Materials are true and complete as of the Execution Date;

10.1.10 As of the Execution Date, POZEN has prepared, maintained and retained all Regulatory Materials required to be maintained or reported pursuant to and in accordance with cGCP, cGLP, and cGMP to the extent required, and all Applicable Law and, to POZEN's knowledge, the Regulatory Materials do not contain any materially false and misleading statements; POZEN has conducted, and has caused its contractors and consultants to conduct, any and all formulation development and clinical studies related to the POZEN Product in accordance with cGCP, cGMP, and cGLP, to the extent required, and all other Applicable Law;

10.1.11 The Licensed Patents listed on Schedule 1.58 are all of the Patents Controlled by POZEN that are necessary for the Development, Manufacture, Commercialization, use, sale, offer for sale or importation of the POZEN Product in the Field of Use.

10.1.12POZEN has disclosed to AstraZeneca all information in its possession relating to any interaction with the FDA and other Regulatory Authorities regarding the Initial POZEN Product. POZEN has not received any communication from the FDA that leads it to believe that the studies set forth in Exhibit B may be insufficient to obtain NDA Approval of the Initial POZEN Product from the FDA;

10.1.13POZEN has obtained all necessary licenses, consents, approvals, permits and authorizations to enable it to carry on its research and business related to the Licensed Technology and POZEN Products and all such licenses, consents, approvals, permits and authorizations are in effect;

10.1.14 True and complete copies of all of POZEN's agreements relating to the Licensed Technology or to the Development or Commercialization (excluding marketing research) of POZEN Products have been made available to AstraZeneca and such agreements will be listed on an updated Schedule 10.1 to be agreed by the Parties before the Effective Date. Except as identified on such Schedule 10.1, each such agreement is in full force and effect. POZEN is not, and to its knowledge no other party to any such agreement is, in breach of or in default, in any material respect, under any such agreement; and to POZEN's knowledge, no event or circumstance has occurred which constitutes, or after notice or lapse of time or both, would constitute a material breach or default thereunder on the part of POZEN or any other party thereto, or which would result in a right to accelerate or a loss of material rights under any such agreement that has not been cured or waived;

10.1.15 Neither POZEN nor any Third Party engaged by it, in any capacity, has been debarred or is subject to debarment or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the FDA or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations;

10.1.16 True, complete and correct copies of all licenses and other agreements under which any Third Party has or grants to POZEN any right or license to the Licensed Patents, including any amendments to such agreements, have been made available to AstraZeneca;

10.1.17 All applicable fees have been timely paid to file, prosecute and maintain the Licensed Patents. To the knowledge of POZEN without inquiry, (i) the Licensed Patents are subsisting, or pending, and are not invalid or unenforceable, and (ii) the conception, development and reduction to practice of the Licensed Patents have not constituted or involved the misappropriation of trade secrets or other rights or property of any Third Party;

10.1.18 The development of the Licensed Technology has not been funded, in whole or in part, by the United States Government.

10.1.19 The execution and delivery of this Agreement, the performance contemplated hereby, and the grant of rights and licenses hereunder will not (i) result in a breach of any judgment, decree, order or approval of any court of law or authority applicable to the Licensed Technology or POZEN Product; (ii) cause any acceleration or maturity of any contract

or of any obligation relating to the Licensed Technology or POZEN Product; (iii) result in the creation or imposition of any encumbrance upon or give to any other person or entity any interest or right (including any right of termination or cancellation or change) in or with respect to the Licensed Technology or POZEN Product except as expressly permitted herein; or result in any termination of, or change in the terms of, or conditions of, or rights or obligations under, any permit or approval of any authority applicable to the Licensed Technology or POZEN Product; or (iv) result in a violation of, or be in material conflict with, or constitute a material default, under any agreement in existence as of the Execution Date between POZEN and Third Parties and that it is not party to any other agreements that limits AstraZeneca's rights under this Agreement.

10.2 Notice of Developments. From the Execution Date until the Effective Date of this Agreement, POZEN will give AstraZeneca prompt written notice upon becoming aware of any development, event or circumstance that could reasonably be expected to result in a breach of or inaccuracy in any of POZEN's representations and warranties in Section 10.1 (POZEN Representations and Warranties). On the Effective Date, POZEN shall deliver to AstraZeneca an updated Schedule 10.1 reflecting all exceptions to the representations and warranties made by POZEN as of the Effective Date.

10.3 AstraZeneca Warranties. AstraZeneca hereby warrants and represents to POZEN as of the Execution Date and the Effective Date that AstraZeneca is not subject to any order, ruling or judgment of any governmental or Regulatory Authority that could reasonably be expected to impair or delay the ability of AstraZeneca to perform its obligations under this Agreement.

10.4 Reciprocal Representations and Warranties. Each Party represents and warrants to the other Party that: (a) this Agreement is a legal and valid obligation binding upon its execution and enforceable against it in accordance with its terms and conditions; and (b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all necessary corporate action, and the person executing this Agreement on behalf of such Party has been duly authorized to do so by all requisite corporate actions.

10.5 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTIONS 10.1 (POZEN WARRANTIES) AND 10.3 (ASTRAZENECA WARRANTIES) AND 10.4 (RECIPROCAL REPRESENTATIONS AND WARRANTIES), EACH PARTY MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND POZEN AND LICENSEE EACH SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY OR MERCHANTABILITY, OR ANY WARRANTY AS TO THE VALIDITY OR ENFORCEABILITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

10.6 POZEN Non-Compete. POZEN covenants that it will not at any time prior to the expiration of the Royalty Term, and will ensure that its Affiliates do not, directly or

indirectly, develop or commercialize or license any Third Party to develop or commercialize any product having a [redacted] provided, that after [redacted] following the Commercial Launch of a POZEN Product in the European Union, POZEN and its Affiliates shall be free, in the European Union only, to Develop, Commercialize or license a Third Party to Develop or Commercialize a product having a [redacted] Without limiting AstraZeneca's rights under this Agreement or otherwise, in case of any breach of this Section 10.6 (POZEN Non-Compete), AstraZeneca will notify POZEN and, if such breach is not cured by POZEN within [redacted] after receipt of such notice, [redacted]

10.7 POZEN Subcontractors. POZEN will not, without AstraZeneca's prior written consent (not to be unreasonably withheld), engage or use any Third Party contract research organizations or other contractors (other than individuals hired as consultants) involved in the conduct of Development activities under this Agreement. All subcontractors identified in Schedule 10.7 (which such schedule will be agreed upon by the Parties before the Effective Date) are hereby approved by AstraZeneca. Any subcontract between POZEN and a Third Party to perform POZEN's responsibilities under this Agreement will be in writing and include provisions requiring the Third Party (i) to assign to POZEN all rights in any inventions relating to a Product and conceived by such Third Party in the course of performing such activities, along with all intellectual property rights therein, and (ii) to comply with confidentiality provisions at least as restrictive as those set forth in Section 11 (Confidentiality) with respect to all materials and information received by such Third Party in connection with such activities.

10.8 [redacted]

10.9 Other Covenants.

10.9.1 POZEN will not enter into any agreement, whether written or oral with respect to, or otherwise assign, transfer, license, convey or otherwise encumber its rights, title or interest in the Licensed Technology (including by granting any covenant not to sue with respect thereto) to any Person in a manner that is inconsistent with the rights and licenses granted to AstraZeneca under this Agreement.

10.9.2 Each Party will obtain from each of its Affiliates, sublicensees, employees and agents and from the employees and agents of its Affiliates, sublicensees and agents who are or will be involved in the Development of the POZEN Products or of the Licensed Technology, rights to any and all inventions, information, and intellectual property rights conceived in the course of performance of this Agreement, necessary to enable such Party to grant the licenses and other rights granted to the other Party under this Agreement.

11. CONFIDENTIALITY.

11.1 Definition. During the Term and subject to the terms and conditions of this Agreement, a Party (a **"Disclosing Party"**) may communicate to the other Party (a **"Receiving Party"**) information in connection with this Agreement or the performance of its obligations hereunder, including scientific and manufacturing information and plans, marketing and business plans, and financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business (collectively, **"Confidential Information"**). Without limiting the foregoing, "Confidential Information" is hereby deemed to include any information disclosed by one Party to the other Party pursuant to that certain confidentiality agreement between the Parties dated as of March 27, 2006 or that certain confidentiality agreement between the Parties dated as of June 15, 2006. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, during the Term, the Licensed Know-How will be deemed to be the Confidential Information of both Parties.

11.2 Exclusions. Notwithstanding the foregoing, information of a Disclosing Party will not be deemed Confidential Information with respect to a Receiving Party for purposes of this Agreement to the extent the Receiving Party can demonstrate by competent evidence that such information:

11.2.1 was already known to the Receiving Party or its Affiliates, as evidenced by their written records, other than under an obligation of confidentiality or non-use, at the time of disclosure to the Receiving Party;

11.2.2 was generally available or was otherwise part of the public domain at the time of its disclosure to the Receiving Party;

11.2.3 became generally available or otherwise became part of the public domain after its disclosure to the Receiving Party, through no fault of or breach of its obligations under this Section 11 (Confidentiality) by the Receiving Party;

11.2.4 was disclosed to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Party that controls such information and know-how not to disclose such information or know-how to others; or

11.2.5 was independently discovered or developed by the Receiving Party or its Affiliates, as evidenced by their written records, without the use of, and by personnel who had no access to, Confidential Information belonging to the Party that controls such information and know-how.

11.3 Disclosure and Use Restriction. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the parties, the parties agree that, during the Term and for [redacted] thereafter, the Receiving Party will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as expressly provided for in this Agreement any Confidential Information of the Disclosing Party. The Receiving Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement or in connection with the exercise of its rights hereunder. The Receiving Party

will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information.

11.4 Authorized Disclosure. A Receiving Party may disclose Confidential Information of a Disclosing Party to the extent that such disclosure is:

11.4.1 made in response to a valid order of a court of competent jurisdiction or other governmental or regulatory body of competent jurisdiction; provided, however, that such Receiving Party will have given notice to the Disclosing Party [redacted] of receipt of such order and given the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;

11.4.2 otherwise required by law; provided, that the Disclosing Party will provide the Receiving Party with notice of such disclosure at least [redacted] in advance thereof to the extent practicable and take reasonable steps as requested by the Disclosing Party to protect the Disclosing Party's rights;

11.4.3 made by a Receiving Party, in connection with the performance of this Agreement, (a) to Affiliates, employees, consultants, representatives or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 11 (Confidentiality) or (b) to Regulatory Authorities (provided, that in the case of disclosures to Regulatory Authorities, the Receiving Party will, to the extent practicable, provide the Disclosing Party with notice of such disclosure at least [redacted] in advance thereof and will reasonably consider any comments received from the Disclosing Party);

11.4.4 made by a Receiving Party to existing or potential acquirers or merger candidates; potential sublicensees or collaborators (to the extent contemplated hereunder); investment bankers; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Section 11 (Confidentiality); or

11.4.5 made by the Receiving Party with the prior written consent of the Disclosing Party.

11.4.6 In addition to the foregoing, within [redacted] after the Effective Date, the Parties shall mutually agree in good faith on a written document specifying the

statements regarding [redacted] are permitted to make in response to appropriate questions from [redacted] relating to POZEN Products, and the Parties shall update such document by mutual agreement as appropriate from time to time, such agreement not to be unreasonably withheld, conditioned or delayed. [redacted] shall not make any public statement [redacted] that is not consistent with such agreed written document.

