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

Delaware
(State or other jurisdiction of incorporation or organization)
520 Lake Cook Road, Suite 520
Deerfield, Illinois
(Address of principal executive offices)

27-2179987
(I.R.S. Employer Identification No.)

(224) 383-3000
(Registrant’s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, par value $0.0001 per share
The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒.

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. Large accelerated filer ☐ Accelerated filer ☒
Non-accelerated filer ☒ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

The aggregate market value of the registrant’s voting common stock held by non-affiliates of the registrant, based upon the $2.46 per share closing sale price of the registrant’s common stock on June 28, 2013 (the last business day of the registrant’s most recently completed second quarter), was approximately $128,221,687. Solely for purposes of this calculation, the registrant’s directors and executive officers and holders of 10% or more of the registrant’s outstanding shares of common stock have been assumed to be affiliates and an aggregate of 11,187,697 shares of the registrant’s voting common stock held by such persons on June 28, 2013 are not included in this calculation.

As of March 11, 2014, the registrant had outstanding 67,733,417 shares of its common stock.
Explanatory Note

Horizon Pharma, Inc. (the “Company”) is filing this Amendment No. 1 (the “Amendment”) to its Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 13, 2014 (the “Original Filing”), for the sole purpose of re-filing revised redacted versions of Exhibits 10.43, 10.44, 10.45, 10.46 and 10.49, reflecting changes to the Company’s confidential treatment request with respect to certain portions of the exhibits.

No other changes have been made to the Original Filing or any other exhibits. This Amendment speaks as of the filing date of the Original Filing and does not reflect events occurring after the original filing date or modify or update those disclosures that may be affected by subsequent events.

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report.

1. Financial Statements
   See financial statements listed on the Index to Financial Statements F-3 to F-43 of the Company’s Annual Report on Form 10-K for the year ended December 31, 2013.

2. Financial Statement Schedules
   These schedules have been omitted because the required information is included in the consolidated financial statements or notes thereto or because they are not applicable or not required.

3. Exhibits
   The exhibits listed on the Index to Exhibits filed with this Amendment are filed as part of the Company’s Annual Report on Form 10-K for the year ended December 31, 2013.
Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: May 23, 2014

By: /s/ Robert J. De Vaere

Robert J. De Vaere
Executive Vice President and Chief Financial Officer
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Amendment to Transfer, License and Supply Agreement, dated December 17, 2008, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck Serono GmbH (which was subsequently assigned to Mundipharma Laboratories GmbH in April 2011).

Transfer, License and Supply Agreement, dated March 26, 2009, by and among Horizon Pharma AG, Horizon Pharma GmbH and Merck GesmbH.

Form of Employee Proprietary Information and Inventions Agreement.

Amendment to Transfer, License and Supply Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma Medical Company.

Exclusive Distribution Agreement, dated March 24, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.

Amendment to Exclusive Distribution Agreement, dated July 7, 2009, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.


Amended and Restated Executive Employment Agreement, dated July 27, 2010, by and between Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D. FACP.

Amendment to Manufacturing and Supply Agreement, dated March 4, 2011, by and between Horizon Pharma AG and Jagotec AG.

Manufacturing and Supply Agreement, dated May 25, 2011, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.

Non-Employee Director Compensation Policy.

Sales Contract, dated July 1, 2010, by and between Horizon Pharma USA, Inc. and BASF Corporation.

Manufacturing and Supply Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma Medical Company.

Exclusive Distribution Agreement, dated November 4, 2010 by and between Horizon Pharma AG and Mundipharma International Corporation Limited.


Amendment to Manufacturing and Supply Agreement, effective as of September 25, 2013, by and between Horizon Pharma USA, Inc. and sanofi-aventis U.S. LLC.

Standard Office Lease, effective August 31, 2011, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.

Letter Agreement, dated October 17, 2012, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.

Letter Agreement, dated March 21, 2013, by and among Horizon Pharma AG, Mundipharma International Corporation Limited and Mundipharma Medical Company.

Amendment No. 1 to Exclusive Distribution Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.

Amendment No. 1 to Manufacturing and Supply Agreement, dated March 5, 2012, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.32+(6) Form of Restricted Stock Unit Purchase Agreement.
10.34+(7) Executive Employment Agreement, dated June 1, 2012, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Todd N. Smith.
10.35*(9) First Amendment to Lease, dated July 31, 2012, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.36*(18) Second Amendment to Lease, dated December 10, 2013, by and between Horizon Pharma USA, Inc. and Long Ridge Office Portfolio, L.P.
10.37*(10) Sales Agreement, dated August 14, 2012, between Horizon Pharma, Inc. and Cowen and Company, LLC.
10.39*(18) Amendment No. 2 to Exclusive Distribution Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma International Corporation Limited.
10.40(18) Amendment No. 2 to Manufacturing and Supply Agreement, dated October 25, 2013, by and between Horizon Pharma AG and Mundipharma Medical Company.
10.43* Asset Purchase Agreement, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.
10.44* License Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.
10.45* Supply Agreement, dated November 22, 2013, by and between Horizon Pharma USA, Inc. and AstraZeneca AB.
10.46* Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.
10.47*(18) Amendment No. 1 to Amended and Restated Collaboration and License Agreement for the United States, dated November 18, 2013, by and between Horizon Pharma USA, Inc. and POZEN Inc.
10.48*(18) Letter Agreement, dated November 18, 2013, by and among Horizon Pharma USA, Inc., AstraZeneca AB and POZEN Inc.
10.49* Master Manufacturing Services Agreement, dated October 31, 2013, by and between Horizon Pharma, Inc. and Patheon Pharmaceuticals, Inc.
10.51(15) Capped Call Confirmation, dated November 19, 2013, by and between Horizon Pharma, Inc. and Société Générale.
10.54+(16) First Amendment to Amended and Restated Executive Employment Agreement, dated January 16, 2014, by and among Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Jeffrey W. Sherman, M.D., FACP.
ASSET PURCHASE AGREEMENT

By and between

AstraZeneca AB

and

Horizon Pharma USA, Inc.

Dated as of November 18, 2013
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ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this “Agreement”) is made and executed as of November 18, 2013 (the “Execution Date”), by and between AstraZeneca AB, a Swedish corporation (“AstraZeneca”), and Horizon Pharma USA, Inc., a Delaware corporation (“Horizon”). AstraZeneca and Horizon are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, AstraZeneca and certain of its Affiliates (as defined below) are engaged in the sourcing and Exploitation (as defined below) of the Product in the Horizon Territory (collectively, the “Product Business”);

WHEREAS, AstraZeneca wishes to sell or grant to Horizon, and Horizon desires to purchase or obtain from AstraZeneca, certain assets and rights associated with the Product Business, upon the terms and conditions hereinafter set forth and set forth in the License Agreement (as defined below);

WHEREAS, at the Closing, AstraZeneca and Horizon intend to enter into the Ancillary Agreements, other than the Guarantee, the Three Party Letter Agreement and the Post-Transition Safety Data Exchange Agreement (each as defined below); and

WHEREAS, concurrently with the execution and delivery of this Agreement, AstraZeneca and Horizon Pharma, Inc., a Delaware corporation and ultimate parent company of Horizon (“Guarantor”), has executed and delivered to AstraZeneca the Guarantee, in which the Guarantor has unconditionally guaranteed all obligations of Horizon under this Agreement and the other Ancillary Agreements.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and of the representations, warranties, conditions, agreements and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

1.1 Certain Defined Terms. As used herein, the following terms shall have the following meanings:

1.1.1 “Accountants” means an accounting firm of national reputation in the United States (excluding each of AstraZeneca’s and Horizon’s respective regular outside accounting firms) as may be mutually acceptable to AstraZeneca and Horizon; provided, however, if AstraZeneca and Horizon are unable to agree on such accounting firm within 10 days or any such mutually selected accounting firm is unwilling or unable to serve, then AstraZeneca shall deliver to Horizon a list of three other accounting firms of national reputation in the United States that have not performed services for AstraZeneca or Horizon in the preceding three-year period, and Horizon shall select one of such three accounting firms.
1.1.2 “Accounts Receivable” means all accounts receivable, notes receivable and other indebtedness due and owed by any Third Party to AstraZeneca or any of its Affiliates arising from sales of the Product by or on behalf of AstraZeneca or its Affiliates in the Horizon Territory prior to the Closing Date.

1.1.3 “Act” means the United States Federal Food, Drug, and Cosmetic Act and the guidelines, guidances and requirements promulgated thereunder.

1.1.4 “Adverse Event” means, with respect to a product, any undesirable, untoward or noxious event or experience associated with the use, or occurring during or following administration, of such product in humans, occurring at any dose, whether expected and whether considered related to or caused by such product, including such an event or experience as occurs in the course of the use of such product in professional practice, in a clinical trial, from overdose, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected pharmacological or biological therapeutic action of such product, and including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32, 314.80 or 600.80, as applicable, or to foreign Governmental Authorities under corresponding applicable Law outside the United States.

1.1.5 “Affiliate” means, with respect to a Person, any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.1.6 “Agreement” has the meaning set forth in the preamble hereto.

1.1.7 “Allocation” has the meaning set forth in Section 2.3.2.

1.1.8 “Ancillary Agreements” means the Guarantee, the Supply Agreement, the Bill of Sale, the License Agreement, the Patent Assignment, the Three Party Letter Agreement, the Joint Defense Agreement, the Quality Agreement, the Bailment Agreement, the Patheon Letter, the Vimovo Litigation Records Side Letter, the Transition Agreement, the Post-Transition Safety Data Exchange Agreement and the Transition Safety Data Exchange Agreement.

1.1.9 “APA Licensed Intellectual Property” means the APA Licensed Know-How, the Licensed Copyrights, the Licensed Domain Names, the APA Licensed Trademarks and the APA Manufacturing Technology.

1.1.10 “APA Licensed Know-How” means any data, information and know-how that (a) is not generally known, (b) is Controlled by AstraZeneca or its Affiliates and (c) is used by or on behalf of AstraZeneca or its Affiliates as of the Closing Date for the Exploitation of the Product in the Horizon Territory, but excludes the Merck Know-How and know-how
1.1.11 “APA Licensed Trademarks” means the Trademark VIMOVO and the other Trademarks and logos listed on Schedule 1.1.11.

1.1.12 “APA Manufacturing Technology” means all Patent Rights (including foreign equivalents of the Merck Patents) and all data, information and know-how that (a) with respect to data, information and know-how, are not generally known, (b) are Controlled by AstraZeneca or any of its Affiliates as of the Closing Date and (c) are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Products as of the Closing Date, but excludes the Merck Know-How and Merck Patents; provided, that if any data, information or know-how (but not, for clarity, Patent Rights) included in APA Manufacturing Technology becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 5.5 of this Agreement), such data, information or know-how shall no longer be deemed APA Manufacturing Technology.

1.1.13 “Apportioned Obligations” has the meaning set forth in Section 5.9.2(b).

1.1.14 “Arbitration Notice” has the meaning set forth in Section 9.2.2.

1.1.15 “Arbitrators” has the meaning set forth in Section 9.2.2.

1.1.16 “Assumed Liabilities” has the meaning set forth in Section 2.2.1.

1.1.17 “AstraZeneca” has the meaning set forth in the preamble hereto.

1.1.18 “AstraZeneca Confidential Information” has the meaning set forth in Section 5.5.3.

1.1.19 “AstraZeneca FDA Intent Letters” means the letters to the FDA in the form of Exhibit A, indicating AstraZeneca’s intent to transfer the rights to the Purchased Regulatory Approvals to Horizon.

1.1.20 “AstraZeneca FDA Transfer Letters” means the letters to the FDA in the form of Exhibit B, transferring the rights to the Purchased Regulatory Approvals to Horizon.

1.1.21 “AstraZeneca Indemnitees” has the meaning set forth in Section 7.1.2.

1.1.22 “AstraZeneca Marks” means the trade names, corporate names and corporate logos of AstraZeneca or AstraZeneca’s Affiliates that are used by AstraZeneca or any of AstraZeneca’s Affiliates in connection with the Product in the Horizon Territory or the Product Business prior to or as of the Closing Date, but that are also used by AstraZeneca or any of its Affiliates for any other purpose.
1.1.23 “AstraZeneca Permitted Purpose” has the meaning set forth in Section 5.5.2.

1.1.24 “AstraZeneca Territory” means worldwide, excluding the Horizon Territory.

1.1.25 “AstraZeneca’s Knowledge” means the actual knowledge of the individuals listed on Schedule 1.1.25, after reasonable inquiry in the course of performing their respective duties.

1.1.26 “Bailment Agreement” means that certain Bailment Agreement, in substantially the form of Exhibit C.

1.1.27 “Bill of Sale” means that certain Bill of Sale and Assignment and Assumption Agreement, in substantially the form of Exhibit D.

1.1.28 “Business Day” means any day other than Saturday, Sunday or a day on which banking institutions in New York, New York, United States, London, England or Stockholm, Sweden are permitted or obligated by Law to remain closed.

1.1.29 “Calendar Year” means each successive period of 12 calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the this Agreement shall commence on the Closing Date and end on December 31 of the year in which the Closing Date occurs.

1.1.30 “Carve-Out Financial Statements” has the meaning set forth in Section 5.11.

1.1.31 “cGCP” means the ethical, scientific, and quality standards required by FDA for designing, conducting, recording, and reporting trials that involve the participation of human subjects, as set forth in FDA regulations in 21 C.F.R. Parts 50, 54, 56, and 312, and by the International Conference on Harmonization E6: Good Clinical Practices Consolidated Guideline, or as otherwise required by applicable Law.

1.1.32 “cGMP” means standards and methods to be used in, and the facilities or controls to be used for, the Manufacture of a drug, as set forth in FDA regulations in 21 C.F.R. Parts 210 and 211 or otherwise required by applicable Law.

1.1.33 “Claim Notice” has the meaning set forth in Section 7.2.2.

1.1.34 “Closing” has the meaning set forth in Section 2.4.1.

1.1.35 “Closing Date” means the date on which the Closing occurs.


1.1.37 “Confidential Information” has the meaning set forth in Section 5.5.1.
1.1.38 “Confidentiality Agreement” means that certain Confidentiality Agreement, dated March 7, 2013, by and between AstraZeneca LP and Horizon Pharma, Inc.

1.1.39 “Contract” means any contract, agreement, lease, sublease, license, sublicense or other legally binding commitment or arrangement (whether oral or written).

1.1.40 “Control” means, with respect to any Copyright, Domain Name, Patent Right, Trademark, data, information or other item of know-how, Regulatory Approval or Regulatory Documentation, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the licenses and other grants set forth in the License Agreement and before giving effect to the transactions contemplated by this Agreement), to assign or grant a license, sublicense or other right to or under such Copyright, Domain Name, Patent Right, Trademark, data, information or other item of know-how, Regulatory Approval or Regulatory Documentation, as provided for herein or in any Ancillary Agreement.

1.1.41 “Controlling Party” has the meaning set forth in Section 7.2.2.

1.1.42 “Copyright” means copyrights and rights in copyrightable works, copyright registrations, or any application therefor and all extensions, restorations, reversions and renewals of any of the foregoing.

1.1.43 “Disclosing Party” has the meaning set forth in Section 5.5.1.

1.1.44 “Disclosure Schedules” means the disclosure schedules of AstraZeneca related to the representations and warranties of AstraZeneca set forth in Section 3.1.

1.1.45 “Dispute” has the meaning set forth in Section 9.2.1.

1.1.46 “Domain Names” means any and all internet or global computing network addresses or locations, including all generic top-level domains (“gTLDs”) and country code top-level domains (“ccTLDs”).

1.1.47 “Duexis” means the pharmaceutical product containing ibuprofen and famotidine in a single fixed combination dosage form, which product is being commercialized as of the Closing Date by Horizon or its Affiliates in the Horizon Territory as Duexis®.

1.1.48 “Encumbrance” means, with respect to any Purchased Asset, any mortgage, lien (including liens for Taxes), license, pledge, security interest or encumbrance.

1.1.49 “End Date” has the meaning set forth in Section 8.1.2.

1.1.50 “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 [...***...].

***Confidential Treatment Requested
1.1.51 “Ex-US Licensed Patents” means the Patent Rights that are the foreign equivalents of the Merck Patents, excluding any such Patent Rights included in the APA Manufacturing Technology.

1.1.52 “Excluded Assets” means all assets, property, rights and interests of AstraZeneca and its Affiliates other than the Purchased Assets, including (a) all intellectual property and intellectual property rights of AstraZeneca and its Affiliates other than the Purchased Patents, (b) all rights with respect to the Product in the AstraZeneca Territory, (c) all tangible personal property of AstraZeneca or any of its Affiliates (other than tangible Purchased Assets), (d) all Accounts Receivable, and (e) all Manufacturing-related assets of AstraZeneca or any of its Affiliates.

1.1.53 “Excluded Liabilities” means all Liabilities of AstraZeneca or any of its Affiliates other than the Assumed Liabilities and shall include:

(a) any product liability, liability for adverse reactions, liability for recalls, liability for product and packaging complaints for any Product sold in the Horizon Territory prior to the Closing (whether direct or as a result of or as a result of successor liability, transferee liability, joint and several liability or contractual liability) or any Liability for Litigation relating to the Product, Purchased Assets, the APA Licensed Intellectual Property, the ex-US Licensed Patents or the Licensed Regulatory Documentation pending or overtly threatened prior to the Closing other than the Vimovo Litigation;

(b) any Liability (whether direct or as a result of successor liability, transferee liability, joint and several liability or contractual liability) for Taxes in the Pre-Closing Tax Period except to the extent provided in Section 5.9;

(c) any Liability under or relating to or arising from any Excluded Assets;

(d) any Liability (whether arising under Contract or otherwise) to Pozen or Merck relating to the Product Business or Purchased Assets, other than Liability under the Pozen US Agreement arising after the Closing;

(e) any Liability arising out of or resulting from non-compliance with any Law by AstraZeneca or its Affiliates with respect to the Product Business or Purchased Assets prior to the Closing;

(f) any Liability of AstraZeneca or any of its Affiliates to pay any fees or commissions to any broker, finder or agent with respect to this Agreement or the transactions contemplated hereby; and

(g) any Liability of AstraZeneca or any of its Affiliates relating to sale of the Product outside the Horizon Territory prior to, on and after the Closing.

For clarity, the “Excluded Liabilities” do not include any Liability arising out of or relating to any Product or Other Product sold by or on behalf of Horizon; provided, that

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each Party’s Liability with respect to Product sold on behalf of Horizon by AstraZeneca or its Affiliate pursuant to the Transition Agreement shall be as set forth in the Transition Agreement.

1.1.54 “Execution Date” has the meaning set forth in the preamble hereto.

1.1.55 “Existing Inventory” means inventory of finished Product (together with any Product packaging materials thereon) owned by AstraZeneca or any of its Affiliates as of Closing that is labeled and held for sale in the Horizon Territory and has not been shipped to a wholesaler or distributor prior to the Closing.

1.1.56 “Exploit” means to make, have made, import, export, use, have used, sell, offer for sale, have sold, research, develop, commercialize, register, hold or keep (whether for disposal or otherwise), transport, distribute, promote, market, or otherwise dispose of, but excludes, to Manufacture or have Manufactured.

1.1.57 “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.1.58 “Field” means the treatment of human diseases and conditions by means of a pharmaceutical product.

1.1.59 “Financial Information” has the meaning set forth in Section 3.1.13.

1.1.60 “Fundamental Reps” means the representations and warranties set forth in in Section 3.1.1 (Entity Status), Section 3.1.2 (Authority), Section 3.1.4 (No Broker), Section 3.1.6(a) (Title to the Purchased Assets), Section 3.2.1 (Corporate Status), Section 3.2.2 (Authority) and Section 3.2.4 (No Broker).

1.1.61 “GAAP” means generally accepted accounting principles in the United States.

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

1.1.63 “Governmental Authority” means any supranational, international, federal, state or local court, administrative agency or commission or other governmental authority or instrumentality, domestic or foreign, including the FDA and any corresponding foreign agency.

1.1.64 “Guarantee” means the Guarantee, dated the Execution Date, by Guarantor in favor of AstraZeneca.

1.1.65 “Guarantor” has the meaning set forth in the recital hereto.

1.1.66 “Horizon” has the meaning set forth in the preamble hereto.
1.1.67 “Horizon Confidential Information” has the meaning set forth in Section 5.5.2.

1.1.68 “Horizon FDA Intent Letters” means the letters to the FDA in the form of Exhibit E, indicating Horizon’s intent to accept the transfer of rights to the Purchased Regulatory Approvals from AstraZeneca.

1.1.69 “Horizon FDA Transfer Letters” means the letters to the FDA in the form of Exhibit F, accepting the transfer of rights to the Purchased Regulatory Approvals from AstraZeneca.

1.1.70 “Horizon Indemnitees” has the meaning set forth in Section 7.1.1.

1.1.71 “Horizon Material Adverse Effect” means any event, fact, condition, occurrence, change or effect that prevents or materially impedes or delays the consummation by Horizon of the transactions contemplated by this Agreement or the Ancillary Agreements.

1.1.72 “Horizon Permitted Purpose” has the meaning set forth in Section 5.5.3.

1.1.73 “Horizon Territory” means the United States and its territories and possessions.

1.1.74 “IND” means an Investigational New Drug Application as defined in the Act.

1.1.75 “Indemnification Certificate” has the meaning set forth in Section 7.2.1.

1.1.76 “Indemnified Party” has the meaning set forth in Section 7.2.1.

1.1.77 “Indemnifying Party” has the meaning set forth in Section 7.2.1.

1.1.78 “Joint Defense Agreement” means the certain Joint Defense Agreement executed and delivered by the Parties on the Execution Date.

1.1.79 “Law” means any domestic or foreign, federal, state or local statute, law, treaty, judgment, ordinance, rule, administrative interpretation, regulation, guidance, order or other requirement of any Governmental Authority, in each case, that has the force of law.

1.1.80 “Liabilities” means any debts, liabilities, obligations, commitments, claims or complaints, whether accrued or fixed, known or unknown, fixed or contingent, determined or determinable (including all adverse reactions, recalls, product and packaging complaints and other liabilities) and whether or not the same would be required to be reflected in financial statements or disclosed in the notes thereto.

1.1.81 “License Agreement” means that certain License Agreement, in substantially the form of Exhibit G.
1.1.82 “Licensed Copyrights” means all Copyrights in the Horizon Territory that are Controlled by AstraZeneca and that are used by AstraZeneca or any of AstraZeneca’s Affiliates in connection with the Product Business, including those Copyrights listed on Schedule 1.1.82(a) and excluding the Copyrights listed as excluded on Schedule 1.1.82(b).

1.1.83 “Licensed Domain Names” means the Domain Names listed on Schedule 1.1.83.

1.1.84 “Licensed Regulatory Documentation” means any and all Regulatory Documentation related to the Product or any Other Product, in each case, Controlled by AstraZeneca or any of its Affiliates as of and following the Closing, excluding the Regulatory Documentation included in the Purchased Assets.

1.1.85 “Litigation” means any claim, action, arbitration, mediation, hearing, investigation, proceeding, litigation, suit, warning letter, findings of deficiency or non-compliance, notice of violation or request for recall (whether civil, criminal, administrative, investigative or informal).

1.1.86 “Loss” or “Losses” means any Liabilities, losses, damages, judgments, assessments, levies, fines, penalties, amounts paid in settlement, costs and expenses, including reasonable fees and disbursements of counsel and accountants’, investigators’, and experts’ fees and expenses.

1.1.87 “Manufacture” and “Manufacturing” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.1.88 “Material Adverse Effect” means an event, fact, condition, occurrence, change or effect that is, or would reasonably be expected to (a) be materially adverse to the business, results of operations or condition (financial or otherwise) of the Product Business, the Purchased Assets and the Assumed Liabilities, taken as a whole, or (b) prevent or materially impede or delay the consummation by AstraZeneca of the transactions contemplated by this Agreement and the Ancillary Agreements; provided, however, that, except as provided in clause (vii) below, none of the following, and no events, facts, conditions, occurrences, changes or effects resulting from the following, shall be deemed (individually or in combination) to constitute, or shall be taken into account in determining whether there has been, a “Material Adverse Effect”: (i) political or economic conditions in the Horizon Territory or conditions affecting the capital or financial markets generally; (ii) conditions generally affecting any industry or industry sector in which the Product Business operates or competes or in which the Product is Manufactured or Exploited, including increases in operating costs; (iii) any change in accounting requirements or applicable Law; (iv) any hostility, act of war, sabotage, terrorism or military actions, or any escalation of any of the foregoing; (v) any hurricane, flood, tornado, earthquake or other natural disaster or force majeure event; (vi) the public announcement of the execution or delivery of the Agreement or the pendency of the transactions contemplated hereby; (vii) the failure of the Product Business to achieve any financial projections, predictions or
forecasts (provided, that the underlying causes of such failure shall not be excluded); and (viii) the taking of any action by AstraZeneca or any of its Affiliates that is expressly contemplated by this Agreement or that Horizon has expressly requested be taken; except, in each of clauses (i) through (v), for those conditions that have a disproportionate effect on the Product Business, the Purchased Assets and Assumed Liabilities, taken as a whole, relative to other Persons operating businesses similar to the Product Business in the Horizon Territory.

1.1.89 “Merck Agreements” means any agreement between AstraZeneca or any of its Affiliates, on the one hand, and any Merck Party or any of its Affiliates, on the other hand, with respect to, among other things, Esomeprazole, as amended.

1.1.90 “Merck” means Merck Sharp & Dohme Corp.

1.1.91 “Merck Covenant” has the meaning set forth in Section 2.1.2.

1.1.92 “Merck-Exploitation” means the act of making, having made, manufacturing, having manufactured, developing, using, selling, offering for sale, importing, exporting, marketing or promoting a product.

1.1.93 “Merck Know-How” means any data, information and know-how that (a) is not generally known, (b) is owned or otherwise controlled by a Merck Party pursuant to one or more Merck Agreements and (c) is used by or on behalf of AstraZeneca or its Affiliates as of the Execution Date or the Closing Date, for the Manufacture, having Manufactured or Exploitation of the Product in the Horizon Territory.

1.1.94 “Merck Parties” means Merck, KBI Inc., KBI-E Inc., Merck Holdings, Inc. and KBI Sub Inc.

1.1.95 “Merck Patent Litigation” has the meaning set forth in Section 5.1.3.

1.1.96 “Merck Patents” means the Patent Rights set forth on Schedule 1.1.96.

1.1.97 “Merck Product” means any product that both (a) combines (as the sole active ingredients) Esomeprazole and a therapeutic level of Naproxen in any fixed combination dosage form and (b) is marketed and promoted [...***...] for (x) one or more indications for which [...***...], together with (y) the prevention, treatment or amelioration of, or decrease in the risk of, [...***...] in patients at risk of [...***...], so long as such prevention, treatment or amelioration of, or decrease in the risk of, [...***...] is described or referenced in the product prescribing information.

1.1.98 “Merck-Related Persons” has the meaning set forth in Section 2.1.2.

1.1.99 “Naproxen” means that certain pharmaceutical compound with the chemical name (S)-6-methoxy-(alpha)-methyl-2-naphthaleneacetic acid, including any [...***...].

1.1.100 “NDA” means a New Drug Application as defined in the Act.

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1.1.101 “NDC” means “National Drug Code,” which is the eleven digit code registered by a company with the FDA with respect to a pharmaceutical product.

1.1.102 “Nexium” means any product containing Esomeprazole as the sole active ingredient in any presentation form that is sold under a Nexium Trademark.

1.1.103 “Nexium Business” means Exploitation activities pertaining to Nexium.

1.1.104 “Nexium Trademark” means the Trademarks and logos listed on Schedule 1.1.104.

1.1.105 “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).

1.1.106 “Non-Controlling Party” has the meaning set forth in Section 7.2.2.

1.1.107 “Notice” has the meaning set forth in Section 9.3.1.

1.1.108 “Other Product” means (a) any product, other than the 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 Pozen Patents, infringe one or more Valid Claims of the Pozen Patents and (b) any product, other than the Product and any product described in clause (a), 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) where the right to Exploit such product is owned or Controlled by AstraZeneca or its Affiliates. For the avoidance of doubt, “Other Product” does not include any product containing acetyl salicylic acid (including salts and derivatives thereof) and does not include DUEXIS.

1.1.109 “Owned Registered Product IP” has the meaning set forth in Section 3.1.11(b).

1.1.110 “Party(ies)” has the meaning set forth in the preamble hereto.

1.1.111 “Patent Assignment” means that certain Patent Assignment, in substantially the form of Exhibit H.

1.1.112 “Patent Rights” means: (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisions and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing.
patents or patent applications; and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.1.113 “Patheon Letter” means that certain Letter, in substantially the form of Exhibit I.

1.1.114 “Payee” has the meaning set forth in Section 5.9.1.

1.1.115 “Payer” has the meaning set forth in Section 5.9.1.

1.1.116 “Payments” has the meaning set forth in Section 5.9.1.

1.1.117 “Permitted Encumbrance” means any (a) Encumbrance for accrued Taxes not yet due or delinquent or for those Taxes being contested in good faith by appropriate proceedings for which an adequate reserve has been taken; (b) Encumbrance caused by Law that does not or would not be reasonably expected to materially detract from the current value of, or materially interfere with, the present use and enjoyment of any Purchased Asset subject thereto or affected thereby in the ordinary course of business of the Product Business; (c) right, title or interest of a licensor or licensee under a license that is reasonably apparent from the text of the applicable license agreement, provided that any such license is disclosed on Schedule 1.1.117 and made available to Horizon prior to the Execution Date and (d) any Encumbrance disclosed on Schedule 1.1.117.

1.1.118 “Person” means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

1.1.119 “Post-Closing Tax Period” has the meaning set forth in Section 5.9.2(b).

1.1.120 “Post-Transition Safety Data Exchange Agreement” means that certain Safety Data Exchange Agreement, in a form reasonably acceptable to each Party, to be executed by the Parties prior to the transfer of the Purchased Regulatory Approvals to Horizon.

1.1.121 “Pozen” means Pozen Inc.

1.1.122 “Pozen Original Agreement” means that certain Collaboration and License Agreement, dated August 1, 2006, but and between Pozen and AstraZeneca, as amended as of the Execution Date.

1.1.123 “Pozen Patent Litigation” has the meaning set forth in Section 5.1.2.

1.1.124 “Pozen Patents” means the Patent Rights set forth on Schedule 1.1.124.
1.1.125 “Pozen ROW Agreement” means that certain Amended and Restated Collaboration and License Agreement for outside the United States, dated on or prior to the Closing Date, by and between Pozen and AstraZeneca.

1.1.126 “Pozen US Agreement” means that certain Amended and Restated Collaboration and License Agreement for the United States, dated on or prior to the Closing Date, by and between Pozen and AstraZeneca, in substantially the form of Exhibit J.

1.1.127 “Pre-Closing Period” has the meaning set forth in Section 4.1.1.

1.1.128 “Pre-Closing Tax Period” has the meaning set forth in Section 5.9.2(b).