11.5 Use of Name. Neither Party may make public use of the other Party's name except (a) in connection with announcements and other disclosures relating to this Agreement and the activities contemplated hereby as permitted in Section 11.6 (Press Releases), (b) as required by Applicable Law, and (c) otherwise as agreed in writing by such other Party.

11.6 Press Releases.

11.6.1 On or after the Execution Date of this Agreement at a mutually agreed time, each Party will issue a mutually agreed press release announcing the existence of this Agreement each in the form and substance to be mutually agreed upon in advance. For subsequent press releases and other written public disclosures relating to this Agreement or the Parties' relationship hereunder (each, a **"Public Disclosure"**), each Party will use reasonable efforts to submit to the other Party a draft of such Public Disclosures for review and comment by the other Party at least [redacted] prior to the date on which such Party plans to release such Public Disclosure, and in any event will submit such drafts at least [redacted] prior to the release of such Public Disclosure, and will review and consider in good faith any comments provided in response. Notwithstanding the foregoing, subject to Section [redacted]

11.6.2 If a Party is unable to comply with the foregoing [redacted] notice requirement because of a legal obligation or stock exchange requirement to make more rapid disclosure, such Party will not be in breach of this Agreement but will in that case provide notice as promptly as practicable under the circumstances.

11.6.3 A Party may publicly disclose, without regard to the preceding requirements of this Section 11.6 (Press Releases), information that was previously disclosed in a Public Disclosure that was in compliance with such requirements.

11.7 Terms of Agreement to be Maintained in Confidence. The Parties agree that the terms of this Agreement are confidential and will not be disclosed by either Party to any Third Party (except to a Party's professional advisors, including without limitation accountants, financial advisors, and attorneys) without prior written permission of the other Party; provided, however, that (a) either Party may make any filings of this Agreement required by law or regulation in any country so long as such Party uses its reasonable efforts to obtain confidential treatment for portions of this Agreement as available, consults with the other Party, and permits the other Party to participate, to the greatest extent practicable, in seeking a protective order or other confidential treatment; (b) either Party may disclose this Agreement on a confidential basis to potential Third Party investors or acquirors or, in the case of AstraZeneca, to potential Sublicensees, in each case in connection with due diligence or similar investigations; and (c) a

Party may publicly disclose, without regard to the preceding requirements of this Section 11.7, information that was previously disclosed in compliance with such requirements.

12. TERM AND TERMINATION

12.1 HSR Act. To the extent required by the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (**"HSR Act"**), each Party will (i) file or cause to be filed, as promptly as practicable after the date hereof, with the United States Federal Trade Commission (**"FTC"**) and the United States Department of Justice (**"DOJ"**), all reports and other documents required to be filed by such Party under the HSR Act concerning the transactions contemplated hereby and (ii) promptly comply with or cause to be complied with any requests by the FTC or DOJ for additional information concerning such transactions, in each case so that the waiting period applicable to this Agreement and the transactions contemplated hereby under the HSR Act will expire as soon as practicable after the date hereof. Each Party agrees to request, and to cooperate with the other Party in requesting, early termination of any applicable waiting period under the HSR Act. The filing fees payable in connection with the filings will be borne by AstraZeneca as the acquiring party under this Agreement. This Agreement is effective on the date after which the waiting period pursuant to the HSR Act has expired, or the date on which the transaction contemplated in this Agreement has been approved by the FTC and DOJ or, if the Parties agree that no filing is required under the HSR Act, the date first written above (**"Effective Date"**).

12.2 Term. The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with this Section 12 (Term and Termination), will expire upon the expiration of the Royalty Term for all POZEN Products in all countries (the **"Term"**).

12.3 Termination for Material Breach. In the event that either Party (the **"Breaching Party"**) shall be in material default of any of its material obligations under this Agreement, in addition to any other right and remedy the other Party (the **"Non-Breaching Party"**) may have, the Non-Breaching Party may terminate this Agreement in its entirety or with respect to the country or countries to which such material default applies by [redacted] prior written notice (the **"Notice Period"**) to the Breaching Party, specifying the breach and its claim of right to terminate; provided, that the termination shall not become effective at the end of the Notice Period if the Breaching Party cures the breach complained about during the Notice Period (or, if such default cannot be cured within such Notice Period, if the Breaching Party commences actions to cure such default within the Notice Period and thereafter diligently continues such actions); provided, further, that in the event that AstraZeneca is the Party in material default and the default is with respect to AstraZeneca's failure to use Diligent Efforts as required under this Agreement with respect to the Initial POZEN Products in the United States or in a particular Major Ex-U.S. Market Country, POZEN shall have the right to terminate this Agreement only with respect to such country and not in its entirety. It is understood that termination pursuant to this Section 12.3 (Termination for Material Breach) shall be a remedy of last resort and may be invoked only in the case where the breach cannot be reasonably remedied by the payment of money damages or other remedy under applicable law. If either Party initiates a dispute resolution procedure as permitted under this Agreement prior to the end of the Notice Period to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, including any litigation following therefrom, the termination shall become

effective only if and when such dispute is finally resolved through such dispute resolution procedure. This Section 12.3 (Termination for Material Breach) defines exclusively the Parties' right to terminate in case of any material breach of this Agreement.

12.4 Termination for Cause.

12.4.1 AstraZeneca Termination for Cause. AstraZeneca may terminate this Agreement to the extent set forth below without penalty upon written notice to POZEN, as follows:

(a) Subject to Section 12.4.1(n), if a Pre-Approval Failure described in paragraph [redacted] Section 1.82 (Pre-Approval Failure) occurs with respect to [redacted] AstraZeneca may, at its option, terminate the Agreement either [redacted] following such Pre-Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted] following the election of such product pursuant to such Section).

(b) Subject to Section 12.4.1(n), if a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs with respect to [redacted], AstraZeneca may, at its option, terminate this Agreement either with respect to [redacted] following such Pre-Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted] following the election of such product pursuant to such Section).

(c) Subject to Section 12.4.1(n), if a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs with respect to a [redacted], AstraZeneca may, at its option, terminate this Agreement [redacted] following such Pre-Approval Failure(or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted]

following the election of such product pursuant to such Section)..

(d) If a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs with respect to the [redacted], AstraZeneca may, at its option, terminate this Agreement either [redacted] following such Pre-Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted] following the election of such product pursuant to such Section)..

(e) If a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs with respect to the [redacted] AstraZeneca may, at its option, terminate this Agreement [redacted] following such Pre-Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted] following the election of such product pursuant to such Section)..

(f) If, following a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure), AstraZeneca fails [redacted] then AstraZeneca may, at its option, terminate this Agreement as follows: (i) if such Pre-Approval Failure related [redacted] provided, in each case, that written notice of termination must be delivered to POZEN within thir[redacted] following the expiration of such [redacted] period.

(g) If the Regulatory Authority in a particular country or territory requires the development of a particular formulation of a POZEN Product (whether for use in clinical testing or otherwise) and the Parties fail to develop a formulation and a manufacturing process for the applicable POZEN Product despite using Diligent Efforts to do so, then AstraZeneca may, at its option, terminate this Agreement solely with respect to such country; provided, that written notice of termination must be delivered to POZEN within [redacted] following the permanent abandonment of the applicable formulation development program.

(h) If a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs, AstraZeneca may, at its option, terminate this

Agreement either [redacted] following such Pre-Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted] following the election of such product pursuant to such Section).

(i) If a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs, AstraZeneca may, at its option, terminate this Agreement either [redacted] provided, that written notice of termination must be delivered to POZEN not later than the date of NDA Approval of the Initial POZEN Product in the U.S.

(j) If a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs, AstraZeneca may, at its option, terminate this Agreement [redacted] provided, that written notice of termination must be delivered to POZEN within [redacted] following such Pre-Approval Failure (or, if AstraZeneca has elected a substitute POZEN Product in accordance with Section 3.4.2(a) or if POZEN has consented to AstraZeneca's election of a substitute POZEN Product under Section 3.4.2(b) and, in either case, AstraZeneca has proposed an updated development plan for such substitute product as required by Section 3.4.2(b), within [redacted] following the election of such product pursuant to such Section).

(k) If a Post-Approval Failure occurs anywhere in the Territory, AstraZeneca may, at its option, terminate the Agreement either [redacted] provided, that written notice of termination must be delivered to POZEN within [redacted] following such Post-Approval Failure.

(l) If, after AstraZeneca receives POZEN's updated Schedule 10.1 pursuant to Section 10.1, AstraZeneca determines in its reasonable discretion that a change to Schedule 10.1 either (i) materially adversely affects the value of rights granted to AstraZeneca under this Agreement, or (ii) materially adversely affects POZEN's ability to perform its obligations under this Agreement, AstraZeneca may, at its option, terminate this Agreement in its entirety; provided, that written notice of termination must be delivered to POZEN within [redacted] following AstraZeneca's receipt of POZEN's updated Schedule 10.1.

(m) AstraZeneca may, at its option, terminate this Agreement in its entirety to the extent provided in Section 3.4.2 (Substitution).

(n) If a Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) occurs because [redacted]

[redacted], then POZEN may elect, at its option, to deem the Pre-Approval Failure described in paragraph [redacted] of Section 1.82 (Pre-Approval Failure) to have occurred [redacted] as applicable, for the purposes of this Section 12.4.1.

12.4.2 POZEN Termination for Cause. Subject to Section 12.6.3 (Effect of Termination for Cause or for Material Breach), POZEN may terminate this Agreement to the extent set forth below without penalty upon written notice to AstraZeneca, which notice must be delivered to AstraZeneca within [redacted] following the occurrence of the relevant event described in paragraphs (a), (b), (c) and (d) below:

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

12.5 Termination at Will. AstraZeneca may terminate this Agreement in its entirety or with respect to all countries outside of the United States at any time at will upon [redacted] prior written notice to POZEN.

12.6 Consequences of Expiration and Termination.

12.6.1 Effect of Expiration. Upon expiration (but not earlier termination) of the Term pursuant to Section 12.2 (Term), AstraZeneca will have a non exclusive, irrevocable, perpetual, worldwide, fully-paid license, with the right to sublicense, under the Licensed Technology to research, develop, make, use, sell, offer for sale, and import the POZEN Product in the Field of Use.

12.6.2 Effect of Termination Generally. The use by either party hereto of a termination right provided for under this Agreement and in accordance with this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other party with respect thereto. Subject to the preceding sentence, termination of this Agreement shall not preclude either party from claiming any other damages, compensation or relief that it may be entitled to upon such termination or for any breach of this Agreement.

12.6.3 Effect of Termination for Cause or for Material Breach.

(a) If either Party terminates this Agreement pursuant to Section 12.3 (Termination for Material Breach) in its entirety or with respect to a particular country, or if either Party terminates this Agreement pursuant to Section 12.4 (Termination for Cause) in its entirety or with respect to a particular country or group of countries, all rights and licenses granted by POZEN to AstraZeneca and all obligations of AstraZeneca and POZEN under this Agreement will terminate immediately with respect to all countries in which this Agreement has been terminated.

(b) If AstraZeneca terminates this Agreement pursuant to Section 12.4.1 (Termination for Cause) as a result of a TPP Failure but [redacted], then AstraZeneca will pay POZEN a termination fee of [redacted] (which termination fee shall be the sole and exclusive consideration owed to POZEN on account of such termination).

12.6.4 Effect of Termination At Will. Upon termination of this Agreement pursuant to Section 12.5 (Termination at Will), all rights and licenses granted by POZEN to AstraZeneca under this Agreement will terminate immediately. In addition, the following provisions will apply:

(a) If the termination notice is given [redacted] AstraZeneca will pay POZEN a termination fee in an amount determined, as follows (which termination fee shall be the sole and exclusive consideration owed to POZEN on account of such termination):

(i) If the termination notice [redacted]

(ii) If the termination notice [redacted]

(iii) If the termination notice [redacted]

(iv) If the termination notice [redacted]

(b) If such termination becomes effective after [redacted] AstraZeneca shall, at its sole option, do one of the following (which, in either case, shall be the sole and exclusive consideration owed to POZEN on account of such termination):

(i) pay POZEN an amount equal to [redacted] if the Agreement is terminated [redacted] if the Agreement is terminated [redacted] or

(ii) only if AstraZeneca is able to convey to POZEN materially the same freedom to operate with respect to the Manufacture and Commercialization of any POZEN Product Commercialized by AstraZeneca at the time of such termination (the **"Commercialized POZEN Product"**) as AstraZeneca enjoyed immediately prior to such termination (x) worldwide (if the Agreement is terminated in its entirety), or (y) in all countries outside the United States (if the Agreement is terminated with respect to all countries outside the United States), perform the actions described in paragraphs (1) through (10) below:

(1) To the extent permitted by Applicable Law, AstraZeneca shall transfer and assign to POZEN all Regulatory Materials and Marketing Approvals that are Controlled by AstraZeneca for Commercialized POZEN Product either (x) worldwide (if the Agreement is terminated in its entirety), or (y) in all countries outside the United States (if the Agreement is terminated with respect to all countries outside the United States).

(2) In the case of termination of this Agreement in its entirety, AstraZeneca shall transfer to POZEN or its designee the management and continued performance of any clinical trials for the Commercialized POZEN Product ongoing as of the effective date of such termination, which clinical trials will be conducted at POZEN's expense after such transfer.

(3) Upon POZEN's request, AstraZeneca shall transfer to POZEN at AstraZeneca's full manufacturing cost any stock of finished Commercialized POZEN Product held by AstraZeneca or its Affiliates for either (x) the entire Territory (if the Agreement is terminated in its entirety), or (y) in all countries outside the United States (if the Agreement is terminated with respect to all countries outside the United States).

(4) AstraZeneca shall for a reasonable period of time, provide such assistance, at no cost to POZEN, to transfer or transition to POZEN all other technology or know-how Controlled by AstraZeneca, or then-existing commercial arrangements (to the extent transferable in accordance with the terms and conditions of such arrangements) as may be reasonably necessary or useful for POZEN to commence or continue developing, manufacturing, or Commercializing the Commercialized POZEN Products, to the extent AstraZeneca is then performing or having performed such activities (including without limitation transferring, upon request of POZEN, any agreements or arrangements with Third Party suppliers or vendors to supply or sell the Commercialized POZEN Product, to the extent such agreements or arrangements are transferable in accordance with their terms and conditions).

(5) AstraZeneca shall transfer to POZEN or its designee any then-current manufacturing processes for the Commercialized POZEN Product. In addition, to the extent that AstraZeneca or its Affiliate is then manufacturing Commercialized POZEN Product, AstraZeneca will negotiate in good faith a supply agreement for the Commercialized POZEN Product on commercially reasonable terms under which AstraZeneca will continue to manufacture, and will supply to POZEN, at a cost that equals [redacted] of AstraZeneca's actual manufacturing costs (calculated in accordance with AstraZeneca's standard cost and accounting policies), POZEN's requirements of POZEN Product, for a period of up to [redacted] in order to permit POZEN to establish sufficient manufacturing capacity for Commercialized POZEN Product; provided, however, that POZEN shall use commercially reasonable efforts to transition manufacture of the Commercialized POZEN Product to a Third Party as soon as reasonably practicable.

(6) The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that at all times that AstraZeneca is supplying POZEN Product under such agreement, allow a delegation consisting of a reasonable number of representatives of POZEN, no more than once per calendar year, to inspect and audit any AstraZeneca facility where such Commercialized POZEN Product, including its active pharmaceutical ingredients [redacted] is Manufactured, and the documentation generated in connection with the Manufacture and testing of such Commercialized POZEN Product for the purpose of verifying that the POZEN Product is being manufactured in accordance with applicable Laws. The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that such inspections will take place during regular business hours and after at least thirty (30) days prior notice to AstraZeneca. POZEN will discuss the results of any inspection with AstraZeneca. Any inspection by or on behalf of POZEN, if it occurs, does not relieve AstraZeneca of its obligation to comply with all Applicable Laws and does not constitute a waiver of any right otherwise available to POZEN. POZEN will treat all information subject to review under this paragraph in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party representative retained by POZEN (and reasonably acceptable to AstraZeneca) to enter into a reasonably acceptable confidentiality agreement with AstraZeneca obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

(7) The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that, during any period when AstraZeneca is supplying Commercialized POZEN Product under such agreement,

AstraZeneca shall notify POZEN promptly following notice from the FDA or any Regulatory Authority of a visit to any AstraZeneca facility where such Commercialized POZEN Product is Manufactured. The supply agreement entered into between POZEN and AstraZeneca as contemplated by paragraph (5) above shall provide that AstraZeneca will inform POZEN of the results of any inspection by a Regulatory Authority that does or could reasonably be expected to affect the Manufacture of such Commercialized POZEN Product. AstraZeneca will promptly provide POZEN with copies of notifications from any Regulatory Authority (including, without limitation, any Form No. 483 notification, Enforcement Inspection Reports, Notice of Adverse Finding, etc.). POZEN will treat all information subject to review under this paragraph in accordance with the provisions of Section 11 (Confidentiality) and will cause any Third Party auditor retained by POZEN (and reasonably acceptable to AstraZeneca) to enter into a reasonably acceptable confidentiality agreement with AstraZeneca obligating such auditor to maintain all such information in confidence pursuant to such confidentiality agreement.

(8) During any period when AstraZeneca is supplying POZEN Product under the supply agreement between POZEN and AstraZeneca contemplated by paragraph (5) above, or POZEN is using such Commercialized POZEN Product, AstraZeneca shall grant to POZEN rights of reference (including by providing a letter of authorization to the applicable Regulatory Authorities) to any AstraZeneca IND or NDA pertaining to Esomeprazole. Upon the expiration of such right, POZEN will send written notice to such effect to the applicable Regulatory Authority.

(9) AstraZeneca shall grant to POZEN an exclusive, royalty-bearing license, with the right upon prior written notice to AstraZeneca to sublicense through multiple tiers, under any Patents Controlled by AstraZeneca that would be infringed by the manufacture, use or sale of Commercialized POZEN Products, solely to make, have made, use, sell, offer for sale, have sold, import, and export such Commercialized POZEN Products in the Field of Use in the Territory (if the Agreement is terminated in the entirety) or outside the United States (if the Agreement is terminated with respect to all countries outside the United States). In consideration of the foregoing license, POZEN shall pay to AstraZeneca royalties on net sales of Commercialized POZEN Products at the rates specified in Section 8.4 (Royalties). For purposes of the foregoing royalty obligations, the references to "AstraZeneca" in Section 8.3 through 8.7 inclusive, and in the related definitions shall be deemed to be, and shall be, references to "POZEN" for purposes of this paragraph. The royalties provided for under this paragraph shall be the sole payments due by POZEN to AstraZeneca in connection with the practice of such license, and AstraZeneca shall be solely responsible for any payment obligations it may have to Merck & Co., Inc. or its affiliates in connection therewith.

(10) AstraZeneca shall grant to POZEN a worldwide, non-exclusive, perpetual, irrevocable license under the Product Trademarks to use such marks for the promotion and sale of Commercialized POZEN Products, including the Initial POZEN Product, in the Field of Use in the Territory (if the Agreement is terminated in the entirety) or outside the United States (if the Agreement is terminated with respect to all countries outside the United States).

For the avoidance of doubt, in the event that, upon termination pursuant to Section 12.5 (Termination at Will) after First Commercial Sale of the Initial POZEN Product in the U.S.,

AstraZeneca is not able to convey to POZEN the same freedom to operate with respect to the Manufacture and Commercialization of Commercialized POZEN Products as AstraZeneca enjoyed immediately prior to such termination in all material respects, then AstraZeneca shall be obligated to make the applicable payment to POZEN specified in Section 12.6.4(b)(i) (Effect of Termination at Will).

(c) Any termination fee due pursuant to Section 12.6.4(a) or Section 12.6.4(b) (Effect of Termination at Will) above shall be due and payable as follows:

(i) if AstraZeneca exercises its termination right under Section 12.5 (Termination At Will) after achievement of a Milestone Event for which a payment would be due under Section 8.2 (Development Milestone Payments) but before the applicable Milestone Due Date for such Milestone Event, such termination fee shall be due on such Milestone Due Date in lieu of the milestone payment; and

(ii) in all cases other than those described in Section 12.6.4(c)(i) (Effect of Termination at Will) above, such termination fee shall be due within [redacted] after AstraZeneca's exercise of is termination right under Section 12.5 (Termination at Will).

12.7 Termination for Insolvency. This Agreement may be terminated by written notice by either Party at any time during the Term upon the declaration by a court of competent jurisdiction that the other Party is bankrupt and, pursuant to the U.S. Bankruptcy Code such other Party's assets are to be liquidated; upon the filing or institution of bankruptcy, liquidation or receivership proceedings (other than reorganization proceedings under Chapter 11 of the U.S. Bankruptcy Code); or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; or in the event a receiver or custodian is appointed for such Party's business; provided, however, that in the case of any involuntary proceeding, such right to terminate shall only become effective if the proceeding is not dismissed within 60 days after the filing thereof (each of the foregoing, a **"Bankruptcy Event"**).

12.8 Effect of Bankruptcy. All rights and licenses with respect to Patents and Know-How granted under or pursuant to this Agreement by one Party to the other Party are, for all purposes of Section 365(n) of Title 11 of the United States Code (**"Title 11"**), licenses of rights to "intellectual property" as defined in Title 11. [redacted]

[redacted] POZEN agrees not to interfere with AstraZeneca and its Affiliates' exercise of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use commercially reasonable efforts to assist AstraZeneca and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or desirable for AstraZeneca or its Affiliates to exercise such rights and licenses in accordance with this Agreement. Each party agrees and acknowledges that all payments by AstraZeneca to POZEN payable under this Agreement other than royalty payments pursuant to Section 8.4 (Royalties) and commercialization milestone payments under Section 8.3 (Sales Milestone Payments) do not constitute "royalties" within the meaning of Section 365(n) of Title 11 or relate to licenses of intellectual property hereunder.

12.9 Post Termination Royalties. Upon any termination of this Agreement pursuant to (i) Section 12.4.1 (Termination for Cause) and [redacted] (ii) Sections 12.4.1 and 1.82(h), then, for a period of [redacted] following any such termination, AstraZeneca shall pay POZEN a royalty on Net Sales of Products sold by AstraZeneca, its Affiliates or Sublicensees in an amount equal to [redacted] of the royalty amount calculated according to Section 8.4.1 (Royalty Rate), in accordance with the terms and conditions of Sections 8.4 (Royalties) through 8.7 (Taxes) of this Agreement.

12.10 Formulation Technology. If AstraZeneca terminates this Agreement for any reason other than for material breach by POZEN under Section 12.3 or as a result of POZEN's insolvency under Section 12.7, then, subject to the terms and conditions of this Agreement, AstraZeneca agrees to grant to POZEN, and does hereby grant effective automatically upon such termination, a worldwide, perpetual, irrevocable, non-exclusive license under the Formulation Technology, with the right to grant sublicenses and authorize the grant of sublicenses to the extent provided in this Section 12.10, to make, have made, use, sell, offer for sale, and import POZEN Products; provided, that nothing herein gives POZEN any right or license under any other intellectual property rights Controlled by AstraZeneca, regardless of whether such rights are necessary in order to exploit the Formulation Technology pursuant to this Section 12.10. POZEN may grant sublicenses and the right to grant further sublicenses under the foregoing license only as follows: (i) for any sublicense relating to the development or commercialization of a Commercialized POZEN Product, POZEN may grant such sublicense upon notice to AstraZeneca, but without obtaining AstraZeneca's consent, and (ii) for any sublicense relating to POZEN Products other than Commercialized POZEN Products, POZEN may grant such sublicense with AstraZeneca's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed).