1.1.129 “Product” means the pharmaceutical product(s) containing non-enteric coated Esomeprazole and enteric-coating Naproxen that is the subject of NDA#22-511 in the Horizon Territory, which products are being commercialized by AstraZeneca or its Affiliates as of the Execution Date in the Horizon Territory as VIMOVO™.

1.1.130 “Product Business” has the meaning set forth in the first recital hereto.

1.1.131 “Product Promotional Materials” means all Product materials that have been submitted by or on behalf of AstraZeneca or its Affiliates to the FDA under Form 2253, and the advertising, promotional and media materials, sales training materials (including related quizzes and answers, if any), existing customer lists, co-pay cards, other marketing data and materials, trade show materials (including displays) and videos, including materials containing clinical data, if any, to the extent approved for use by AstraZeneca’s internal promotional review process for the commercialization of the Product in the Horizon Territory until December 31, 2013.

1.1.132 “Product Records” means all books and records relating exclusively to the Product in the Horizon Territory or to the Product Business (other than the Regulatory Documentation) to the extent owned by or maintained by or on behalf of AstraZeneca or any of its Affiliates, but excluding, in all cases, the following books, documents, records and files (a) all books, documents, records and files prepared for the transactions contemplated under this Agreement, including bids received from Third Parties and strategic, financial or Tax analyses relating to the divestiture of the Purchased Assets, the Assumed Liabilities, the Product and the Product Business (b) all books, documents, records and files related solely to the Manufacture of the Product, (c) any attorney work product, attorney client communications and other items protected by established legal privilege, unless the books and records can be transferred without losing such privilege, (d) human resources and any other employee books and records, (e) any financial, Tax and accounting records to the extent not related to the Product in the Horizon Territory, (f) all books and records related to the Merck Patents or the Merck Parties, and (g) any items to the extent applicable Law prohibits their transfer.

1.1.133 “Purchase Price” has the meaning set forth in Section 2.3.1.

1.1.134 “Purchased Assets” has the meaning set forth in Section 2.1.1.

1.1.135 “Purchased Contracts” has the meaning set forth in Section 2.1.1(a).
1.1.136 “Purchased Patents” means the Patent Rights that are listed on Schedule 1.1.136.

1.1.137 “Purchased Regulatory Approvals” has the meaning set forth in Section 2.1.1(b).

1.1.138 “Quality Agreement” means that certain Quality Agreement, dated as of the Closing Date, in substantially the form of Exhibit K.

1.1.139 “Receiving Party” has the meaning set forth in Section 5.5.1.

1.1.140 “Regulatory Approval” means, with respect to the Product or any Other Product, any and all approvals (including NDAs and supplements and amendments thereto and active INDs), licenses, registrations (except manufacturing establishment registrations) or authorizations of any Governmental Authority necessary to commercially distribute, sell or market the Product or such Other Product, as applicable, including, where applicable, (a) pricing or reimbursement approvals, (b) pre- and post-approval marketing authorizations, and (c) labeling approvals.

1.1.141 “Regulatory Authority” means any Governmental Authority that is concerned with the safety, efficacy, reliability, Manufacture, investigation, sale or marketing of pharmaceutical products, medical products, biologics or biopharmaceuticals, including the FDA.

1.1.142 “Regulatory Documentation” means, with respect to the Product or any Other Product, all (a) documentation comprising the Regulatory Approvals, including all submissions, reports and correspondence relating thereto, (b) correspondence and reports necessary to, or otherwise describing the ability to, commercially distribute, sell or market the Product or such Other Product, as applicable, submitted to or received from Governmental Authorities (including minutes and official contact reports relating to any communications with any Governmental Authority) and relevant supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, annual and periodic reports, adverse event files and complaint files and (c) data (including clinical and pre-clinical data and CMC data) contained in any of the foregoing. Regulatory Documentation excludes the Product core data sheet, which shall be retained by AstraZeneca or an Affiliate of AstraZeneca commensurate with continuing safety responsibilities for the Product.

1.1.143 “Representatives” has the meaning set forth in Section 4.1.1.

1.1.144 “Required Actions” has the meaning set forth in Section 3.1.11(b)

1.1.145 “Senior Officer” means, with respect to AstraZeneca, its Vice President, Cornerstone and Commercial Excellence, and with respect to Horizon, its Chief Executive Officer.

1.1.146 “Supply Agreement” means that certain Supply Agreement, in substantially the form attached as Exhibit L.
1.1.147 “Tax Return” means any return, declaration, report, claim for refund, information return or statement relating to Taxes, including any schedule or attachment thereto, filed or maintained, or required to be filed or maintained, in connection with the calculation, determination, assessment or collection of any Tax and includes any amended returns required as a result of examination adjustments made by the Internal Revenue Service or other Tax authority.

1.1.148 “Taxes” means all taxes of any kind, and all charges, fees, customs, levies, duties, imposts, required deposits or other assessments, including all federal, state, local or foreign net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker’s compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any Person by any taxing authority or other Governmental Authority under applicable Law.

1.1.149 “Third Party” means any Person other than AstraZeneca, Horizon and their respective Affiliates and permitted successors and assigns.

1.1.150 “Third Party Claim” has the meaning set forth in Section 7.2.2.

1.1.151 “Three Party Letter Agreement” means the letter agreement among AstraZeneca, Horizon and Pozen, dated as of the Execution Date.

1.1.152 “Trademark” means any word, name, symbol, color, product shape, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, product configuration, logo or business symbol, whether or not registered.

1.1.153 “Transfer Taxes” has the meaning set forth in Section 5.9.2(a).

1.1.154 “Transition Agreement” means that certain agreement relating to transition of the Product Business attached as Exhibit M.

1.1.155 “Transition Period” means the period commencing on the Closing Date and ending on the date specified in the Transition Agreement.

1.1.156 “Transition Safety Data Exchange Agreement” means that certain Safety Data Exchange Agreement, in substantially the form attached as Exhibit N.

1.1.157 “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 [...] years after the earliest priority date of such application will not be a “Valid Claim” until such claim issues as a patent claim.

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1.1.158 “Vimovo Litigation” means any and all Litigation arising out of or related to the submission of Abbreviated New Drug Applications to FDA referencing NDA #22-511 that is described on Schedule 1.1.158.

1.1.159 “Vimovo Litigation Records Side Letter” means that certain Side Letter, in substantially the form attached as Exhibit O.

1.1.160 “[...***...]” has the meaning set forth in Section [... ***...].

1.2 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall 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 does not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article, Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,” “hereto,” “hereby,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto; and (g) references to monetary amounts are denominated in United States Dollars.

ARTICLE 2
SALE AND PURCHASE OF ASSETS; LIABILITIES; TRANSITIONAL TRADEMARK LICENSE

2.1 Sale of Purchased Assets.

2.1.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the conditions of this Agreement and the Ancillary Agreements, at and effective as of the Closing, AstraZeneca shall (or shall cause its applicable Affiliates to) sell, transfer, convey, assign and deliver to Horizon, and Horizon shall purchase and accept from AstraZeneca (or such Affiliates), all right, title and interest in and to the Purchased Assets, free and clear of any and all Encumbrances other than Permitted Encumbrances. As used herein, “Purchased Assets” means all right, title and interest of AstraZeneca (or its Affiliates) in and to the following assets and properties:

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(a) all Contracts listed on Schedule 2.1.1(a), excluding, in each case, all rights to any Accounts Receivable and any other rights, claims or causes of action (including warranty claims) of AstraZeneca or any of its Affiliates thereunder related to Excluded Assets or Excluded Liabilities (the “Purchased Contracts”);

(b) all Regulatory Approvals listed on Schedule 2.1.1(b) from and after the Closing (the “Purchased Regulatory Approvals”);

c) the documentation comprising the Purchased Regulatory Approvals, including all submissions, reports and correspondence relating thereto, and, to the extent in the possession or Control of AstraZeneca or any of its Affiliates, all other Regulatory Documentation exclusively relating to the Product in the Horizon Territory;

d) all Product Records;

e) all Product Promotional Materials; and

(f) the Purchased Patents, including the right to sue and recover for past, present or future infringements, misappropriations, dilution, unauthorized use or disclosure, or other conflict with any of the Purchased Patents.

2.1.2 Merck Covenant. AstraZeneca represents and warrants to Horizon that [...***...] each of the Merck Parties has agreed that neither it nor any of its Affiliates nor any other Person (to the extent any Merck Party or any Affiliate thereof has the ability (directly or indirectly) to control the actions of such other Person with respect to the matters described in this section) (collectively, the “Merck-Related Persons”) shall institute, pursue, solicit, encourage or assist any action or actions, cause or causes of action (in law or at equity), suits, arbitration proceedings or claims [...***...] against or adverse to any licensee or sublicensee of either AstraZeneca or Pozen asserting that the Merck-Exploitation of Merck Product infringes any patent application or patent [...***...] that claims or covers a Merck Product or any components or intermediates thereof or the bulk chemical forms of any compounds [...***...] (such agreement, the “Merck Covenant”). AstraZeneca agrees that, from and after the Closing Date [...***...] Horizon shall be entitled to the benefit of the Merck Covenant as provided in this Agreement to the extent that the Manufacture, having Manufactured and Exploitation of any Products and Other Products in the Field in the Horizon Territory by Horizon and its Affiliates, licensees and sublicensees would constitute Merck-Exploitation of a Merck Product. [...***...] in the event that any Merck-Related Person breaches the Merck Covenant [...***...]

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2.1.3 Excluded Assets. Horizon shall not acquire pursuant to this Agreement or any Ancillary Agreement, and AstraZeneca shall retain following the Closing Date, the Excluded Assets.

2.1.4 No Rights in the Other Party’s Territory. Horizon acknowledges and agrees that, except for the license and Manufacturing rights granted to Horizon pursuant to the License Agreement and the Supply Agreement, Horizon shall not receive any rights by virtue of this Agreement or any Ancillary Agreement in the AstraZeneca Territory. AstraZeneca acknowledges and agrees that, except for the license rights granted to AstraZeneca pursuant to the License Agreement and the rights retained by AstraZeneca under this Agreement or the License Agreement, AstraZeneca shall not receive any rights to any of Horizon’s intellectual property or Regulatory Documentation by virtue of this Agreement or any Ancillary Agreement in the Horizon Territory.

2.1.5 Retention of Rights. AstraZeneca retains, on behalf of itself and its Affiliates, a non-exclusive right of reference and use under the Purchased Regulatory Approvals and the Regulatory Documentation included in the Purchased Assets, as may be necessary or useful (a) to perform its obligations under the Supply Agreement, the Quality Agreement, the Transition Agreement, the Transition Safety Data Exchange Agreement or the Post-Transition Safety Data Exchange Agreement or (b) to Manufacture or have Manufactured the Product or any Other Product in the Horizon Territory or to perform research and development activities with respect to the Product or any Other Product in the Horizon Territory, in each case solely to support Exploitation of the Product or any Other Product in the AstraZeneca Territory.

2.2 Liabilities.

2.2.1 Assumed Liabilities. Upon the terms and subject to the conditions of this Agreement, at the Closing, AstraZeneca shall assign and Horizon shall unconditionally assume and agree to pay and discharge when due (a) all Liabilities of AstraZeneca and its ***Confidential Treatment Requested
2.2.2 Excluded Liabilities. Horizon shall not assume any Liabilities of AstraZeneca or any of its Affiliates other than the Assumed Liabilities, and the Excluded Liabilities shall remain the sole obligation and responsibility of AstraZeneca and its Affiliates.

2.3 Consideration.

2.3.1 Purchase Price. In consideration of the conveyances contemplated under Section 2.1, the rights granted to Horizon under the License Agreement and the benefit of the Merck Covenant and the Product samples to be supplied to Horizon by AstraZeneca or an Affiliate pursuant to the Transition Agreement, on the Closing Date, Horizon shall pay to AstraZeneca $35,000,000 (the "Purchase Price"), by wire transfer of immediately available funds to the account designated by AstraZeneca by notice to Horizon at least three Business Days prior to the Closing Date.

2.3.2 Allocation of Consideration. Horizon shall allocate the Purchase Price (including the Assumed Liabilities, to the extent properly taken into account under Section 1060 of the Code), among the APA Licensed Intellectual Property, the Ex-US Licensed Patents, the Licensed Regulatory Documentation and the Purchased Assets (the "Allocation") prior to or within 60 days following the Closing and shall deliver to AstraZeneca a copy of such Allocation (IRS Form 8594) promptly after such determination. AstraZeneca shall have the right to review and raise any objections in writing to the Allocation during the 10-day period after its receipt thereof. If AstraZeneca disagrees with respect to any item in the Allocation, the Parties shall negotiate in good faith to resolve the dispute. If the Parties are unable to agree on the Allocation within 30 days after the commencement of such good faith negotiations (or such longer period as AstraZeneca and Horizon may mutually agree in writing), then the Accountants shall be engaged at that time to review the Allocation, and shall make a determination as to the resolution of such Allocation. The determination of the Accountants regarding the Allocation shall be delivered as soon as practicable following engagement of the Accountants, but in no event more than 60 days thereafter, and shall be final, conclusive and binding upon AstraZeneca and Horizon, and Horizon shall revise the Allocation accordingly. AstraZeneca, on the one hand, and Horizon on the other hand, shall each pay one-half of the cost of the Accountants.

2.4 Closing.

2.4.1 Closing. Pursuant to the terms and subject to the conditions of this Agreement, the closing of the transactions contemplated hereby (the "Closing") shall take place at the offices of Covington & Burling LLP, 1201 Pennsylvania Avenue, N.W., Washington, D.C. at 10:00 a.m., local time, on the first Business Day on which all conditions (other than those that
by their terms are to be satisfied or taken at the Closing) set forth in Article 6 are satisfied (or, to the extent permitted by applicable Law, waived by the Party entitled to the benefits thereof); provided, that the Closing shall not occur prior to the date that is the earlier of (a) the sixth Business Day following the Execution Date and (b) the first Business Day following the Execution Date, or such other time and place as Horizon and AstraZeneca may agree to in writing. The Closing shall be deemed to have occurred at 12:00 a.m., eastern time, on the Closing Date, such that Horizon shall be deemed the owner of the Purchased Assets on and after the Closing Date.

2.4.2 Closing Deliveries

(a) Except as otherwise indicated below, at the Closing, AstraZeneca shall deliver the following to Horizon:

(i) each of the Ancillary Agreements to which AstraZeneca is a party, other than the Post-Transition Safety Data Exchange Agreement, the Three Party Letter Agreement and the Guarantee, validly executed by a duly authorized officer of AstraZeneca;

(ii) a receipt acknowledging receipt of the Purchase Price in satisfaction of Horizon’s obligations pursuant to Section 2.3.1, validly executed by a duly authorized representative of AstraZeneca; and

(iii) the Purchased Assets, provided, that (A) with respect to tangible Purchased Assets delivery shall be made as set forth in Schedule 2.4.2(a)(iii), and (B) AstraZeneca may retain one copy of the Product Records included within the Purchased Assets and the Purchased Contracts (and, for clarity, prior to delivering or making available any files, documents, instruments, papers, books and records containing Product Records to Horizon, AstraZeneca shall be entitled to redact from such files, documents, instruments, papers, books and records any information to the extent that it does not relate to the Product Business; provided, that, upon Horizon’s request, AstraZeneca shall provide Horizon with a general description of any such information redacted by AstraZeneca to the extent that AstraZeneca is permitted to do so;

(iv) the Patheon Letter;

(v) the AstraZeneca FDA Intent Letters;

(vi) the AstraZeneca FDA Transfer Letters; and

(vii) the Vimovo Litigation Records Side Letter.