12.11 Survival. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. The provisions of Sections 8.4 (Royalties), 8.5 (Payments and Sales Reporting), 8.6 (Records; Audits), 9.2 (Prosecution and Maintenance of Joint Patents), 9.3 (Ownership of Inventions), 10.5(Disclaimer of Warranty), 11 (Confidentiality), 12.6 (Consequences of Expiration and Termination), 12.8 (Effect of Bankruptcy), 12.9 (Post Termination Royalties), 12.10 (Formulation Technology), 12.11 (Survival), 13 (Indemnification and Insurance), 14 (Limitation of Liability), and 15 (Miscellaneous) will survive any termination or expiration of this Agreement.

13. INDEMNIFICATION AND INSURANCE

13.1 Indemnification by POZEN. POZEN hereby agrees to save, defend and hold AstraZeneca and its Affiliates and their respective directors, officers, employees and agents (each, a **"AstraZeneca Indemnitee"**) harmless from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, **"Losses"**), to which any AstraZeneca Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (i) the gross negligence or willful misconduct of any POZEN Indemnitee or (ii) the breach by POZEN of any warranty, representation, covenant or agreement made by POZEN in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any AstraZeneca Indemnitee or the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement.

13.2 Indemnification by AstraZeneca. AstraZeneca hereby agrees to save, defend and hold POZEN and its Affiliates and their respective directors, officers, employees and agents (each, an **"POZEN Indemnitee"**) harmless from and against any and all Losses to which any POZEN Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of: (i) the development, manufacture, use, handling, storage, sale or other disposition of any Product by AstraZeneca, its Affiliates or any of their respective Sublicensees, (ii) the gross negligence or willful misconduct of any AstraZeneca Indemnitee, or (iii) the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement; except, in each case, to the extent such Losses result from the gross negligence or willful misconduct of any POZEN Indemnitee or the breach by POZEN of any warranty, representation, covenant or agreement made by POZEN in this Agreement.

13.3 Indemnification Procedure.

13.3.1 Notice of Claim. The indemnified Party will give the indemnifying Party (the **"Indemnifying Party"**) prompt written notice (an **"Indemnification Claim Notice"**) of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under Section 13.1 (Indemnification by POZEN) or Section 13.2 (Indemnification by AstraZeneca); provided, however, that the failure to give such prompt written notice will not relieve Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. In no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). The indemnified Party will furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses. All indemnification claims in respect of a Party, its Affiliates or their respective directors, officers, employees and agents (collectively, the **"Indemnitees"** and each an **"Indemnitee"**) will be made solely by such Party to this Agreement (the **"Indemnified Party"**).

13.3.2 Control of Defense. At its option, the Indemnifying Party may assume

the defense of any claim for which indemnification is sought (a **"Third Party Claim"**) by giving written notice to the Indemnified Party within [redacted] after the Indemnifying Party's receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party. In the event the Indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party will immediately deliver to the Indemnifying Party all original notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim. Should the Indemnifying Party assume the defense of a Third Party Claim, the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim.

13.3.3 Right to Participate in Defense. Without limiting Section 13.3.2 (Control of Defense) above, any Indemnitee will be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 13.3.2 (Control of Defense) (in which case the Indemnified Party will control the defense).

13.3.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnitee's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnitee in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its sole discretion, will deem appropriate, and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time prior to the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 13.3.2 (Control of Defense), the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's sole and absolute discretion). The Indemnifying Party will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of the Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without the prior written consent of the Indemnifying Party.

13.3.5 Cooperation. The Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with the

defense or prosecution of any Third Party Claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith.

13.4 Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any claim will be reimbursed on a Calendar Quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

13.5 Insurance. Each Party will have and maintain such types and amounts of liability insurance as is normal and customary in the industry generally for parties similarly situated, and will upon request provide the other Party with a copy of its policies of insurance in that regard, along with any amendments and revisions thereto.

14. LIMITATION OF LIABILITY

IN NO EVENT WILL EITHER PARTY BE LIABLE FOR LOST PROFITS, LOSS OF DATA, OR FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, ARISING UNDER ANY CAUSE OF ACTION AND ARISING IN ANY WAY OUT OF THIS AGREEMENT. THE FOREGOING LIMITATIONS WILL NOT APPLY TO AN AWARD OF ENHANCED DAMAGES AVAILABLE UNDER THE PATENT LAWS FOR WILLFUL PATENT INFRINGEMENT AND WILL NOT LIMIT EITHER PARTY'S LIABILITY TO THE OTHER PARTY UNDER SECTIONS 7.5 (RESTRICTIVE COVENANT), 10.6 (POZEN NON-COMPETE), 11 (CONFIDENTIALITY), AND 13 (INDEMNIFICATION AND INSURANCE) OF THIS AGREEMENT.

15. MISCELLANEOUS

15.1 Assignment. Without the prior written consent of the other Party hereto (which may be granted at the other Party's discretion), neither Party will sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that either Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Party (a) to any Affiliate of such Party; or (b) in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise. The assigning Party (except if it is not the surviving entity) will remain jointly and severally

liable with the relevant Affiliate or Third Party assignee under this Agreement, and the relevant Affiliate assignee, Third Party assignee or surviving entity will assume in writing all of the assigning Party's obligations under this Agreement. Any purported assignment or transfer in violation of this Section 15.1 (Assignment) will be void ab initio and of no force or effect.

15.2 Termination of Certain Rights Upon POZEN Change of Corporate Control. POZEN shall promptly notify AstraZeneca in writing following consummation of a Change of Corporate Control of POZEN. Notwithstanding anything else in this Agreement to the contrary, in the event of a Change of Corporate Control of POZEN, then AstraZeneca will have the right, exercisable by written notice to POZEN or its successor in interest given within [redacted] after AstraZeneca receives written notice from POZEN of the completion of such Change of Corporate Control: (a) to terminate [redacted] established pursuant to this Agreement; (b) to make all decisions under Section 2.3.3 (Dispute Resolution), (c) to conduct [redacted] regarding POZEN Products, (d) to cause POZEN to [redacted] pertaining to POZEN Products; and (e) to terminate its obligation to make [redacted] to POZEN pursuant to this Agreement other than [redacted] and as reasonably required [redacted] except in the event of subsequent termination of this Agreement by AstraZeneca pursuant to Section 12.5 (Termination at Will) and election by AstraZeneca of the option specified in Section 12.6.4(b)(ii) (Effect of Termination at Will); subject, in each case, to AstraZeneca's continued compliance with all applicable provisions of this Agreement (including, without limitation, Articles 8, 9 and 11). POZEN shall cooperate in providing to AstraZeneca all information, assistance, assignments and other support reasonably requested to assist AstraZeneca in assuming such control. In addition, if POZEN has not completed the Development activities that are its responsibility under this Agreement, then AstraZeneca may assume all responsibility for, at its expense, all such Development activities, and POZEN shall provide to AstraZeneca all information, assistance, assignments and other support reasonably requested to assist AstraZeneca in assuming such responsibility in an efficient and orderly manner. For purposes of clarification, all Confidential Information of AstraZeneca in POZEN's or its successor's possession following AstraZeneca's exercise of its rights under this Section 15.2 shall continue to be subject to all applicable provisions of this Agreement (including, without limitation, Articles 7 and 11).

15.3 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties herein. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law

that would render any provision prohibited or unenforceable in any respect.

15.4 Governing Law; Dispute Resolution.

15.4.1 This Agreement, and any disputes between the Parties related to or arising out of this Agreement, including the Parties' relationship created hereby, the negotiations for and entry into this Agreement, its conclusion, binding effect, amendment, coverage, termination, or the performance or alleged non-performance of a Party of its obligations under this Agreement (each a **"Dispute"**), will be governed by the laws of the State of New York without reference to any choice of law principles thereof that would cause the application of the laws of a different jurisdiction.

15.4.2 In the event of any Dispute, a Party may notify the other Party in writing of such Dispute, and the Parties will try to settle such Dispute amicably between themselves. If the Parties are unable to resolve the Dispute within [redacted] of receipt of the written notice by the other Party, such Dispute will be 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 [redacted] after it was referred to the Chief Executive Officers.

15.4.3 Any Dispute that is not resolved as provided in Section 15.4.2, whether before or after termination of this Agreement, will be resolved by litigation in the courts of competent jurisdiction located in New York, New York; provided, that, at its election, POZEN may submit a Dispute to arbitration in lieu of litigation as provided in Section 15.4.5 by providing written notice to AstraZeneca within the time period specified in Section 15.4.5, in which event the procedures of Section 15.4.5 shall govern resolution of the Dispute. Each Party hereby agrees to the exclusive jurisdiction of such courts and waives any objections as to the personal jurisdiction or venue of such courts.

15.4.4 Notwithstanding the foregoing, nothing in this Section 15.4 (Governing Law; Dispute Resolution) will limit either Party's right to seek immediate temporary injunctive or other temporary equitable relief whenever the facts or circumstances would permit a Party to seek such relief in a court of competent jurisdiction.

15.4.5 In the event AstraZeneca terminates this Agreement for TPP Failure pursuant to Section 12.4.1(i) (Termination for Cause) and POZEN disputes whether such a TPP Failure has occurred, then POZEN shall have the right, at its election, to submit such Dispute to binding arbitration in lieu of litigation by providing written notice of such election to AstraZeneca within [redacted] of receiving notice from AstraZeneca that it has terminated the Agreement for TPP Failure pursuant to Section 12.4.1. If POZEN wishes to submit such Dispute to arbitration, POZEN shall so notify AstraZeneca, and the arbitration shall be conducted before a single arbitrator (**"Arbitrator"**) selected from and administered by the New York, New York office of the American Arbitration Association (the **"Administrator"**) in accordance with its then existing comprehensive arbitration rules and procedures; however, upon the written demand of either Party, the arbitration shall be conducted by and submitted to three Arbitrators selected from and administered by the Administrator's Rules & Procedures. The Arbitrator(s), whether selected by agreement or the Administrator, shall have knowledge of and experience with the process and standards used by the FDA to approve NDA applications for

pharmaceutical products and DDMAC's approval of promotion materials for pharmaceutical products. The arbitration hearing shall be held in New York, New York. The Arbitrator shall be authorized solely to determine whether there has been a TPP Failure as defined in Section 1.103 (TPP Failure). Each Party shall bear its own attorney's fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the Administrator and the Arbitrator. The Arbitrator shall, within [redacted] after the conclusion of the arbitration hearing, issue a written statement of decision describing the material factual findings and conclusions on which the decision is based. Such decision shall be final and binding upon the Parties. If such decision finds that a TPP Failure did not occur, then AstraZeneca's termination of this Agreement shall be deemed to have been made at will pursuant to Section 12.5, and accordingly, AstraZeneca shall pay POZEN the difference between the termination fee provided for in Section 12.6.4(a) and the amount paid by AstraZeneca to POZEN pursuant to Section 12.6.3(b), which payment shall be the sole and exclusive consideration owed to POZEN on account of such termination and such decision. If such decision provides that a TPP Failure did occur, then AstraZeneca's termination of this Agreement shall be deemed to have been made pursuant to Section 12.4.1(i).

15.5 Notices. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier as provided herein), or sent by internationally-recognized overnight courier addressed as follows:

If to POZEN, to:
POZEN Inc. 1414 Raleigh Road, Suite 400 Chapel Hill, NC 27517 USA Attention: President and CEO Facsimile: (919) 913-1039
With a copy to:
Cooley Godward LLP One Freedom Square 11951 Freedom Square

Reston, Virginia 20190 USA Attention: Kenneth J. Krisko Facsimile: (703) 456-8000
If to AstraZeneca, to:
AstraZeneca AB SE-431 83 Mölndal Sweden Attention: Manager Legal Department Mölndal Facsimile: +46 31 776 38 15

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given (i) when delivered, if personally delivered or sent by facsimile on a Business Day, and (ii) on the second Business Day after dispatch, if sent by nationally-recognized overnight courier. It is understood and agreed that this Section 15.5 (Governing Law; Dispute Resolution) is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

15.6 Entire Agreement; Modifications. This Agreement including the Exhibits attached hereto, each of which is hereby incorporated and made part of in this Agreement by reference, together with the AE Agreement (as such term is defined in Section 4.6 (Adverse Event Reporting)), sets forth and constitutes the entire agreement and understanding between the

Parties with respect to the subject matter hereof and supersedes all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment or modification of this Agreement will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. Subject to Section 11.1 (Confidentiality) hereof, the Parties hereby confirm that the Confidentiality Agreement by and between the Parties, dated as of June 15, 2006 is hereby terminated.

15.7 Relationship of the Parties. It is expressly agreed that the Parties' relationship under this Agreement is strictly one of licensor-licensee, and that this Agreement does not create or constitute a partnership, joint venture, or agency. Neither Party will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding (or purport to be binding) on the other.

15.8 Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of claims based on the failure to perform or a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

15.9 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

15.10 No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any Third Party.

15.11 Further Assurance. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

15.12 No Drafting Party. This Agreement has been submitted to the scrutiny of, and has been negotiated by, both Parties and their counsel, and will be given a fair and reasonable interpretation in accordance with its terms, without consideration or weight being given to any such terms having been drafted by any Party or its counsel. No rule of strict construction will be applied against either Party.

15.13 Construction. Except where the context otherwise requires, wherever used, the use of any gender will be applicable to all genders and the word "or" is used 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 means including, without limiting the generality of any description preceding such term. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document refer to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws refer to such laws as from time to time enacted, repealed or amended, (c) the words "herein", "hereof" and "hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (d) all references herein to Sections and Exhibits, unless otherwise specifically provided, refer to the Sections and Exhibits of this Agreement.

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

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement by their respective authorized representatives as of the date first written above.

POZEN INC.

By: _____

Name: JOHN R. PLACHETKA

Title: CHAIRMAN, PRESIDENT & CEO

ASTRAZENECA AB (publ)

By: _____

Name: _____

Title: _____

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement by their respective authorized representatives as of the date first written above.

POZEN INC.

By: _____

Name: _____

Title: _____

ASTRAZENECA AB (publ)