(b) At the Closing, Horizon shall deliver the following to AstraZeneca:

(i) each of the Ancillary Agreements to which Horizon is a party, other than the Post-Transition Safety Data Exchange Agreement and the Three Party Letter Agreement, validly executed by a duly authorized officer of Horizon; and

(ii) the Purchase Price in accordance with Section 2.3.1;
(iii) the Horizon FDA Intent Letters;
(iv) the Horizon FDA Transfer Letters; and
(v) the Vimovo Litigation Records Side Letter.

(e) Horizon shall conduct a quality and completeness review of the Regulatory Documentation transferred to it pursuant to Section 2.4.2(a)(iii) promptly following such transfer and, as soon as possible, but no later than 60 days after each transfer, shall notify AstraZeneca in writing of any problems or issues experienced by Horizon regarding the completeness, navigation or readability of such transferred Regulatory Documentation that Horizon reasonably and in good faith believes are related to the transfer of such Regulatory Documentation (and not, for example, related to Horizon system capabilities or compatibility). AstraZeneca shall use its commercially reasonable efforts to assist Horizon in remedying any such problems or issues (if any) as soon as reasonably practicable following AstraZeneca’s receipt of Horizon’s notice of the same.

2.5 Transitional Trademark License

2.5.1 AstraZeneca hereby grants to Horizon and its Affiliates, and Horizon hereby accepts, a non-exclusive, non-transferable, royalty-free, fully paid-up, license in the Horizon Territory to use the AstraZeneca Marks (a) during the period from the Closing Date until all Product samples that contain AstraZeneca’s NDC have been distributed, but in no event later than March 31, 2014, to distribute Product samples in the Horizon Territory and (b) during the period from the Closing Date until December 31, 2013, (i) to use the Product Promotional Materials in the form provided by AstraZeneca at the Closing in connection with the promotion of such Products in the Horizon Territory and (ii) in connection with AstraZeneca’s sale of the Product in the Horizon Territory on behalf of Horizon pursuant to the Transition Agreement.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of AstraZeneca. AstraZeneca represents and warrants to Horizon as follows, with each such representation and warranty subject to such exceptions, if any, as are set forth in the Disclosure Schedules. Disclosures in any section or paragraph of the Disclosure Schedules shall address only the corresponding section or paragraph of this Agreement, except to the extent that it is reasonably apparent from the face of such disclosure that such disclosure is applicable to other sections or paragraphs of this Agreement.

3.1.1 Entity Status. AstraZeneca is a corporation duly organized, validly existing and in good standing under the Laws of Sweden. AstraZeneca and its Affiliates have all requisite corporate power and authority to own, use and operate the Purchased Assets and to carry on the Product Business as now being conducted.
3.1.2 Authority.

(a) AstraZeneca has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the Ancillary Agreements to which AstraZeneca is a party and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate actions of AstraZeneca. This Agreement constitutes, and each Ancillary Agreement to which it is a party, when executed and delivered by AstraZeneca, will constitute, the valid and legally binding obligation of AstraZeneca, enforceable against AstraZeneca in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

(b) Each Affiliate of AstraZeneca that will enter into an Ancillary Agreement has the requisite entity power and authority to perform its obligations under each Ancillary Agreement to which it is a party and to consummate the transactions contemplated thereby. The execution and delivery of the Ancillary Agreements to which any Affiliate of AstraZeneca is a party and the consummation of the transactions contemplated thereby have been duly authorized by all necessary organizational actions of such Affiliate. Each Ancillary Agreement, when executed and delivered by an Affiliate of AstraZeneca that is a party thereto, will constitute the valid and legally binding obligation of such Affiliate, enforceable against such Affiliate in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

3.1.3 Non-Contravention. The execution, delivery and performance by AstraZeneca of this Agreement and each Ancillary Agreement to which it is a party and the execution, delivery and performance by each Affiliate of AstraZeneca of each Ancillary Agreement to which such Affiliate is a party do not and will not (a) violate the certificate of incorporation or bylaws or comparable organizational documents of AstraZeneca or such Affiliate, as applicable, (b) violate any Law applicable to AstraZeneca or such Affiliate, as applicable, the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or (c) subject to obtaining the consents referred to in Section 3.1.5(d), (i) violate, breach or constitute a default under or result in the termination of any Contract to which AstraZeneca or such Affiliate is a party or to which the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation is subject, including any no shop or exclusivity agreement or any option, right of first refusal, right of first offer, right of first negotiation or similar right, (ii) result in the creation of any Encumbrance upon any Purchased Asset other than Permitted Encumbrances or the imposition of any other contractual restrictions on the use of the Purchased Assets or the conduct of the Product Business or (iii) terminate, amend or modify or give any Person the right to terminate, accelerate, amend or modify, abandon or refuse to perform any Purchased Contract (except to the extent that the assignment of a Purchased Contract to Horizon itself constitutes an amendment or modification),
or (iv) violate any order or judgment of a Governmental Authority to which AstraZeneca or any of its Affiliates is subject relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation, except, in the case of the foregoing clauses (b) and (c), for such violations, breaches, defaults, terminations, amendments, modifications, losses of rights, abandonments or refusals to perform that would not reasonably be expected to materially affect the Product Business, taken as a whole.

3.1.4 No Broker. There is no broker, finder or financial advisor acting or who has acted on behalf of AstraZeneca or any of its Affiliates, who is entitled to receive any brokerage or finder’s or financial advisory fee from Horizon or any of its Affiliates in connection with the transactions contemplated by this Agreement.

3.1.5 No Litigation; Consents.

   (a) There is no Litigation (other than any investigation or finding of deficiency or noncompliance, which are addressed in clause (b) below) pending or to AstraZeneca’s Knowledge, threatened, against AstraZeneca or any of its Affiliates before any Governmental Authority relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or for which the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation is subject.

   (b) To AstraZeneca’s Knowledge there is no investigation or finding of deficiency or noncompliance pending or threatened against AstraZeneca or any of its Affiliates before any Governmental Authority relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or for which the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation is subject.

   (c) There is no order or judgment of a Governmental Authority to which AstraZeneca or any of its Affiliates is subject relating to the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation.

   (d) Except for (i) consents, permits, authorizations, declarations, filings or registrations that have become applicable solely as a result of the specific regulatory status of Horizon or its Affiliates and (ii) items disclosed in Section 3.1.5(d) of the Disclosure Schedules, no notice to, filing with, permit of, authorization of, exemption by, or consent of, any Governmental Authority or other Person is required for AstraZeneca to consummate the transactions contemplated hereby or by the Ancillary Agreements.

3.1.6 Purchased Assets; Sufficiency.

   (a) AstraZeneca has, or its Affiliates have, good title to, or valid contract rights in, as applicable, the Purchased Assets, free and clear of all Encumbrances other than Permitted Encumbrances.
(b) The Purchased Assets, together with the Merck Covenant and rights granted to Horizon under the License Agreement, the Licensed Regulatory Documentation, the APA Manufacturing Technology and any software or other ordinary course and immaterial Third Party licenses that are commercially available (excluding, for clarity, any license of any Patent Rights), constitute all of the intellectual property, Regulatory Approvals and Regulatory Documentation necessary to (i) operate the Product Business, (ii) Manufacture or have Manufactured the Product in the Horizon Territory, and (iii) Manufacture, have Manufactured, research and develop the Product in the AstraZeneca Territory solely for exportation and use of the Product in connection with the Exploitation of Product in the Horizon Territory, in each case ((i)—(iii)) in the same manner that AstraZeneca and its Affiliates are operating the Product Business, Manufacturing or having Manufactured the Product in the Horizon Territory, and Manufacturing, having Manufactured, researching and developing the Product in the AstraZeneca Territory for exportation and use of the Product in connection with the Exploitation of Product in the Horizon Territory, as applicable, as of the Execution Date and as of the Closing. In the event this Section 3.1.6(b) is breached because AstraZeneca has failed to convey any Purchased Assets or to identify and either transfer to Horizon, or grant Horizon a license to or right of reference and use with respect to, as applicable, any intellectual property, Regulatory Approvals or Regulatory Documentation necessary for the representation and warranty in this Section 3.1.6(b) to be true and correct in all respects, such breach shall be deemed cured as of the date AstraZeneca or any of its Affiliates specifically performs its obligation under this Agreement or any Ancillary Agreement to convey title to all Purchased Assets to Horizon or to transfer to Horizon, or grant Horizon a license to or right of reference and use with respect to, as applicable, such intellectual property, Regulatory Approvals or Regulatory Documentation at no additional cost or expense to Horizon; provided that such breach shall not be deemed cured with respect to any Losses incurred by any Horizon Indemnitee prior to such transfer or grant.

3.1.7 Contracts. Each of the Purchased Contracts is in effect and constitutes a legal, valid and binding agreement of AstraZeneca or an Affiliate of AstraZeneca, enforceable in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity. AstraZeneca is not and, to AstraZeneca’s Knowledge, no other party thereto is, in default in the performance, observance or fulfillment of any obligation or covenant contained in any Purchased Contract and no event has occurred that with the passage of time or giving of notice or both would constitute such a breach or default, result in the payment of any damages or penalties or result in the creation of any Encumbrance thereunder or pursuant thereto other than Permitted Encumbrances. AstraZeneca has not received any written notice from a Third Party at any time during the past [***] years regarding any actual, alleged or potential violation or breach of, or default under, any of the Purchased Contracts or stating that such Third Party intends to terminate, cancel or make any material change to any Purchased Contract and there are no pending renegotiations of any of the Purchased Contracts. The Product Business as conducted by AstraZeneca and its Affiliates as of the Execution Date does not rely upon or use rights under any Contract that has expired or been terminated. True and complete copies of all Purchased Contracts and the Pozen Original Agreement have been made available to Horizon. To AstraZeneca’s Knowledge, Pozen is not in breach of the Pozen Original Agreement.

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3.1.8 Compliance with Law.

(a) AstraZeneca and its Affiliates, with respect to the operation of the Product Business, are and during the past [...***...] years prior have been in compliance with all applicable Laws in the Horizon Territory, including (i) any applicable Laws governing the approval, Manufacture, sale, marketing, promotion, or distribution of drugs and the purchase or prescription of or reimbursement for drugs by any Governmental Authority, private health plan or entity, or individual, and (ii) the federal Anti-Kickback Statute (42 U.S.C. §1320a-7(b)), the False Claims Act (42 U.S.C. §1320a-7b(a)), the Foreign Corrupt Practices Act of 1977 (15 U.S.C. §78 et seq.) and the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §1320d et. seq.), and any comparable state or local Laws, in each case, except for such noncompliance that would not reasonably be expected to materially affect the Product Business, the Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation, each taken as a whole. This Section 3.1.8 does not address regulatory matters, which are the subject of Section 3.1.9. During the past [...***...] years, neither AstraZeneca or its Affiliates has received any written notices of any alleged violations, delinquency or investigations for violation of any Law relating to the Product Business or the Purchased Assets or Assumed Liabilities or to which the any of the Purchased Assets, or business activities relating to the Product Business are subject.

(b) AstraZeneca, or an Affiliate of AstraZeneca, possesses, and is in material compliance with, all material permits (other than Regulatory Approvals, which are the subject of Section 3.1.9(b)) necessary for the conduct of the Product Business as it is currently conducted.

3.1.9 Regulatory Matters.

(a) Neither AstraZeneca, any of its Affiliates nor, to AstraZeneca’s Knowledge, any Merck Party, or any Person on behalf of any of the foregoing, is Exploiting any Other Products in the Horizon Territory.

(b) AstraZeneca, or an Affiliate of AstraZeneca, owns all Regulatory Approvals and Regulatory Documentation necessary to conduct the Product Business in the Horizon Territory as currently conducted and such Regulatory Approvals are in full force and effect. AstraZeneca has the right to grant the right of reference and use under the Licensed Regulatory Documentation to Horizon in accordance with the License Agreement. Neither AstraZeneca nor its Affiliates has received any written communication from any Governmental Authority threatening to withdraw or suspend any such Regulatory Approvals. No proceeding is pending or, to AstraZeneca’s Knowledge, threatened regarding the revocation of any such Regulatory Approval. AstraZeneca and its Affiliates have not voluntarily or involuntarily surrendered, terminated or permitted to lapse or expire any Regulatory Approval used or maintained by them in the conduct of the Product Business, except where any such Regulatory Approval has been not renewed in the ordinary course of business. AstraZeneca or its Affiliates have filed with the applicable Governmental Authority all material filings, declarations, listings, registrations, reports or submissions, including adverse event reports required in connection with the conduct of the Product Business. All such filings, declarations, listings, registrations, reports or submissions were in compliance in all material respects with all applicable Laws when filed,

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and no deficiencies have been asserted by any applicable Governmental Authority with respect to any such filings, declarations, listings, registrations, reports or submissions. Neither AstraZeneca nor any of its Affiliates is in violation of the terms of any Regulatory Approval for the Horizon Territory.

(c) There has not been any product recall or market withdrawal or replacement conducted by or on behalf of AstraZeneca concerning the Product in the Horizon Territory or any product recall, market withdrawal or replacement conducted by or on behalf of any Third Party as a result of any alleged defect in the Product in the Horizon Territory. AstraZeneca has made available to Horizon copies of material field alerts, dear doctor letters, complaints and notices of alleged defect or adverse reaction with respect to the Product in the Horizon Territory that have been received in writing by AstraZeneca and its Affiliates.

(d) The Product has been Manufactured in compliance with applicable Law, including cGMP, and applicable Regulatory Approvals. Neither AstraZeneca nor any Affiliate or Third Party engaged by it, in any capacity, in connection with the Manufacture of the Product has received in the past [...***] years or is currently subject to a Warning Letter (as defined in the Act) with respect to any facility manufacturing Product for Exploitation in the Horizon Territory. Subject to backorders or delays in the ordinary course, AstraZeneca or its Affiliate has fulfilled all purchase orders submitted for the Product in the Horizon Territory.

(e) All studies, tests and preclinical and clinical trials conducted by or on behalf of AstraZeneca or its Affiliates relating to the Product were conducted, and all studies, tests and trials currently being conducted by or on behalf of AstraZeneca or its Affiliates in connection with the clinical trials listed in Section 3.1.9(e) of the Disclosure Schedules are being conducted, in either case in all material respects in accordance with cGCP and other applicable Laws. AstraZeneca has completed all pediatric assessments or postmarketing commitments required by the FDA with respect to the Product in the Horizon Territory. Neither AstraZeneca nor any Affiliate of AstraZeneca has received any written notices or correspondence from any applicable Governmental Authority requiring the termination, suspension, material modification or clinical hold of any clinical trials listed in Section 3.1.9(e) of the Disclosure Schedules.

3.1.10 Debarred Personnel. Neither AstraZeneca nor any of its Affiliates, officers, directors, employees, consultants, or, to AstraZeneca’s Knowledge, any of its vendors, contractors, investigators or agents, who has undertaken activities in connection with the Product Business has been debarred or deemed subject to debarment pursuant to Section 306 of the Act, nor, to AstraZeneca’s Knowledge, are any such Persons the subject of a conviction described in such section.

3.1.11 Intellectual Property.

(a) AstraZeneca or one of its Affiliates owns the Merck Patents and the APA Licensed Intellectual Property, jointly with Pozen owns the Purchased Patents and has the right to use the Pozen Patents and has the right to license the APA Licensed Intellectual Property to Horizon in accordance with the License Agreement. The Purchased Patents are the only Joint Patents (as defined in the Pozen Original Agreement) in the Horizon Territory under the Pozen Original Agreement. There are no Patent Rights in the Horizon Territory claiming any

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AstraZeneca Inventions (as defined in the Pozen Original Agreement) under the Pozen Original Agreement. There are no data, information, know-how or Patent Rights owned or controlled by a Merck Party pursuant to any Merck Agreement that claim or cover any Manufacturing, having Manufactured or Exploitation activities with respect to the Product outside the Horizon Territory.

(b) Section 3.1.11(b)(i) of the Disclosure Schedules sets forth a true and complete list of all APA Licensed Intellectual Property owned by AstraZeneca or one of its Affiliates, other than the Purchased Patents, that has not expired or been abandoned and has issued, been registered or granted or that is the subject of an application for registration, issuance or grant in the Horizon Territory (“Owned Registered Product IP”). Section 3.1.11(b)(ii) of the Disclosure Schedules identifies: (i) each Purchased Patent, (ii) the owner(s) thereof; registration, issuance, grant, serial, and application or other identifying number, filing, registration, issuance, grant, renewal, and expiration date, and title, as applicable; and (iii) any other Person that has an ownership interest in such item of Purchased Patent and the nature of such ownership interest. Section 3.1.11(b)(ii) of the Disclosure Schedule describes each filing, payment, and action that, to AstraZeneca’s Knowledge, must be made or taken on or before the date that is 120 days after the Execution Date in order to file, prosecute and maintain each such Purchased Patent (“Required Actions”). All required maintenance fees, annuity fees or renewal fees for Owned Registered Product IP and the Purchased Patents that are due and payable prior to the Closing Date have been or will be paid (without filing any extension delaying payment to a date after the Closing Date).

(c) To AstraZeneca’s Knowledge, the APA Licensed Intellectual Property, the Merck Patents, the Purchased Patents and the Pozen Patents, are valid and subsisting and have not been denied, rejected or invalidated, lapsed, expired, been cancelled or become abandoned. With respect to the Purchased Patents and to AstraZeneca’s Knowledge, with respect to the Merck Patents and the Pozen Patents, all relevant published patents, patent applications, articles and other prior art references have been disclosed to the relevant patent examiner at the U.S. Patent and Trademark Office. To AstraZeneca’s Knowledge, each Person who has or has had any rights in or to the Merck Patents, the Purchased Patents or the Pozen Patents, has executed an agreement assigning his, her or its entire right, title and interest therein, and the inventions embodied, described or claimed therein, to the stated owner thereof.

(d) To AstraZeneca’s Knowledge, all required maintenance fees, annuity fees or renewal fees for the Merck Patents and the Pozen Patents in the Horizon Territory that are due and payable have been paid, and no applications or registrations therefor have lapsed or become abandoned, been cancelled or expired.

(e) To AstraZeneca’s Knowledge, (i) none of the Purchased Patents or the Pozen Patents is involved in any Litigation, inventorship challenge, reissue, interference, reexamination or opposition and (ii) none of the Merck Patents is involved in any Litigation, inventorship challenge, reissue, interference, reexamination or opposition regarding the Product Business.

(f) None of the Licensed Copyrights, APA Licensed Trademarks or Licensed Domain Names or registrations or applications to use or register such items is involved in any pending action, arbitration, mediation, hearing, litigation, claim, suit, cancellation,
nullification, interference, concurrent use or opposition proceeding or, to AstraZeneca’s Knowledge, any investigation or finding of deficiency or noncompliance.

(g) The conduct of the Product Business as currently conducted does not infringe or misappropriate any Third Party’s intellectual property rights in the Horizon Territory. Except for the Vimovo Litigation, no Litigation is pending or, to AstraZeneca’s Knowledge, threatened (i) based upon, challenging or seeking to deny or restrict the use of any of the APA Licensed Intellectual Property, the Purchased Patents or the Pozen Patents, (ii) alleging that AstraZeneca’s conduct of the Product Business infringes or misappropriates the intellectual property rights of any Third Party in the Horizon Territory, or (iii) asserting a Paragraph IV Notification under 21 U.S.C. 355(j)(2)(B) relative to any Patent Rights listed in NDA #22-511.

(h) (i) AstraZeneca is in compliance in all material respects with its obligations under the Merck Agreements and (ii) to AstraZeneca’s Knowledge, neither Merck nor any Merck Party is in breach of the Merck Agreements in each case ((i) and (ii)), except for any noncompliance or breach that would reasonably be expected to adversely affect Horizon’s rights under this Agreement, including Horizon’s rights with respect to the Merck Covenant, or any Ancillary Agreement.

(i) Other than licenses or sublicenses granted to any Third Party for the Manufacture of the Product on behalf of AstraZeneca or any of its Affiliates, (i) neither AstraZeneca nor any Affiliate of AstraZeneca has granted any licenses, sublicenses or other rights (including any covenant not to sue) in or with respect to the Purchased Patents or the Pozen Patents to any Third Parties in the Horizon Territory and (ii) except for the exclusive license granted to KBI-E Inc. under the Merck Patents pursuant to the Merck Agreements and any license granted to a Third Party in connection with the Vimovo Litigation as described on Schedule 3.1.11(i), neither AstraZeneca nor any Affiliate of AstraZeneca has granted any licenses, sublicenses or other rights in or with respect to the Merck Patents to any Third Parties to Exploit the Product or any Other Product in the Horizon Territory. To AstraZeneca’s Knowledge, no Third Party is engaging in any activity that infringes or misappropriates the Owned Registered Product IP, the Purchased Patents, or any other APA Licensed Intellectual Property in the Horizon Territory. Neither AstraZeneca nor any Affiliate of AstraZeneca has received any written notice that any Person is suspected of infringing or misappropriating such intellectual property rights in the Horizon Territory.

(j) Except as set forth in the Pozen US Agreement, there is no royalty or other license payment obligation to any Third Party with respect to the Exploitation of Products or Other Products in the Horizon Territory, other than any amounts that may be payable under any Merck Agreement, which shall be the sole responsibility of AstraZeneca and its Affiliates.

(k) AstraZeneca and, as applicable, AstraZeneca’s Affiliates, have taken reasonable measures to maintain in confidence all APA Licensed Know-How and to protect the secrecy, confidentiality and value of any trade secrets included within the APA Licensed Know-How.
3.1.12 Existing Inventory. As of the Execution Date, AstraZeneca or its Affiliates own at least [...***... units of the Product packaged for commercial sale in the Horizon Territory and at least [...***... units of the Product to be distributed as samples in the Horizon Territory. All Existing Inventory is useable or saleable in the ordinary course of the Product Business. All Existing Inventory has been manufactured in accordance with cGMP and is of good and marketable quality.


3.1.14 Certain Financial Statements. AstraZeneca or an Affiliate of AstraZeneca has made available to Horizon or its Representatives the annual gross sales and net sales (and certain components thereof) for the Product in the Horizon Territory for the past [...***...] completed Calendar Years. Such financial information was prepared from the books and records of AstraZeneca or an Affiliate of AstraZeneca, as applicable, and fairly presents in all material respects the annual gross sales and net sales for the Product in the Horizon Territory for the periods indicated.

3.2 Representations and Warranties of Horizon. Horizon represents and warrants to AstraZeneca as follows:

3.2.1 Corporate Status. Horizon is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware.

3.2.2 Authority. Horizon has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements to which it is a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and Ancillary Agreements to which Horizon is a party and the consummation of the transactions contemplated hereby and thereby have been duly authorized by the necessary corporate actions of Horizon. This Agreement constitutes and each Ancillary Agreement to which Horizon is a party, when executed and delivered by Horizon will constitute, the valid and legally binding obligation of Horizon, enforceable against Horizon in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

3.2.3 Non-Contravention. The execution, delivery and performance by Horizon of this Agreement and each Ancillary Agreement to which it is a party do not and will not (a) violate the certificate of incorporation or bylaws or comparable organizational documents of Horizon, (b) violate any Law applicable to Horizon, (c) violate, breach or constitute a default under or result in the termination of any material Contract to which Horizon is a party, or (d)
violate any order or judgment of a Governmental Authority to which Horizon or any of its Affiliates is subject.

3.2.4 No Broker. There is no broker, finder, financial advisor or other Person acting or who has acted on behalf of Horizon or its Affiliates, who is entitled to receive any brokerage or finder’s or financial advisory fee from AstraZeneca or any of its Affiliates in connection with the transactions contemplated by this Agreement.

3.2.5 Litigation; Consents.

(a) To the knowledge of Horizon, there is no (i) Litigation pending or threatened against Horizon or any of its Affiliates before any Governmental Authority, or (ii) order or judgment of a Governmental Authority to which Horizon or any of its Affiliates is subject, except for such Litigation, orders and judgments that would not reasonably be expected to have a Horizon Material Adverse Effect.

(b) Except for consents, permits or authorizations that if not received, or declarations, filings or registrations that if not made, would not reasonably be expected to have a Horizon Material Adverse Effect, no notice to, filing with, permit of, authorization of, exemption by, or consent of, Governmental Authority or other Person is required for Horizon to consummate the transactions contemplated hereby or by the Ancillary Agreements.

3.2.6 Debarred Personnel. Neither Horizon nor any of its employees or consultants has been debarred or deemed subject to debarment pursuant to Section 306 of the Act nor, to the knowledge of Horizon, are any such Persons the subject of a conviction described in such section.

3.2.7 Financial Capacity. Horizon will have on the Closing Date immediately available cash that is sufficient to enable it to complete the transactions contemplated hereby and to perform all of its obligations under this Agreement and the Ancillary Agreements.

3.2.8 Compliance with Applicable Law. Horizon is aware of applicable Law in the Horizon Territory relating to marketing, distribution and sale of the Product, and can legally import, store, market, distribute and sell the Product in the Horizon Territory immediately as of the Closing.

3.3 Exclusivity of Representations.

3.3.1 HORIZON ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN SECTION 2.1.2 AND SECTION 3.1 OR MADE BY ASTRAZENECA OR ITS AFFILIATES IN THE LICENSE AGREEMENT OR THE SUPPLY AGREEMENT, (A) ASTRAZENECA HAS MADE NO REPRESENTATION OR WARRANTY WHATSOEVER HEREIN OR OTHERWISE RELATED TO THE TRANSACTIONS CONTEMPLATED HEREBY AND (B) HORIZON HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREBY.
ARTICLE 4
PRE-CLOSING COVENANTS

4.1 Access and Information.

4.1.1 During the period commencing on the Execution Date and ending on the earlier to occur of (a) the Closing and (b) the termination of this Agreement in accordance with Article 8 (the “Pre-Closing Period”), AstraZeneca shall afford Horizon and its officers, employees, agents, attorneys, consultants, advisors and other representatives (collectively, “Representatives”), continued reasonable access to AstraZeneca employees to discuss the Product Business and full access to the books and records of AstraZeneca, to the extent maintained in connection with the Product Business, shall use its commercially reasonable efforts to provide to Horizon such information, books and records to the extent that they relate to the Product Business, as Horizon may reasonably request; provided, however, that AstraZeneca may restrict the foregoing access to the extent that in the reasonable judgment of AstraZeneca, any Law applicable to AstraZeneca, the Purchased Assets, the Product, the APA Licensed Intellectual Property, the Ex-US Licensed Patents, the Licensed Regulatory Documentation or the Product Business requires it to so restrict such access and AstraZeneca shall provide Horizon with a general description of the type of any such information withheld by AstraZeneca to the extent that AstraZeneca is permitted to do so; and provided, further, that such access shall not unreasonably disrupt AstraZeneca’s ordinary course operations. Notwithstanding anything to the contrary contained in this Agreement, AstraZeneca shall not be required to disclose any information or provide any such access if such disclosure or access could, in AstraZeneca’s reasonable judgment, (i) violate (A) applicable Law, including applicable antitrust Laws, or (B) any binding agreement entered into prior to the Execution Date (including any confidentiality agreement to which AstraZeneca is a party), (ii) jeopardize any attorney/client privilege or other established legal privilege or (iii) disclose any trade secrets not included in the APA Licensed Intellectual Property or Purchased Assets; provided, that AstraZeneca shall provide Horizon with a general description of the type of any such information withheld by AstraZeneca to the extent that AstraZeneca is permitted to do so.

4.1.2 During the period commencing on the Execution Date and ending on the earlier to occur of (a) the Closing and (b) the termination of this Agreement in accordance with Article 8, Horizon hereby agrees that neither it nor any of its Affiliates or Representatives is authorized to contact, and shall not contact, any licensor, licensee, competitor, supplier, distributor or customer of AstraZeneca with respect to the Product, the Purchased Assets, the APA Licensed Intellectual Property, the Ex-US Licensed Patents, the Licensed Regulatory Documentation, the Merck Patents, the Product Business, this Agreement, the Ancillary

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Agreements or the transactions contemplated hereby or thereby, without the prior written consent of AstraZeneca, which consent may be withheld in AstraZeneca’s sole discretion. Notwithstanding the foregoing, after the Execution Date Horizon shall be permitted to engage in discussions and negotiations with (i) Pozen, (ii) any Third Party that is providing any services to AstraZeneca or any of its Affiliates with respect to the study entitled [...***...] or (iii) Patheon Inc., Patheon Pharmaceuticals Inc., [...***...] and [...***...] with respect to the Manufacture or Product on behalf of Horizon solely for Exploitation in the Horizon Territory.

4.2 Ordinary Course of Business. During the Pre-Closing Period, except (a) as set forth in Schedule 4.2 or as otherwise contemplated by this Agreement or any Ancillary Agreement, (b) as required by applicable Law, (c) as required by the terms of any agreement binding upon AstraZeneca or its Affiliates as of the Execution Date, (d) for any actions taken by AstraZeneca to (i) perform its obligations under the Transition Agreement, (ii) obtain any Third Party consents, permits or authorizations in connection with the transactions contemplated by this Agreement or any Ancillary Agreement or (iii) conduct transition planning in preparation for the transfer of the Purchased Assets to Horizon, or (e) as Horizon shall otherwise consent in writing, AstraZeneca shall conduct the Product Business in substantially the same manner as heretofore conducted and in the ordinary course of business and shall use its commercially reasonable efforts to preserve substantially intact the Product Business, and substantially preserve the current relationships of the Product Business with customers, suppliers and other Persons with which the Product Business has material business relations. In furtherance of the foregoing and in no way limiting the foregoing, during the Pre-Closing Period, AstraZeneca shall:

(a) promptly take all Required Actions and any other office actions with respect to any Purchased Patents;

(b) keep in full force and effect all material rights relating to the Product Business and not amend or otherwise modify such rights;

(c) not enter into or amend or waive any material rights under any Purchased Contract or permit any of the Purchased Assets to become subject to any Encumbrance other than Permitted Encumbrances or commit to do any of the foregoing;

(d) not sell Product to wholesalers or distributors in the Horizon Territory in quantities that exceed the average order size from such wholesalers or distributors during the three month period preceding the Execution Date, except to the extent such increased orders are submitted to AstraZeneca and its Affiliates by such wholesalers or distributors other than at the direct request of AstraZeneca or its Affiliates; or

(e) not enter into any settlement of any Litigation with any Governmental Authority or other Person relating to the Product Business or any Purchased Assets or any Assumed Liability other than the Merck Patent Litigation or commit to do any of the foregoing; and comply with all applicable Laws and orders of Governmental Authorities relating to the Product Business.

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4.3 Obligation to Consummate the Transaction. Each of the Parties agrees that, subject to this Section 4.3, it shall use its reasonable best efforts to take, or cause to be taken, all action, and to do, or cause to be done, all things necessary, proper or advisable to the extent permissible under applicable Law, to consummate and make effective the transactions contemplated by this Agreement and to ensure that the conditions set forth in Article 6 are satisfied, insofar as such matters are within the control of either of them. Without limiting the generality of the foregoing, as soon as reasonably practicable after the Execution Date, AstraZeneca shall use its commercially reasonable efforts (not requiring the payment of money) to obtain the consents referred to in Section 3.1.5(d).