By: _____

Name: DENISE GOODE

Title: LICENSING DIRECTOR

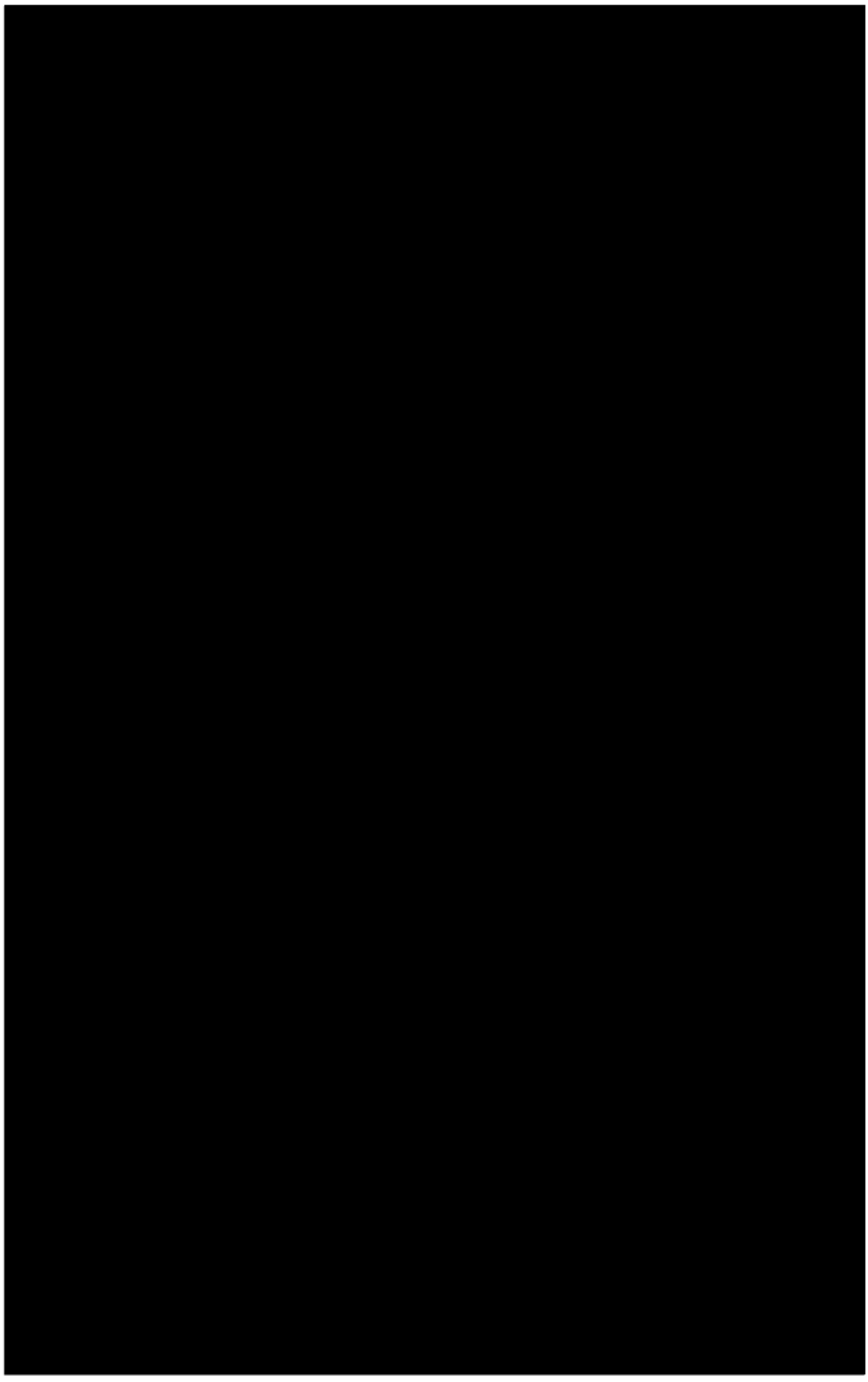
EXHIBIT A

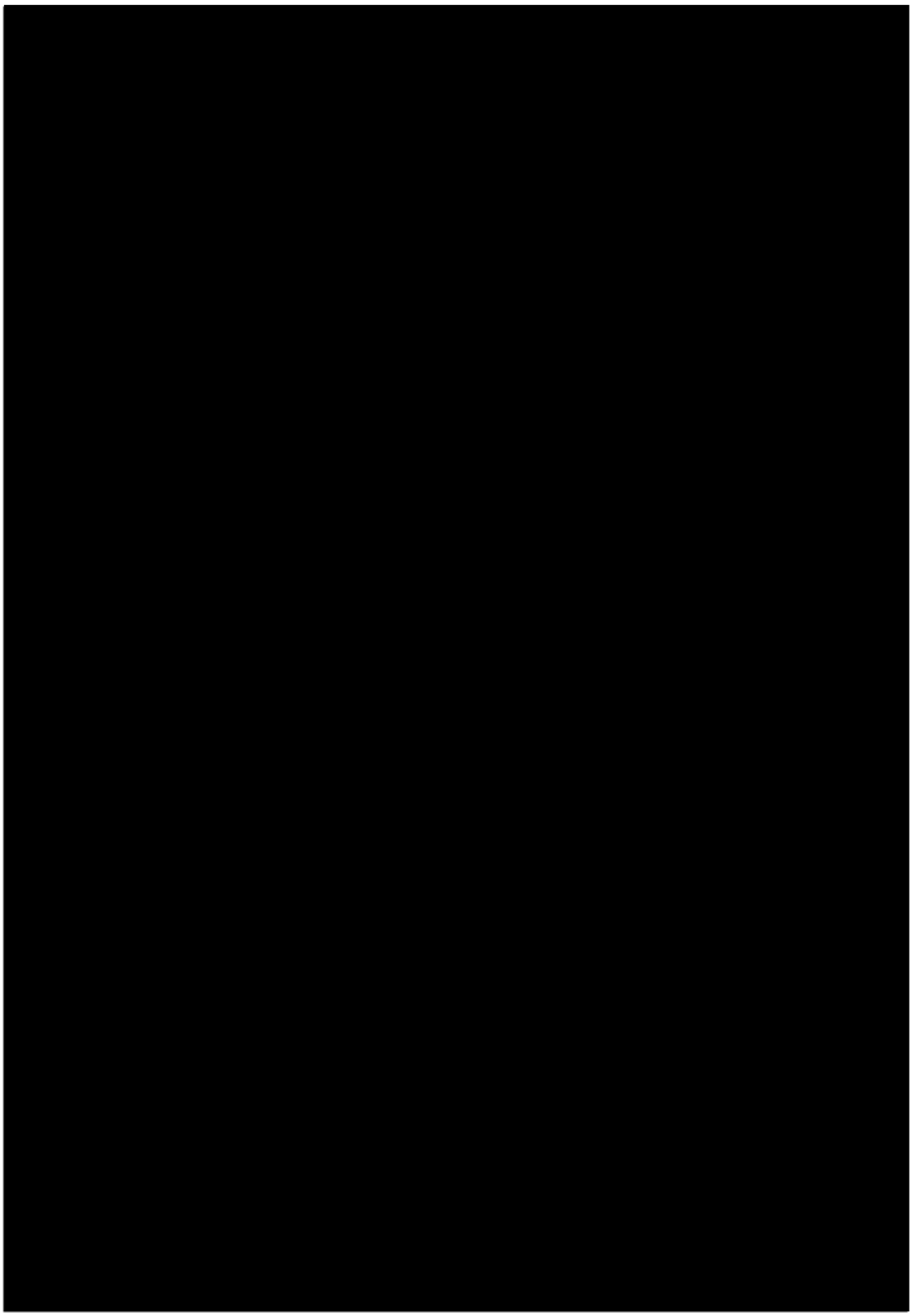
FORMULATION BUDGET

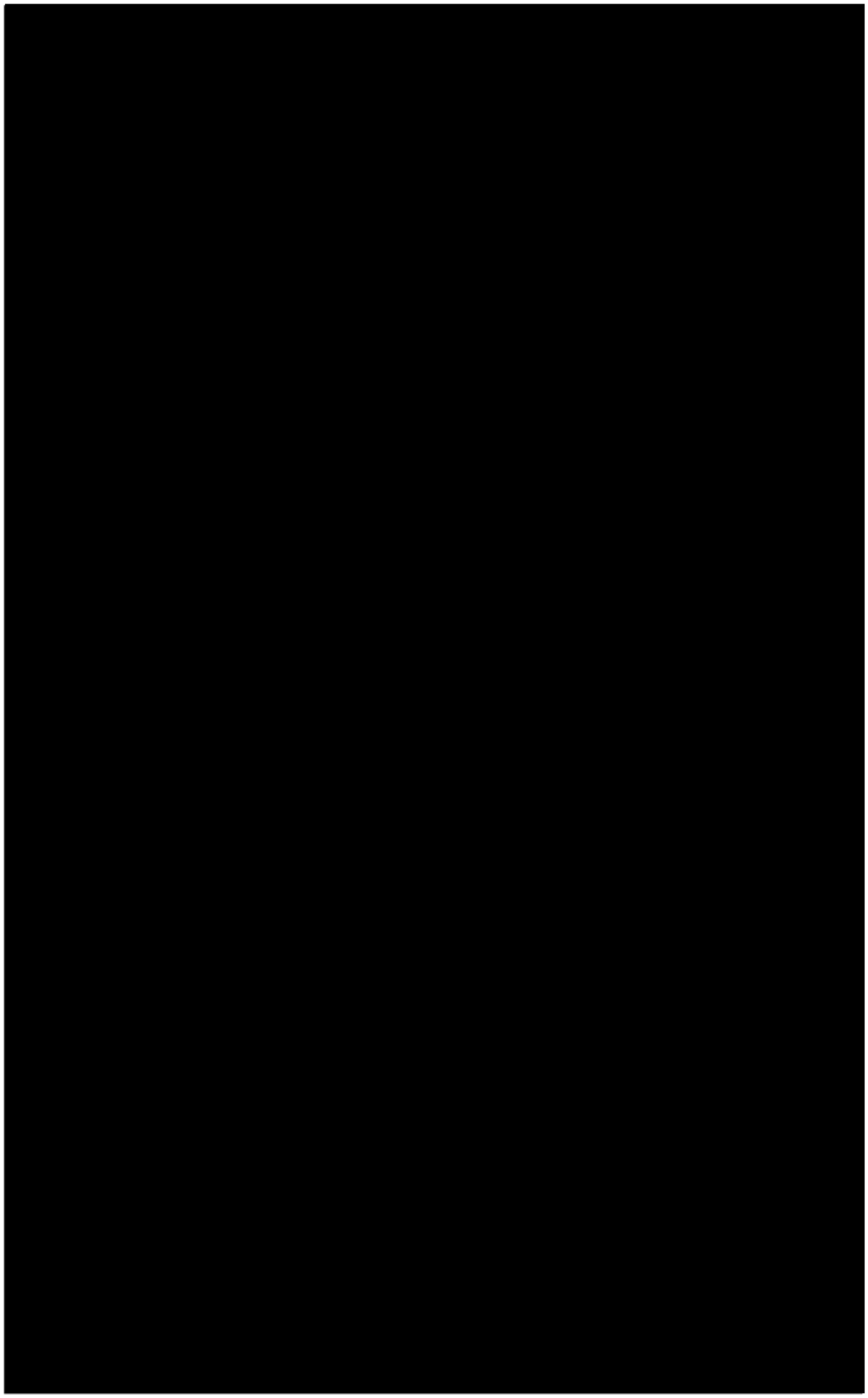
EXHIBIT B

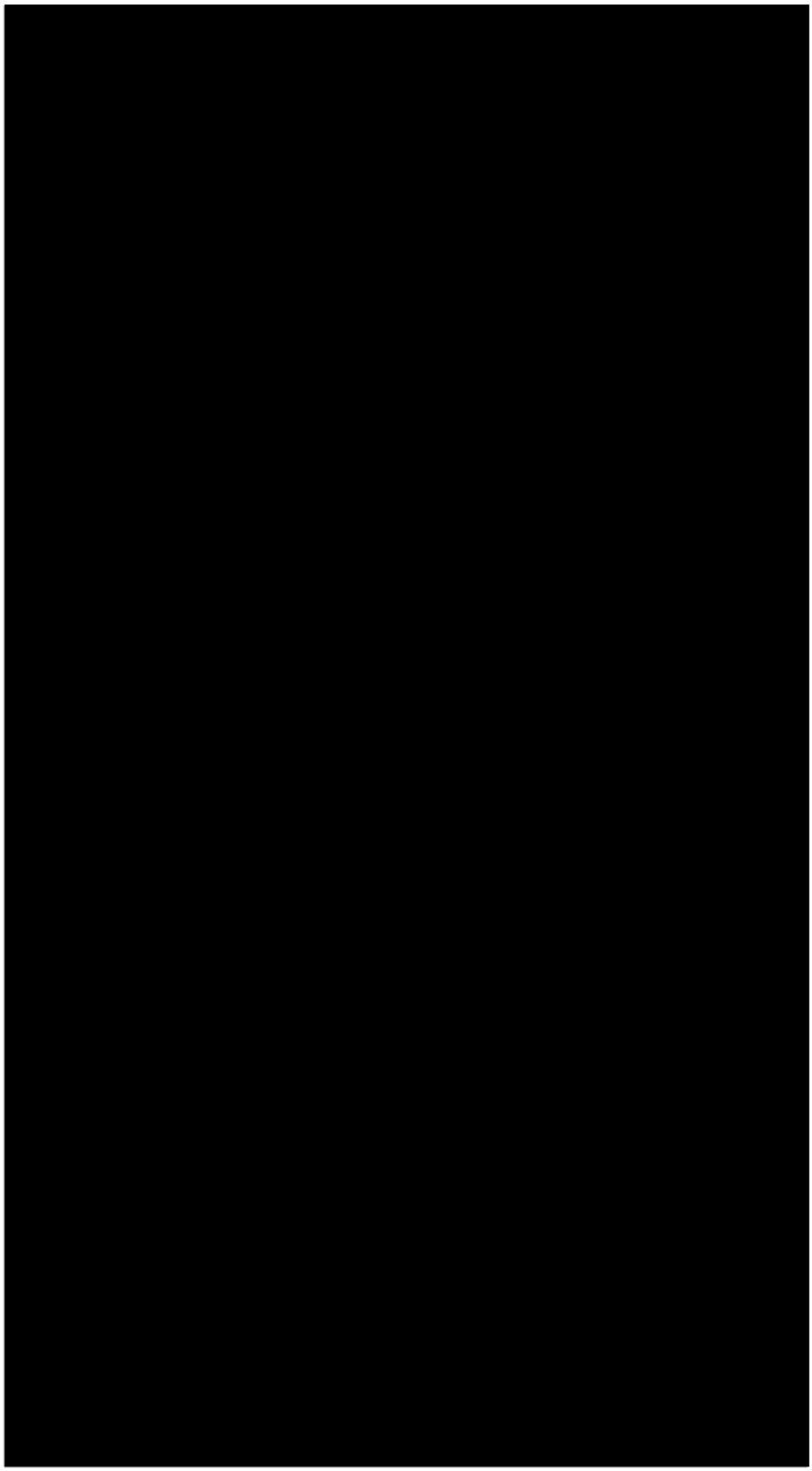
INITIAL U.S. DEVELOPMENT PLAN

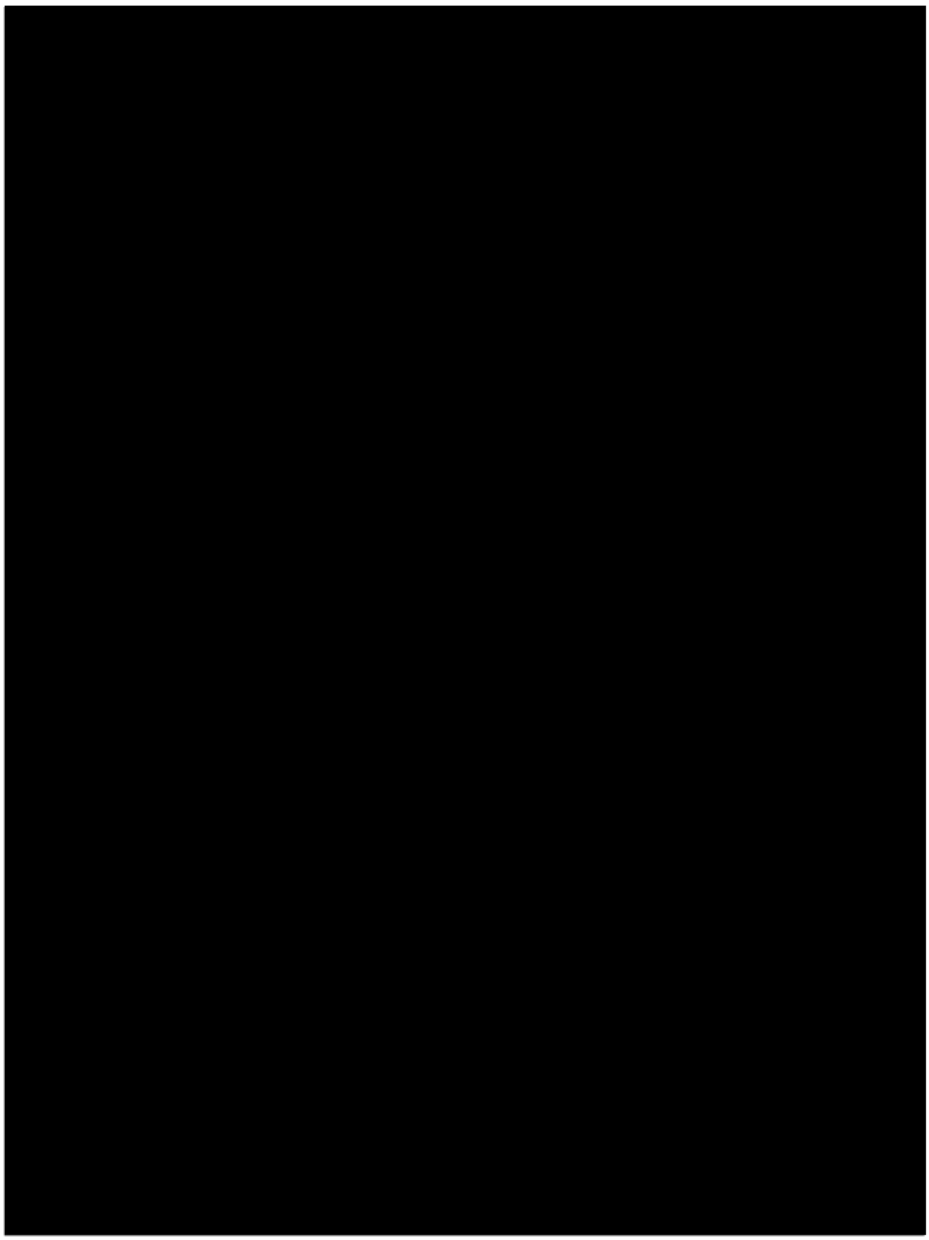
[redacted]











EXHIBITS C AND E
U.S AND ROW DEVELOPMENT PLAN TIMELINES

U.S. DEVELOPMENT PLAN TIMELINE

[redacted]