4.4 Notice of Litigation/Developments.

4.4.1 Subject to Section 5.5, from and after the Execution Date until the earlier to occur of the Closing and the termination of this Agreement in accordance with Article 8, each Party shall give prompt written notice to the other Party of any Litigation, examination or audit in which such Party is involved as a party that concerns and would reasonably be expected to materially and adversely affect the Product Business, Purchased Assets, the APA Licensed Intellectual Property or the Licensed Regulatory Documentation or the other Party’s rights in the same or that would otherwise reasonably be expected to have a Material Adverse Effect or Horizon Material Adverse Effect, as applicable, or that would cause any of the conditions to Closing set forth in Article 6 not to be satisfied.

4.4.2 Between the Execution Date and the date that is [...] prior to the Closing Date, AstraZeneca shall have the right to supplement or amend the Disclosure Schedules with respect to any matter that, if existing or occurring prior to the Execution Date, would have been required to be set forth or described in the Disclosure Schedules or that is necessary to correct any information in such Disclosure Schedules that has been rendered inaccurate by an event, condition, fact or circumstance occurring after the Execution Date. Such delivery shall not modify any representation and warranty as of the Execution Date or as of the Closing Date or otherwise affect any rights of Horizon under this Agreement with respect to any breach of any representation or warranty or covenant of AstraZeneca set forth herein or with respect to any claim for indemnification hereunder.

ARTICLE 5
ADDITIONAL COVENANTS

5.1 Cooperation in Litigation and Investigations.

5.1.1 Subject to Section 5.5 and except as set forth in any Ancillary Agreement, from and after the Closing Date, Horizon and AstraZeneca shall fully cooperate with each other in the defense or prosecution of any Litigation, examination or audit instituted prior to the Closing or that may be instituted thereafter against or by either Party relating to or arising out of the conduct of the Product Business or the Exploitation or Manufacture of the Product in the Horizon Territory prior to or after the Closing (other than Litigation between Horizon and

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AstraZeneca or their respective Affiliates arising out of the transactions contemplated hereby or by the Ancillary Agreements). In connection therewith, and except as set forth in any Ancillary Agreement, from and after the Closing Date, each of AstraZeneca and Horizon shall make available to the other during normal business hours and upon reasonable prior written notice, but without unreasonably disrupting its business, all records to the extent relating to the Purchased Assets, the APA Licensed Intellectual Property, the Licensed Regulatory Documentation, the Assumed Liabilities and the Excluded Liabilities held by it and reasonably necessary to permit the defense or investigation of any such Litigation, examination or audit (other than Litigation between Horizon and AstraZeneca or their respective Affiliates arising out of the transactions contemplated hereby or by the Ancillary Agreements, with respect to which applicable rules of discovery shall apply), and shall preserve and retain all such records for the length of time contemplated by its standard record retention policies and schedules. The Party requesting such cooperation shall pay the reasonable out-of-pocket costs and expenses of providing such cooperation (including legal fees and disbursements) incurred by the Party providing such cooperation and by its officers, directors, employees and agents, and any applicable Taxes in connection therewith.

5.1.2 From and after the Closing, subject to this Section 5.1.2, Horizon shall, at its cost and expense, control, direct and maintain control over the Vimovo Litigation with respect to the Pozen Patents and the Purchased Patents (the “Pozen Patent Litigation”) with counsel of Horizon’s choosing. Horizon shall keep AstraZeneca reasonably informed with respect to the status of and any material developments in the Pozen Patent Litigation. Horizon may settle or otherwise resolve the Pozen Patent Litigation, in its sole discretion; provided, that Horizon shall notify AstraZeneca of its intent to settle the Pozen Patent Litigation and consider in good faith AstraZeneca’s comments with respect thereto.

5.1.3 From and after the Closing, subject to this Section 5.1.3, AstraZeneca shall, at its cost and expense, control, direct and maintain control over the Vimovo Litigation with respect to the Merck Patents (the “Merck Patent Litigation”) with counsel of AstraZeneca’s choosing. AstraZeneca shall keep Horizon reasonably informed with respect to the status of and any material developments in the Merck Patent Litigation. AstraZeneca may settle or otherwise resolve the Merck Patent Litigation, in its sole discretion, including [...***...]; provided, that AstraZeneca shall notify Horizon of its intent to settle the Merck Patent Litigation and consider in good faith Horizon’s comments with respect thereto.

5.2 Further Assurances. Each of AstraZeneca and Horizon shall, at any time or from time to time after the Closing, at the request of the other, execute and deliver to the other all such instruments and documents or further assurances as the other may reasonably request in order to (a) vest in Horizon all of AstraZeneca’s right, title and interest in and to the Purchased Assets as contemplated hereby, (b) effectuate Horizon’s assumption of the Assumed Liabilities and (c) grant to each Party all rights contemplated herein to be granted to such Party under the ***Confidential Treatment Requested
Ancillary Agreements; provided, however, that after the Closing, apart from such customary further assurances, neither AstraZeneca nor Horizon shall have any other obligations except as specifically set forth and described herein or in the Ancillary Agreements. Without limitation of the foregoing, except as expressly set forth in the Ancillary Agreements, neither AstraZeneca nor Horizon shall have any obligation to assist or otherwise participate in the amendment or supplementation of the Purchased Regulatory Approvals or otherwise to participate in any filings or other activities relating to the Purchased Regulatory Approvals other than as necessary to effect the assignment thereof to Horizon in connection with the Closing pursuant to this Agreement.

5.3 Transition Agreement. During the Transition Period, AstraZeneca and Horizon shall cooperate to transition the Exploitation of the Product in the Horizon Territory, and related administrative activities, from AstraZeneca to Horizon and to ensure that Horizon commences the performance of such activities hereunder with the least disruption to customers, in each case, in accordance with and to the extent provided for in the Transition Agreement.

5.4 Publicity. No public announcement related to this Agreement or the transactions contemplated herein will be issued without the joint approval of AstraZeneca and Horizon, which approval shall not be unreasonably withheld, conditioned or delayed, except in any public disclosure which either AstraZeneca or Horizon, in its good faith judgment, believes is required by applicable Law or by any stock exchange on which its securities or those of its Affiliates are listed. If either Party, in its good faith judgment, believes such disclosure is required, such Party will use its commercially reasonable efforts to consult with the other Party and its Representatives, and to consider in good faith any revisions proposed by the other Party or its Representatives, as applicable, prior to making (or prior to any of its Affiliates making) such disclosure, and shall limit such disclosure to only that information which is legally required to be disclosed.

5.5 Confidentiality.

5.5.1 All Confidential Information provided by one Party (or its Representatives or Affiliates) (collectively, the “Disclosing Party”) to the other Party (or its Representatives or Affiliates) (collectively, the “Receiving Party”) shall be subject to and treated in accordance with the terms of this Section 5.5. As used in this Section 5.5, “Confidential Information” means (a) all information disclosed to the Receiving Party by the Disclosing Party in connection with this Agreement but not any Ancillary Agreement, including all information with respect to the Disclosing Party’s licensors, licensees or Affiliates, (b) all information disclosed to the Receiving Party by the Disclosing Party under the Confidentiality Agreement, and (c) all memoranda, notes, analyses, compilations, studies and other materials prepared by or for the Receiving Party to the extent containing or reflecting the information in the preceding clause (a) or (b). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by competent written documentation:

(i) was already known to the Receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;
(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party other than through any act or omission of the Receiving Party in breach of this Agreement or the Confidentiality Agreement;

(iv) is subsequently disclosed to the Receiving Party by a Third Party without obligations of confidentiality with respect thereto; or

(v) is subsequently independently discovered or developed by the Receiving Party without the aid, application or use of Confidential Information or Ancillary Confidential Information (as defined in the License Agreement).

5.5.2 All Confidential Information obtained by AstraZeneca (or its Affiliates or Representatives) from Horizon (or its Affiliates or Representatives) and all Confidential Information relating solely to the Product Business (other than Confidential Information relating to (x) the APA Licensed Intellectual Property, the Ex-US Licensed Patents or the Licensed Regulatory Documentation, (y) the Pozen Original Agreement or the Pozen ROW Agreement or (z) the Merck Parties or the Merck Patents), the Purchased Assets and the Assumed Liabilities (the "Horizon Confidential Information") shall be deemed to be Confidential Information disclosed by Horizon to AstraZeneca for purposes of this Section 5.5 and shall be used by AstraZeneca solely as required to (a) perform its obligations or exercise or enforce its rights under this Agreement, any Ancillary Agreement (including for purposes of engaging in pharmacovigilance tasks, including maintaining the global safety database for the Product), the Pozen ROW Agreement or any Contract related to the Product pursuant to which AstraZeneca or any of its Affiliates obtains rights to the APA Licensed Intellectual Property, the Ex-US Licensed Patents or the Merck Patents, (b) undertake Manufacturing activities in support of Horizon’s operations in the Horizon Territory, or (c) comply with applicable Law (each of (a) through (c), a "AstraZeneca Permitted Purpose"), and for no other purpose. For a period of 10 years after the Execution Date, AstraZeneca shall not disclose, or permit the disclosure of, any of the Horizon Confidential Information to any Person except those Persons to whom such disclosure is necessary in connection with any AstraZeneca Permitted Purpose. AstraZeneca shall treat, and will cause its Affiliates and the Representatives of AstraZeneca or any of its Affiliates to treat, the Horizon Confidential Information as confidential, using the same degree of care as AstraZeneca normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

5.5.3 All Confidential Information obtained by Horizon (or its Affiliates or Representatives) from AstraZeneca (or its Affiliates or Representatives) other than the Horizon Confidential Information (the "AstraZeneca Confidential Information") shall be used by Horizon solely as required to (a) perform its obligations or exercise or enforce its rights under this Agreement, any Ancillary Agreement or the Pozen US Agreement, (b) undertake Manufacturing activities in support of Horizon’s operations in the Horizon Territory or (c) comply with applicable Law (each of (a) and (b), a "Horizon Permitted Purpose"), and for no other purpose. For a period of 10 years after the Execution Date, Horizon shall not disclose, or permit the disclosure of, any of AstraZeneca Confidential Information to any Person except (x)
those Persons to whom such disclosure is necessary in connection with a Horizon Permitted Purpose or (y) in connection with any due diligence or disclosure obligations under any financing arrangement or equity offering pursuant to obligations of confidentiality and non-use no less stringent than those set forth in this Section 5.5. Horizon shall treat, and will cause its Affiliates and the Representatives of Horizon or any of its Affiliates to treat, AstraZeneca Confidential Information as confidential, using the same degree of care as Horizon normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

5.5.4 In the event either Party is requested pursuant to, or required by, applicable Law to disclose any of the other Party’s Confidential Information (i.e., AstraZeneca Confidential Information or Horizon Confidential Information, as applicable), it will notify the other Party in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party’s sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, provided that such Party furnishes only that portion of the Confidential Information which such Party is advised by an opinion of its counsel is legally required and such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Confidential Information.

5.5.5 Nothing in this Section 5.5 shall be construed as preventing or in any way inhibiting either Party from complying with applicable Law governing activities and obligations undertaken pursuant to this Agreement or any Ancillary Agreement in any manner which it reasonably deems appropriate.

5.6 FDA Letters. Horizon and AstraZeneca shall file the Horizon FDA Intent Letters and the AstraZeneca FDA Intent Letters, respectively, with the FDA within one Business Day after the Closing Date. Horizon and AstraZeneca shall file the Horizon FDA Transfer Letters and the AstraZeneca FDA Transfer Letters, respectively, with the FDA pursuant to the Transition Agreement. Transfer of title to the NDA and the INDs for the Product shall be effective as of the Closing.

5.7 Regulatory Responsibilities. Except as set forth in the Transition Agreement or as required by a Party to comply with applicable Law or to exercise its rights and obligations hereunder or under any Ancillary Agreement, (a) as of the Closing Date, Horizon shall have the sole right and responsibility for preparing, obtaining and maintaining all Regulatory Approvals necessary for continuing the Product Business after Closing, and for conducting communications with Governmental Authorities of competent jurisdiction, for the Product and any Other Product in the Horizon Territory, and (b) AstraZeneca (on its own behalf or through AstraZeneca’s licensees, sublicensees or distributors, as applicable) shall have the sole right and responsibility for preparing, obtaining and maintaining all Regulatory Approvals, and for conducting communications with Governmental Authorities of competent jurisdiction, for the Product or any Other Product in the AstraZeneca Territory. Without limitation of the foregoing, promptly
following the Closing, Horizon shall obtain such FDA approvals as are necessary for Horizon’s own Product labeling and shall comply with such FDA approvals upon receipt thereof.

5.8 Commercialization. Except to the extent otherwise provided in the Transition Agreement or the License Agreement, from and after the Closing Date, (a) Horizon, at its own cost and expense, shall be responsible for and have sole discretion over the commercialization, marketing strategy, promotion, distribution and sale of the Product and any Other Product in the Horizon Territory and shall independently determine and set prices for the Product and any Other Product in the Horizon Territory, including the selling price, volume discounts, rebates and similar matters; (b) Horizon shall be responsible, at its own cost and expense, for all marketing, advertising and promotional materials in the Horizon Territory related to the Product and any Other Product; and (c) Horizon or its Affiliates shall be responsible for receiving and processing all orders, undertaking all invoicing, collection and receivables, and providing all customer service related to the sale of the Product and any Other Product in the Horizon Territory.

5.9 Certain Tax Matters.

5.9.1 Withholding Taxes. The amounts payable by one party (the “Payer”) to another Party (the “Payee”) pursuant to this Agreement (“Payments”) shall not be reduced on account of any Taxes unless required by applicable Law. The Payee alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by the Payer) levied on account of, or measured in whole or in part by reference to, any Payments it receives. The Payer 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 Payee is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Tax, it may deliver to the Payer or the appropriate Governmental Authority (with the assistance of the Payer 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, or to relieve the Payer of its obligation to withhold Tax, and the Payer shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, provided that the Payer has received evidence, in a form reasonably satisfactory to the Payer, of the Payee’s delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least 15 days prior to the time that the Payments are due. If, in accordance with the foregoing, the Payer withholds any amount, it shall pay to the Payee the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to the Payee proof of such payment within 60 days following that payment.

5.9.2 Transfer Taxes and Apportioned Obligations.

(a) All amounts payable hereunder or under any Ancillary Agreement are exclusive of all recordation, transfer, documentary, excise, sales, value added, use, stamp, conveyance or other similar Taxes, duties or governmental charges, and all recording or filing fees or similar costs, imposed or levied by reason of, in connection with or attributable to this Agreement and the Ancillary Agreements or the transactions contemplated hereby and thereby (collectively, “Transfer Taxes”). Horizon shall be solely responsible for the payment of all Transfer Taxes, and shall pay all amounts due and owing in respect of any Transfer Taxes, these
amounts in addition to the sums otherwise payable, at the rate in force at the due time for payment or such other time as is stipulated under applicable Law.

(b) All personal property and similar ad valorem obligations levied with respect to the Purchased Assets for a taxable period which includes (but does not end on) the Closing Date (collectively, the “Apportioned Obligations”) shall be apportioned between AstraZeneca and Horizon based on the number of days of such taxable period ending on the day prior to the Closing Date (such portion of such taxable period, the “Pre-Closing Tax Period”) and the number of days of such taxable period on and after the Closing Date (such portion of such taxable period, the “Post-Closing Tax Period”). AstraZeneca shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Pre-Closing Tax Period, and Horizon shall be liable for the proportionate amount of such Apportioned Obligations that is attributable to the Post-Closing Tax Period.

(c) Apportioned Obligations and Transfer Taxes shall be timely paid, and all applicable filings, reports and returns shall be filed, as provided by applicable Law. The paying Party shall be entitled to reimbursement from the non-paying Party in accordance with Section 5.9.2(a) or Section 5.9.2(b), as the case may be. Upon payment of any such Apportioned Obligation or Transfer Tax, the paying Party shall present a statement to the non-paying Party setting forth the amount of reimbursement to which the paying Party is entitled under Section 5.9.2(a) or Section 5.9.2(b), as the case may be, together with such supporting evidence as is reasonably necessary to calculate the amount to be reimbursed. The non-paying Party shall make such reimbursement promptly but in no event later than 10 days after the presentation of such statement.

5.9.3 Cooperation and Exchange of Information. Each of AstraZeneca and Horizon shall (a) provide the other with such assistance as may reasonably be requested by the other in connection with the preparation of any Tax Return, audit or other examination by any taxing authority or judicial or administrative proceeding relating to Liability for Taxes in connection with the Product Business or the Purchased Assets, (b) retain and provide the other with any records or other information that may be relevant to such Tax Return, audit or examination, proceeding or determination and (c) inform the other of any final determination of any such audit or examination, proceeding or determination that affects any amount required to be shown on any Tax Return of the other for any period.

5.9.4 Survival of Covenants. The covenants contained in this Section 5.9 shall survive until 30 days after the expiration of the applicable statute of limitations (including extensions thereof).

5.10 Accounts Receivable and Payable.

5.10.1 Accounts Receivable. The Parties acknowledge and agree that all Accounts Receivable outstanding on the Closing Date shall remain the property of AstraZeneca or its Affiliates and shall be collected by AstraZeneca or its Affiliates subsequent to the Closing. In the event that, subsequent to the Closing, Horizon or an Affiliate of Horizon receives any payments from any obligor with respect to an Account Receivable, then Horizon shall, within 30 days of receipt of such payment, remit the full amount of such payment to AstraZeneca. In the
case of the receipt by Horizon of any payment from any obligor of both AstraZeneca and Horizon then, unless otherwise specified by such obligor, such payment shall be applied first to amounts owed to Horizon with the excess, if any, remitted to AstraZeneca. In the event that, subsequent to the Closing, AstraZeneca or any of its Affiliates receives any payments from any obligor with respect to an account receivable of Horizon for any period after the Closing Date, then AstraZeneca shall, within 30 days of receipt of such payment, remit the full amount of such payment to Horizon. In the case of the receipt by AstraZeneca of any payment from any obligor of both AstraZeneca and Horizon then, unless otherwise specified by such obligor, such payment shall be applied first to amounts owed to AstraZeneca with the excess, if any, remitted to Horizon.

5.10.2 Accounts Payable. In the event that, subsequent to the Closing, Horizon or an Affiliate of Horizon receives any invoices from any Third Party with respect to any account payable of the Product Business outstanding prior to the Closing, then Horizon shall, within 30 days of receipt of such invoice, provide such invoice to AstraZeneca. In the event that, subsequent to the Closing, AstraZeneca or any of its Affiliates receives any invoices from any Third Party with respect to any account payable of Horizon or any of its Affiliates for any period after the Closing, then AstraZeneca shall, within 30 days of receipt of such invoice, provide such invoice to Horizon.

5.11 Financial Information. Within [...] following the Closing Date and continuing until such time as Horizon files the Carve-Out Financial Statements with the Securities and Exchange Commission, AstraZeneca shall cause its auditors to provide to Horizon audited and unaudited financial statements for the Product Business as of the dates and for the periods as are jointly agreed to by AstraZeneca and Horizon and their respective auditors (the “Carve-Out Financial Statements”), and, if applicable, AstraZeneca shall provide and shall use its commercially reasonable efforts to cause its Affiliates and Representatives to provide, information requested by Horizon and reasonably necessary to prepare any applicable pro forma financial information required to be filed by Horizon with the Securities and Exchange Commission in connection with the transactions contemplated by this Agreement. The Carve-Out Financial Statements will be derived from AstraZeneca’s historical financial statements, will be prepared in accordance with GAAP throughout the periods covered thereby, comply as to form in all material respects with the published rules and regulations of the Securities and Exchange Commission applicable to the presentation of acquired company financial statements [...], and accurately present in all material respects the financial position of the Product Business as of the dates thereof and the results of operations of the Product Business for the periods covered thereby. Horizon shall be solely responsible for any information it files with or furnishes to the Securities and Exchange Commission and shall promptly reimburse AstraZeneca for all out-of-pocket costs and expenses reasonably incurred by AstraZeneca and its Affiliates in connection with complying with this Section 5.11.

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ARTICLE 6
CONDITIONS PRECEDENT

6.1 Conditions to Obligations of Horizon and AstraZeneca. The obligations of Horizon and AstraZeneca to complete the transactions contemplated by this Agreement are subject to the satisfaction at or prior to the Closing of the following conditions:

6.1.1 No Adverse Law; No Injunction. No Law shall have been enacted, entered, promulgated or enforced by any Governmental Authority that prohibits the consummation of all or any part of the transactions contemplated by this Agreement or the Ancillary Agreements, and no order by any Governmental Authority restraining, enjoining or otherwise preventing the consummation of the transactions contemplated hereby shall be in effect; and

6.1.2 Governmental Approvals. All required consents of, notifications to and filings with any Governmental Authority shall have been made and any waiting periods applicable to the transactions contemplated hereby pursuant to any applicable Law shall have expired or been terminated.

6.2 Conditions to Obligations of Horizon. The obligation of Horizon to complete the transactions contemplated by this Agreement is subject to the satisfaction or waiver by Horizon at or prior to the Closing of the following additional conditions:

6.2.1 Representations and Warranties. The representations and warranties of AstraZeneca contained in Section 3.1 other than the Fundamental Reps included in Section 3.1 shall be true and correct (disregarding any materiality or Material Adverse Effect qualifications within the representation and warranty) in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), except for breaches of such representations and warranties that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, and each Fundamental Rep included in Section 3.1 shall be true and correct in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date);

6.2.2 Covenants. AstraZeneca shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date;

6.2.3 No Material Adverse Effect. Since the Execution Date, no Material Adverse Effect shall have occurred; and

6.2.4 Closing Deliveries. AstraZeneca shall have delivered to Horizon each of the items listed in Section 2.4.2(a).

6.3 Conditions to Obligations of AstraZeneca. The obligation of AstraZeneca to complete the transactions contemplated by this Agreement is subject to the satisfaction or waiver by AstraZeneca at or prior to the Closing of the following additional conditions:
6.3.1 **Representations and Warranties.** The representations and warranties of Horizon contained in Section 3.2 other than the Fundamental Reps included in Section 3.2 shall be true and correct (disregarding any materiality or Horizon Material Adverse Effect qualifications within the representation and warranty) in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), except for breaches of such representations and warranties that would not, individually or in the aggregate, reasonably be expected to have a Horizon Material Adverse Effect, and each Fundamental Rep included in Section 3.2 shall be true and correct in all respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date);

6.3.2 **Covenants.** Horizon shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date; and

6.3.3 **Closing Deliveries.** Horizon shall have delivered to AstraZeneca each of the items listed in Section 2.4.2(b).

6.4 **Frustration of Closing Conditions.** With respect to the conditions to Horizon’s and AstraZeneca’s respective obligations to consummate the transactions contemplated by this Agreement as provided hereunder and each such Party’s right to terminate this Agreement as provided in Section 8.1, neither Horizon nor AstraZeneca may rely on the failure of any condition set forth in this Article 6 to be satisfied if such failure was caused by such Party’s failure to act in good faith or to use its reasonable best efforts to cause the condition to be satisfied to the extent required by Section 4.3.

**ARTICLE 7**

**INDEMNIFICATION**

7.1 **Indemnification.**

7.1.1 **Indemnification by AstraZeneca.** Following the Closing, but subject to the provisions of this Article 7, AstraZeneca shall indemnify, defend and hold harmless Horizon and its Affiliates, and their respective officers, directors, and employees (collectively, “Horizon Indemnitees”) from and against any and all Losses incurred by any Horizon Indemnitee arising out of or related to:

(a) any breach by AstraZeneca of any of the representations or warranties made by AstraZeneca in this Agreement as of the Execution Date and as of the Closing as if the representations and warranties are given as of the Closing Date;

(b) any failure of AstraZeneca to perform any breach by AstraZeneca of any of its covenants, agreements or obligations contained in this Agreement;

(c) any Excluded Liability; or
any failure of AstraZeneca to pay any of its share of Transfer Taxes or Apportioned Obligations allocated to AstraZeneca under Section 5.9.2.

7.1.2 Indemnification by Horizon. Following the Closing, but subject to the provisions of this Article 7, Horizon shall indemnify and hold harmless AstraZeneca and its Affiliates, and their respective officers, directors, and employees (collectively, “AstraZeneca Indemnitees”) from and against any and all Losses incurred by any AstraZeneca Indemnitee arising out of or related to:

(a) any breach by Horizon of any of the representations or warranties made by Horizon in this Agreement as of the Execution Date and as of the Closing as if the representations and warranties are given as of the Closing Date;

(b) any failure of Horizon to perform or any breach by Horizon of any of its covenants, agreements or obligations contained in this Agreement;

(c) any Assumed Liability;

(d) any failure of Horizon to pay Withholding Taxes under Section 5.9.1; or

(e) any failure of Horizon to pay Transfer Taxes or Apportioned Obligations allocated to Horizon under Section 5.9.2.

7.2 Claim Procedure.

7.2.1 Indemnification Claim Procedure. Except as provided in Section 7.2.2 with respect to Third Party claims, in the event of a claim made by a Horizon Indemnitee or an AstraZeneca Indemnitee (the “Indemnified Party”), the Indemnified Party shall give reasonably prompt written notice to the other Party (the “Indemnifying Party”), which notice (an “Indemnification Certificate”) shall: (a) state that the Indemnified Party has paid or properly accrued or reasonably anticipates that it will have to pay or accrue Losses that are subject to indemnification by the Indemnifying Party pursuant to Section 7.1.1 or Section 7.1.2, as applicable, and (b) specify in reasonable detail the individual items and amounts of such Losses, the date each such item was paid or properly accrued, or the basis for such anticipated Liability, and a description of the basis of such Indemnified Party’s claim for indemnification; provided, however, that the failure to give reasonably prompt notice shall not relieve the applicable Indemnifying Party of its indemnification obligations under this Agreement except to the extent that the Indemnifying Party is materially prejudiced by any delay in receiving such notice. In the event that the Indemnifying Party agrees to or is determined to have an obligation to reimburse the Indemnified Party for Losses as provided in this Article 7, the Indemnifying Party shall, subject to the provisions of Section 7.3, promptly (but in any event, within 30 days) pay such amount to the Indemnified Party by wire transfer of immediately available funds to the account specified in writing by the Indemnified Party. The Indemnifying Party may defer making such payment if it objects in a written statement to the claim made in the Indemnification Certificate and delivers such statement to the Indemnifying Party prior to the expiration of such 30-day period. An Indemnifying Party’s failure to object within such 30-day period to any claim set forth in an Indemnification Certificate shall be deemed to be the Indemnifying Party’s
acceptance of, and waiver of any objections to, such claim. If an Indemnifying Party shall so object in writing to any claim or claims made in any Indemnification Certificate, the Indemnifying Party and the Indemnified Party shall attempt in good faith for a period of 20 days following the Indemnified Party’s receipt of such objection notice to agree upon the respective rights of the parties with respect to each of such claims. If no such agreement can be reached after such 20-day period of good faith negotiation, either the Indemnifying Party or the Indemnified Party may pursue dispute resolution pursuant to Section 9.2.

7.2.2 Third Party Claim Procedure. In the event an Indemnified Party becomes aware of a claim made by a Third Party (including any action or proceeding commenced or threatened to be commenced by any Third Party) that such Indemnified Party reasonably believes may result in an indemnification claim pursuant to Section 7.1, such Indemnified Party shall promptly (and in any event within three Business Days after becoming aware of such claim) notify the Indemnifying Party in writing of such claim (such notice, the “Claim Notice” and such claim, a “Third Party Claim”). The Claim Notice shall be accompanied by reasonable supporting documentation submitted by the Third Party making such claim and shall describe in reasonable detail (to the extent known by the Indemnified Party) the facts constituting the basis for such Third Party Claim and the amount of the claimed damages; provided, however, that no delay or failure on the part of the Indemnified Party in delivering a Claim Notice shall relieve the Indemnifying Party from any Liability hereunder except to the extent of any damage or Liability caused by or arising out of such delay or failure. Within 30 days after receipt of any Claim Notice, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of the Third Party Claim referred to therein at the Indemnifying Party’s sole cost and expense (which shall be subject to Section 7.3) with counsel reasonably satisfactory to the Indemnified Party; provided, however, that the Indemnifying Party shall not have the right to assume the defense to the extent the Third Party Claim seeks an injunction or equitable relief or involves a criminal act alleged against the Indemnified Party. If the Indemnifying Party does not so assume control of the defense of such Third Party Claim, the Indemnified Party shall control the defense of such claim. The Party not controlling the defense of such Third Party Claim (the “Non-Controlling Party”) may participate therein at its own expense; provided, however, that if the Indemnifying Party assumes control of the defense of such Third Party Claim and the Indemnifying Party and the Indemnified Party have materially conflicting interests or different defenses available with respect to such Third Party Claim that cause the Indemnified Party to hire its own separate counsel with respect to such proceeding, the reasonable fees and expenses of a single counsel to the Indemnified Party shall be considered “Losses” for purposes of this Agreement (to the extent that the claim is subject to indemnification hereunder). The Party controlling the defense of such Third Party Claim (the “Controlling Party”) shall keep the Non-Controlling Party reasonably advised of the status of such Third Party Claim and the defense thereof and shall consider in good faith recommendations made by the Non-Controlling Party with respect thereto. The Non-Controlling Party shall furnish the Controlling Party with such information as it may have with respect to such Third Party Claim (including copies of any summons, complaint or other pleading that may have been served on such party and any written claim, demand, invoice, billing or other document evidencing or asserting the same) and shall otherwise cooperate with and assist the Controlling Party in the defense of such claim. Neither the Indemnified Party nor the Indemnifying Party shall agree to any settlement of, or the entry of any judgment arising from, any such Third Party Claim without the prior written consent of the other Party, which consent
shall not be unreasonably withheld, conditioned or delayed; provided, however, that the consent of the Indemnified Party shall not be required with respect to any such settlement or judgment if the Indemnifying Party agrees in writing to pay or cause to be paid any amounts payable pursuant to such settlement or judgment (net of the applicable deductible amount specified in Section 7.3.1) and such settlement or judgment includes no admission of liability by or other obligation on the part of the Indemnified Party and includes a complete release of the Indemnified Party from further Liability.

7.3 Limitations on Indemnification.

7.3.1 For purposes of computing the amount of any Losses incurred by any Indemnified Party pursuant to Article 7, any materiality, Material Adverse Effect, or Horizon Material Adverse Effect qualification contained in any representation and warranty or covenant giving rise to the claim for indemnity hereunder shall be disregarded, but for clarity, the foregoing shall not apply with respect to determining whether there has been a breach of any representation and warranty.