ROW DEVELOPMENT PLAN TIMELINE

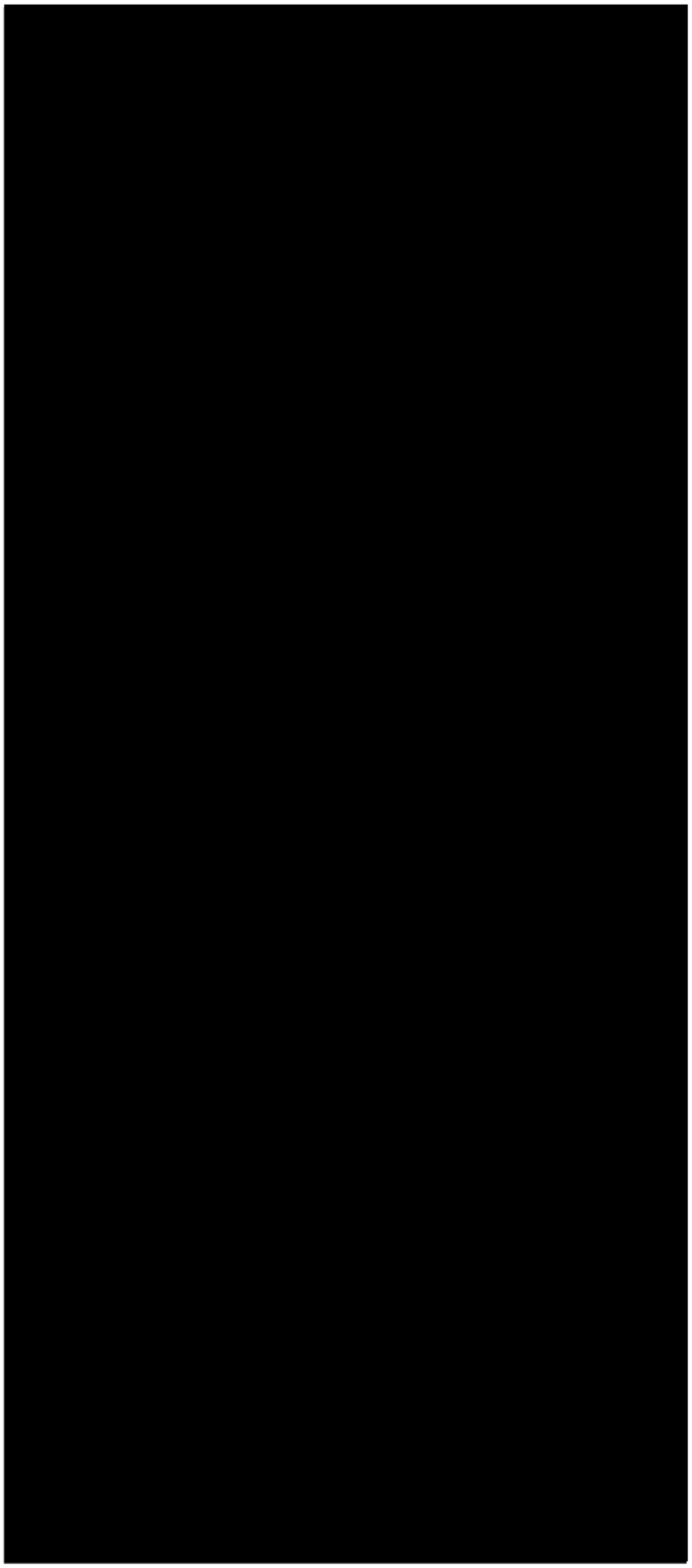
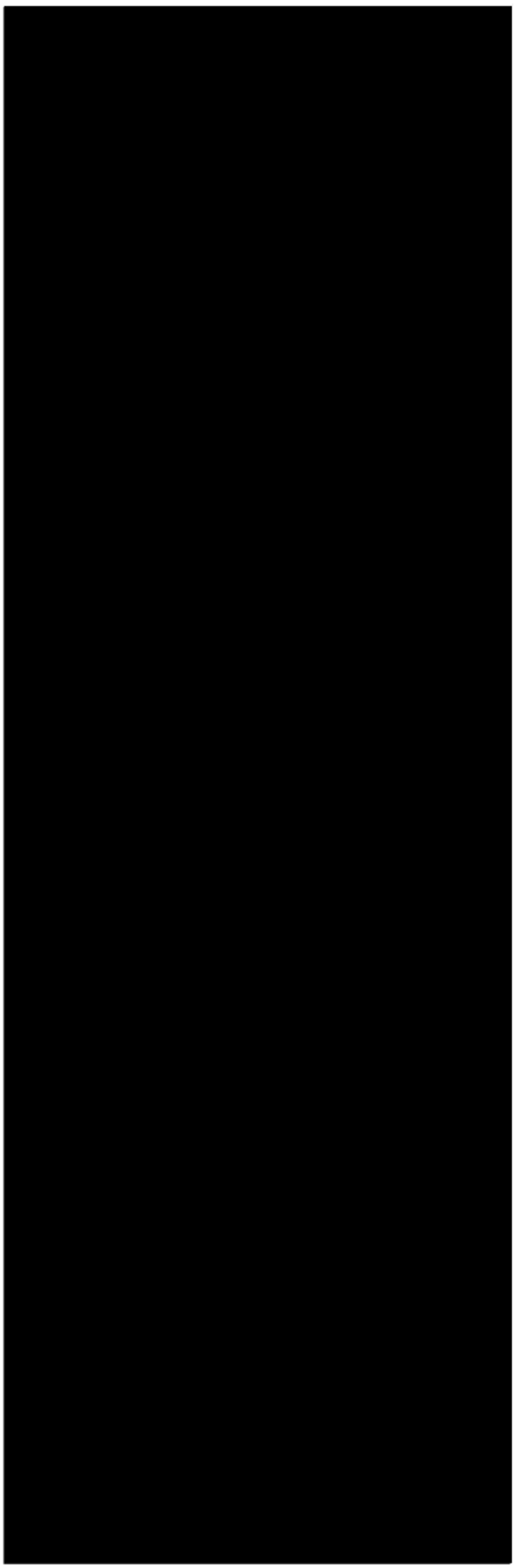


EXHIBIT D

INITIAL ROW DEVELOPMENT PLAN

[redacted]



Patent Owner Ex. 2067
Mylan v. Pozen
IPR2017-01995

EXHIBIT E

ROW DEVELOPMENT PLAN TIMELINE

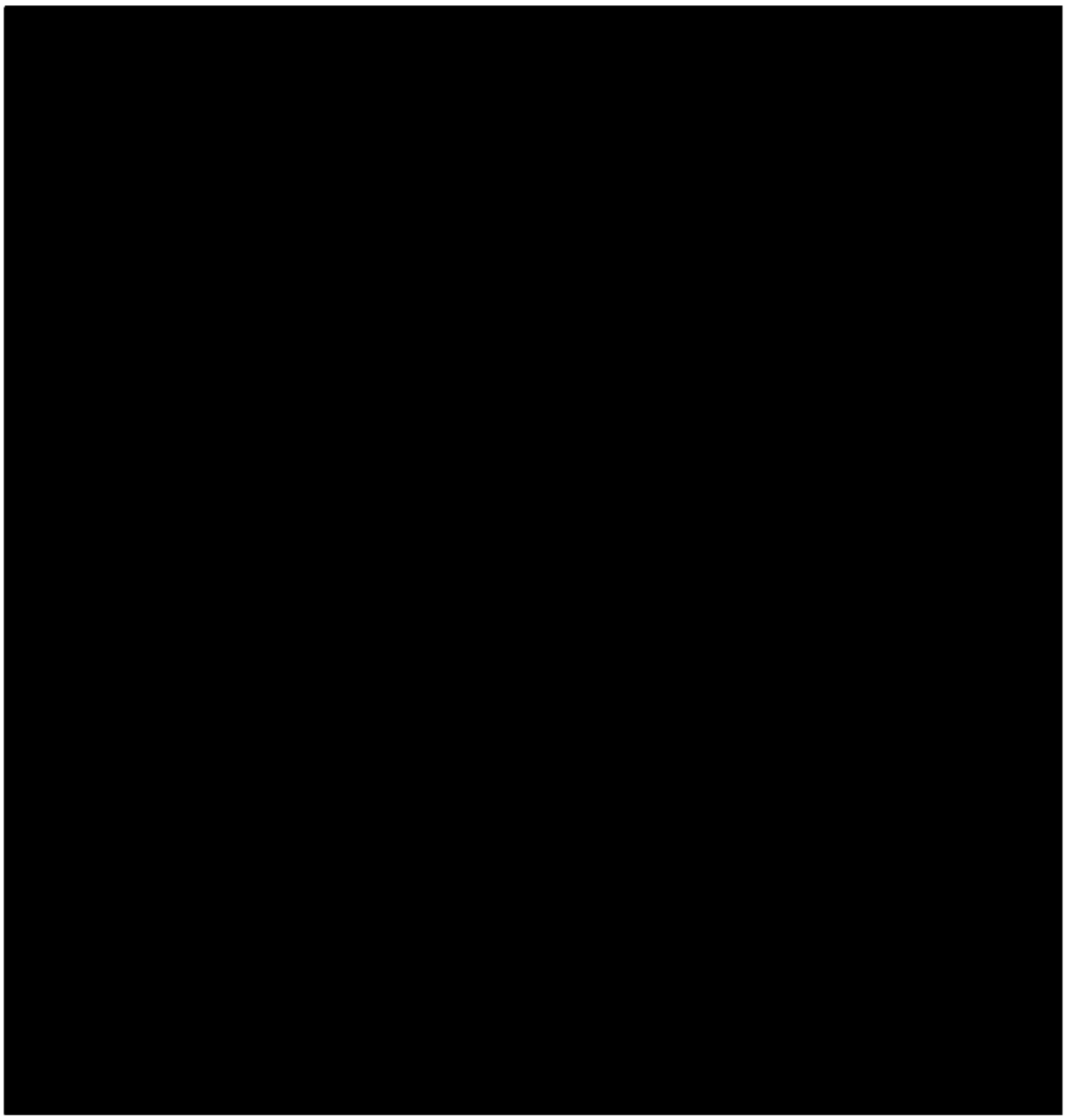
(See Exhibit C)

EXHIBIT F

TPP STUDIES

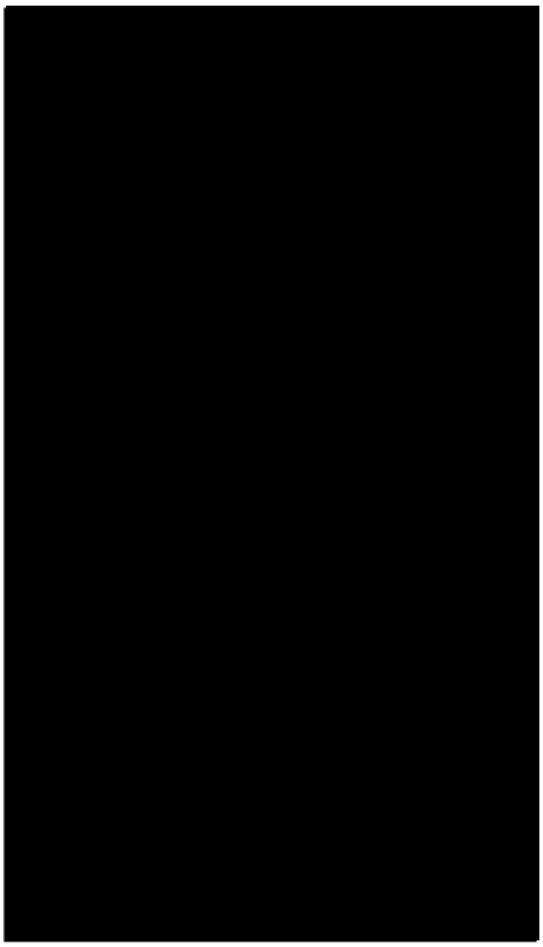
SCHEDULE 1.58

LICENSED PATENTS



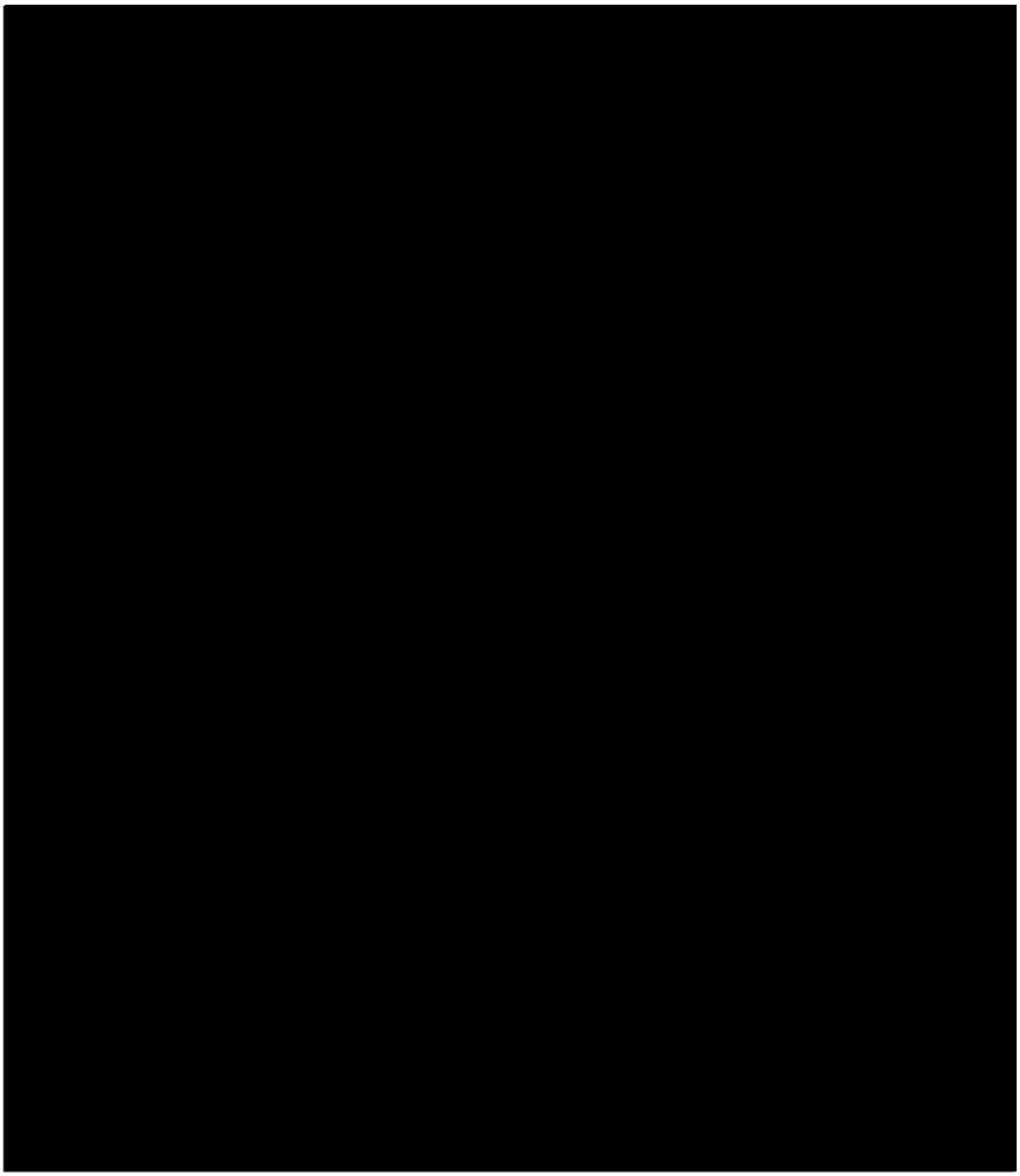
SCHEDULE 4.1.2

IMS MAT DATA

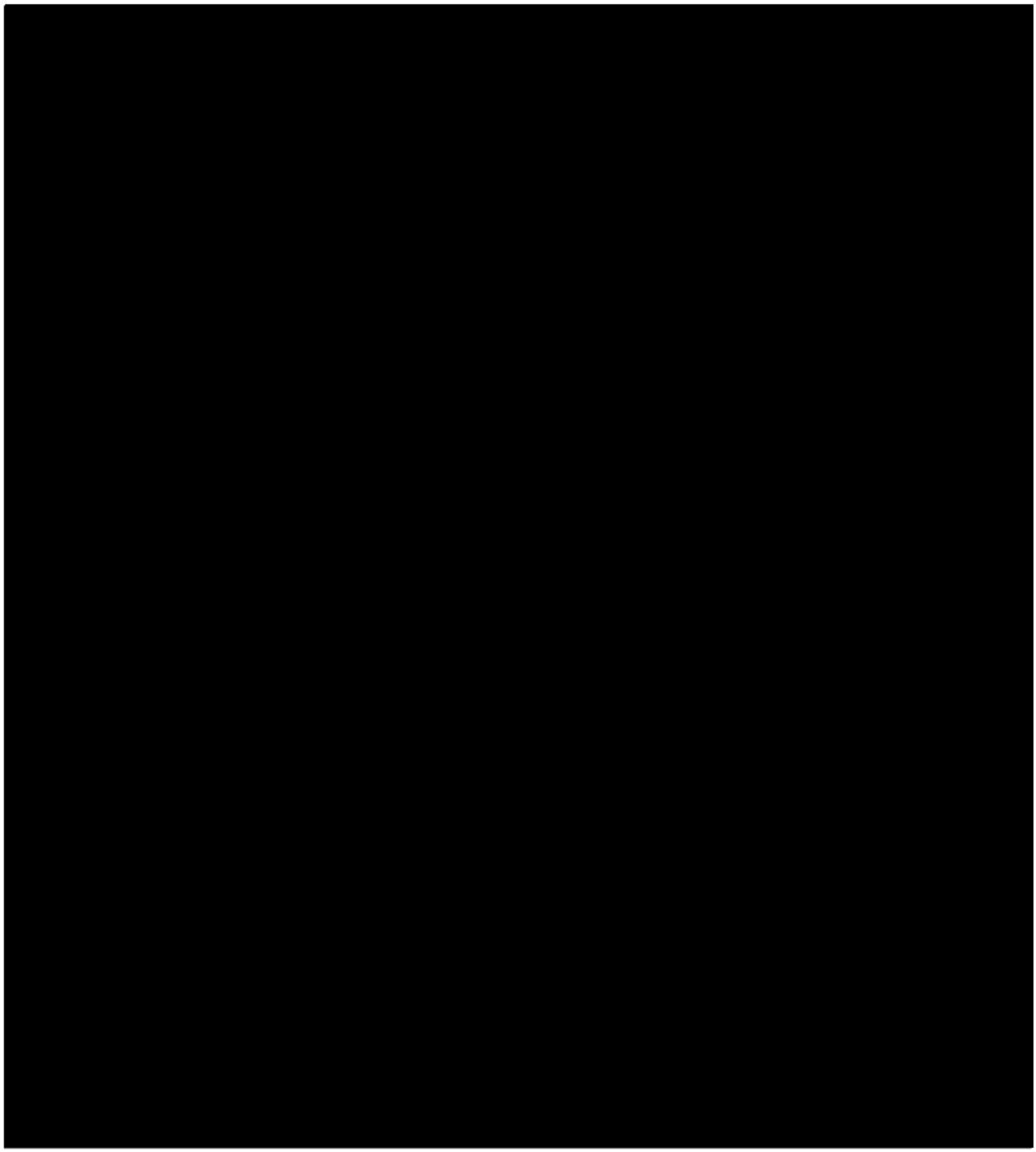


SCHEDULE 6.1

INITIAL POZEN PRODUCT SPECIFICATIONS



SCHEDULE 8.4.1



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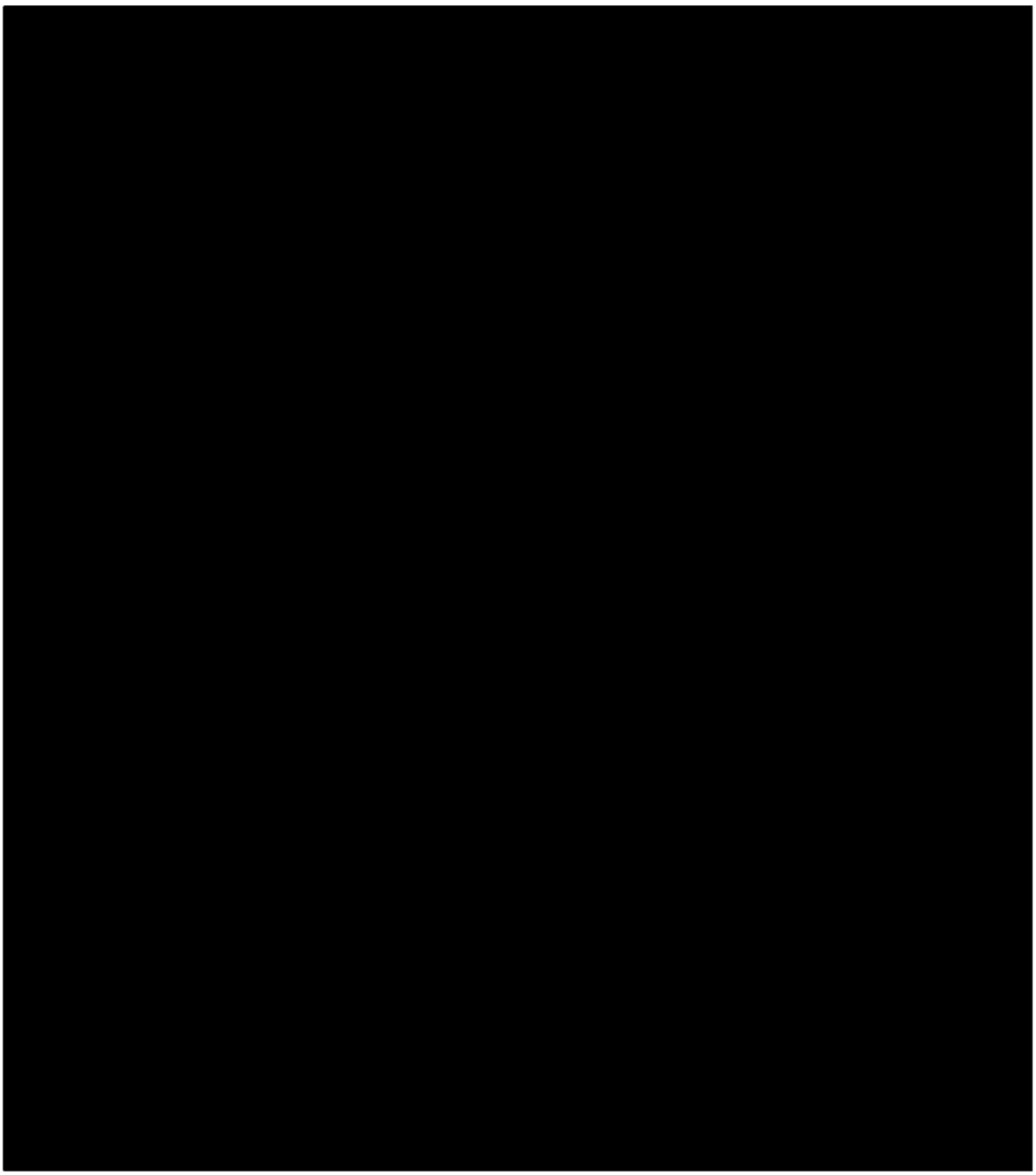

SCHEDULE 10.1

Part 10.1.14 – Agreements

[To be agreed by the Parties prior to the Effective Date]

SCHEDULE 10.7

POZEN Subcontractors

[To be agreed by the Parties prior to the Effective Date]