7.3.2 The provisions for indemnity under Section 7.1.1(a) or Section 7.1.2(a) shall be effective only when the aggregate amount of all Losses for claims (and series of related claims arising from the same circumstances) exceeds [...***...], in which case the Indemnified Party shall be entitled to indemnification of the Indemnified Party’s Losses in excess thereof. In no event shall any Indemnifying Party have liability for indemnification under Section 7.1.1(a) or Section 7.1.2(a), as applicable, for any amount exceeding, in the aggregate, [...***...]; provided, however, that the limitations on indemnification under this Section 7.3.1 shall not apply to breaches of any Fundamental Rep.

7.3.3 The amount of Losses recovered by an Indemnified Party under Section 7.1.1 or Section 7.1.2, as applicable, shall be reduced by (a) any amounts actually recovered by the Indemnified Party from a Third Party in connection with such claim and (b) the amount of any insurance proceeds paid to the Indemnified Party relating to such claim, both in the case of clause (a) and clause (b) net of any costs of recovery or increases in insurance premiums resulting from such claim. If any amounts referenced in the preceding clauses (a) and (b) are received after payment by the Indemnifying Party of the full amount otherwise required to be paid to an Indemnified Party pursuant to this Article 7, the Indemnified Party shall repay to the Indemnifying Party, promptly after such receipt, any amount that the Indemnifying Party would not have had to pay pursuant to this Article 7 had such amounts been received prior to such payment.

7.3.4 If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Losses pursuant to Section 7.1.1 or Section 7.1.2 and the Indemnifying Party could have recovered all or a part of such Losses from a Third Party based on the underlying claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against such Third Party as are necessary to permit the Indemnifying Party to recover from the Third Party the amount of such payment.

7.3.5 The representations and warranties of AstraZeneca and Horizon contained in this Agreement shall survive the Closing and continue in full force and effect

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thereafter through and including the date that is [...] after the Closing Date; provided, that the Fundamental Reps shall remain in full force and effect and shall survive indefinitely or, if applicable, until 60 days following the expiration of the applicable statute of limitations. None of the covenants or agreements contained in this Agreement shall survive the Closing other than those that by their terms expressly contemplate performance after the Closing Date and such surviving covenants and agreements shall survive the Closing until fully performed.

7.3.6 TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT (A) AS A RESULT OF FRAUD OR WILLFUL MISCONDUCT AND (B) TO THE EXTENT OWED BY THE INDEMNIFIED PARTY TO A THIRD PARTY UNDER A THIRD PARTY CLAIM, NEITHER HORIZON NOR ASTRAZENECA SHALL BE LIABLE TO THE OTHER, OR THEIR AFFILIATES, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY OR PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, INCLUDING LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (WHETHER OR NOT FORESEEABLE AT THE EXECUTION DATE), CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION WITH, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES WHICH ARE BASED UPON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND MISREPRESENTATION), BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

7.4 Tax Treatment of Indemnification Payments. All payments made pursuant to this Article 7 shall be treated as adjustments to the Purchase Price for all Tax purposes, unless otherwise required by applicable Law.

7.5 Exclusive Remedy. Except as expressly provided otherwise in this Agreement and subject to Section 9.10, each Party acknowledges and agrees that, following the Closing, the remedies provided for in this Article 7 shall be the sole and exclusive remedies for claims and damages available to the Parties and their respective Affiliates arising out of or relating to this Agreement, except that nothing herein shall limit the Liability of either Party for common law fraud or willful misconduct. This Section 7.5 shall not effect either Party’s ability to exercise any rights or remedies available to such Party under any Ancillary Agreement with respect to claims arising under such Ancillary Agreement.

7.6 Setoff Rights. Neither Party shall have any right of setoff of any amounts due and payable, or any Liabilities arising, under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under any Ancillary Agreement. The payment obligations under each of this Agreement and the Ancillary Agreements remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the respective Ancillary Agreements.

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ARTICLE 8
TERMINATION

8.1 Termination. Prior to the Closing, this Agreement shall terminate on the earliest to occur of any of the following events:

8.1.1 the mutual written agreement of Horizon and AstraZeneca;

8.1.2 by written notice delivered by either Horizon or AstraZeneca to the other, if the Closing shall not have occurred on or prior to December 31, 2013 (the “End Date”) (other than due to a breach of any representation or warranty hereunder of the Party seeking to terminate this Agreement or as a result of the failure on the part of such Party to comply with or perform any of its covenants, agreements or obligations under this Agreement);

8.1.3 by written notice delivered by Horizon to AstraZeneca, if (a) there has been a material misrepresentation or material breach by AstraZeneca of a representation or warranty of AstraZeneca contained in this Agreement or (b) there shall be a material breach by AstraZeneca of any covenant, agreement or obligation of AstraZeneca in this Agreement, and such failure or breach described in clause (a) or (b) would result in the failure of a condition set forth in Section 6.2.1 or Section 6.2.2 that has not been waived by Horizon, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by Horizon to AstraZeneca and (ii) the day that is five Business Days prior to the End Date; provided, that Horizon may not terminate this Agreement pursuant to this Section 8.1.3 if Horizon is in material breach of this Agreement; or

8.1.4 by written notice delivered by AstraZeneca to Horizon, if (a) there has been a material misrepresentation or material breach by Horizon of a representation or warranty of Horizon contained in this Agreement or (b) there shall be a material breach by Horizon of any covenant, agreement or obligation of Horizon in this Agreement, and such failure or breach described in clause (a) or clause (b) would result in the failure of a condition set forth in Section 6.3.1 or Section 6.3.2 and has not been waived by AstraZeneca, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by AstraZeneca to Horizon and (ii) the day that is five Business Days prior to the End Date; provided, that AstraZeneca may not terminate this Agreement pursuant to this Section 8.1.4 if AstraZeneca is in material breach of this Agreement.

8.2 Procedure and Effect of Termination.

8.2.1 Notice of Termination. Termination of this Agreement by either Horizon or AstraZeneca shall be by delivery of a written notice to the other. Such notice shall state the termination provision in this Agreement that such terminating Party is claiming provides a basis for termination of this Agreement. Termination of this Agreement pursuant to the provisions of Section 8.1 shall be effective upon and as of the date of delivery of such written notice as determined pursuant to Section 9.2.

8.2.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 8.1 by Horizon or AstraZeneca, this Agreement shall be terminated and have no further effect, and there shall be no liability hereunder on the part of AstraZeneca, Horizon or
any of their respective Affiliates, except that Sections 5.4 (Publicity), 5.5 (Confidentiality), 8.2.2 (Effect of Termination), 8.2.3 (Withdrawal of Certain Filings) and Article 9 (Miscellaneous) shall survive any termination of this Agreement. For clarity, in the event of termination of this Agreement pursuant to Section 8.1, the Parties shall not enter into any of the Ancillary Agreements not entered into on the Execution Date or have any obligations thereunder. Nothing in this Section 8.2.2 shall relieve either Party of liability for fraud, willful misconduct, intentional misrepresentation or any breach of this Agreement prior to the termination hereof.

8.2.3 Withdrawal of Certain Filings. As soon as practicable following a termination of this Agreement for any reason, but in no event less than 30 days after such termination, Horizon or AstraZeneca shall, to the extent practicable, withdraw all filings, applications and other submissions relating to the transactions contemplated by this Agreement filed or submitted by or on behalf of such Party, any Governmental Authority or other Person.

ARTICLE 9
MISCELLANEOUS

9.1 Governing Law, Jurisdiction, Venue and Service.

9.1.1 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of Law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction.

9.1.2 Jurisdiction. Subject to Section 9.2 and 9.10, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

9.1.3 Venue. Subject to Section 9.2 and 9.10, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

9.1.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 9.3 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any court.
9.2 Dispute Resolution.

9.2.1 Except as provided in Section 9.10, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of 10 Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

9.2.2 If such Senior Officers are unable to resolve any such Dispute within such 10-Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 9.2.2 upon written notice to the other Party (an “Arbitration Notice”) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the “Arbitrators”). Each of Horizon and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made later than 30 days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Horizon and the Arbitrator chosen by AstraZeneca, but in no event later than 30 days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association (“AAA”) (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, USA, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within 15 days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with Applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

9.2.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 9.2, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 9.2.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses) or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 9.2.3 is pending under this Agreement, the Parties shall continue to comply with all terms and provisions of this Agreement. All arbitration
9.3 Notices.

9.3.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “Notice”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 9.3.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 5 days’ prior to such address taking effect in accordance with this Section 9.3. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.

9.3.2 Address for Notice.

If to AstraZeneca, to:
AstraZeneca AB
Pepparredsleden 1
S-431 83 Mölndal
Attention: President
Facsimile: +46 31 7763871

with a copy (which shall not constitute notice) to:
AstraZeneca AB
Pepparredsleden 1
S-431 83 Mölndal
Attention: Senior Counsel and Lead, Legal Dept.
Facsimile: +46 31 7763871

and to:
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Facsimile: (202) 662-6291
Attention: John Hurvitz
9.4 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Horizon Indemnitees and AstraZeneca Indemnitees under Article 9, they shall not be construed as conferring any rights on any other Persons.

9.5 Waiver and Non-Exclusion of Remedies. 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 shall 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 of any right hereunder or of the failure to perform or of a breach by the other Party shall 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.

9.6 Expenses. Except as otherwise specified herein, and whether or not the Closing takes place, each Party shall bear any costs and expenses incurred by it with respect to the transactions contemplated herein.

9.7 Assignment. Except as expressly set forth in this Agreement, neither Party shall have the right or the power to assign, in whole or in part, any of its rights, or delegate the performance of any of its obligations, under this Agreement without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld, conditioned or delayed, and any assignment or delegation of this Agreement or any of such rights or obligations without such authorization shall be void and of no effect; provided, however, that either Party may assign the Agreement, in whole or in part, to an Affiliate without the prior written authorization of the other Party; and provided, further, that either Party shall have the right to assign this Agreement, in whole or in part, in connection with a merger or other
acquisition of the capital stock or all or substantially all of its assets, without the prior written authorization of the other Party. Any permitted assignment or
delegation hereunder by a Party shall not relieve such Party of any of its obligations under this Agreement (whether by operation of law or otherwise), unless,
with respect an assignment to a Third Party, such assignee agrees in writing to assume such Party’s obligations under this Agreement, in which case such
Party shall be relieved of its obligations hereunder from and after the effective date of such assignment and assumption. Subject to the foregoing, this
Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

9.8 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written
agreement executed by both Parties.

9.9 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 shall be fully severable, (b) this
Agreement shall 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 shall remain in full force and effect and shall 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 shall 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.

9.10 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not
performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or
injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or
any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any
requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific
performance, including the defense that a remedy at law would be adequate.

9.11 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement
shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in
interpretation between the English version and such translation, the English version shall control.

9.12 Bulk Sales Statutes. Horizon hereby waives compliance by AstraZeneca with any applicable bulk sales statutes in any jurisdiction in connection
with the transactions under this Agreement.

9.13 Counterparts. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an
original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of
a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

9.14 Entire Agreement. This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Disclosure Schedules, the Ancillary Agreements and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Execution Date.

AstraZeneca AB

By: /s/ Jan-Olof Jacke
    Name: Jan-Olof Jacke
    Title: President

Horizon Pharma USA, Inc.

By: /s/ Timothy P. Walbert
    Name: Timothy P. Walbert
    Title: President and Chief Executive Officer
### APA Licensed Trademarks

<table>
<thead>
<tr>
<th>Country</th>
<th>Mark</th>
<th>App Date / Reg Date</th>
<th>App No / Reg No</th>
<th>Goods</th>
<th>Status</th>
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<tr>
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<td>VIMOVO &amp; Design</td>
<td>App 01-MAY-2009 Reg 01-FEB-2011</td>
<td>App 77726998 Reg 3914867</td>
<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
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<td>App 77670350 Reg 3941225</td>
<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
<td>REGISTERED</td>
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</tbody>
</table>
Schedule 1.1.25

AstraZeneca’s Knowledge

[...***...]

***Confidential Treatment Requested
Schedule 1.1.82(a)

Licensed Copyrights

Copyrights with respect to the following:

- Product Promotional Materials
- All labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with the Product
- The prescribing information for the Product
- Any website associated with any of Licensed Domain Names
Schedule 1.1.82(b)

Excluded Copyrights

None.
Schedule 1.1.83

Licensed Domain Names

vimovo.com
vimovosavingscard.com
vimovofreetrial.com
saveonvimovo.com
learnaboutvimovo.com
vimovosavings.com
### Merck Patents

<table>
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<tr>
<th>Filing Date</th>
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<th>Publication Date</th>
<th>Publication No.</th>
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<td>23 Jan 1995</td>
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<td>05 Apr 2005</td>
<td>6875872</td>
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<td>16 Oct 2000</td>
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<td></td>
<td>08 Jun 2004</td>
<td>6747155</td>
<td>25 May 2018</td>
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Nexium Trademark

Word marks

• NEXIUM
• NEXIUM CONTROL
• NEXIUM OTC
• NEXIAM
• INEXIUM
• NEKSIUM
• THE PURPLE PILL
• In each case, including any derivatives, translations, transliterations or stylized forms of any of the foregoing word marks

Design marks

• Black dots device (Nexium logo)
• White dots device
Color mark

- Purple colored capsule with two gold rings as described below:

  The colors PURPLE and GOLD are claimed as a feature of the mark. The colors PURPLE and GOLD as applied to the surface of a pharmaceutical capsule.

  The capsule (as shown in the drawing below) is PURPLE with two side-by-side GOLD rings that encircle the top of the capsule. The outline of the capsule is in broken lines and is intended merely to show the position of the mark but is not part of the mark. The drawing is lined for the colors PURPLE and GOLD.

Below are representational images of the purple colored capsule with two gold rings. The positioning of text on the capsule may differ from the images shown.
Schedule 1.1.117

Permitted Encumbrances

None.
## Pozen Patents

<table>
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*If Pozen amends the claims of this application to be specifically directed to aspirin products it will no longer be part of the collaboration between AstraZeneca and Pozen and therefore would no longer be a Pozen Patent.
## Schedule 1.1.136

**Purchased Patents**

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<th>Filing</th>
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## Current ANDA Litigation Cases Involving VIMOVO

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<th>Defendants</th>
<th>US District Court</th>
<th>Case No.</th>
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<tbody>
<tr>
<td>AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc.</td>
<td>Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories Ltd.</td>
<td>D.N.J. (Pisano, J.)</td>
<td>Civil Action No. 11-02317 (JAP) (DEA)</td>
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<td>Lupin Ltd. and Lupin Pharmaceuticals Inc.</td>
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<td>D.N.J. (Pisano, J.)</td>
<td>Civil Action No. 11-06348 (JAP) (DEA)</td>
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</table>
Schedule 2.1.1(a)

Purchased Contracts

Amended and Restated Collaboration and License Agreement for the United States by and between Pozen Inc. and AstraZeneca AB, dated as of November 18, 2013.
Schedule 2.1.1(b)

Purchased Regulatory Approvals

NDA # 22-511

IND # 76301
Schedule 2.4.2(a)(iii)

Delivery Schedule of Tangible Purchased Assets

Purchased Regulatory Approvals and Regulatory Documentation included in Purchased Assets that are addressed in the Transition Agreement to be transferred to Horizon as provided therein. Any remaining Regulatory Documentation included in the Purchased Assets to be transferred to Horizon within [...] days after December 16, 2013.

Product Promotional Materials to be transferred as provided in the Transition Plan.

Product Records to be transferred to Horizon no later than December 31, 2013.
Schedule 4.2

Ordinary Course of Business Exceptions

[...***...]

***Confidential Treatment Requested
LICENSING AGREEMENT

By and between

AstraZeneca AB

and

Horizon Pharma USA, Inc.

Dated as of November 22, 2013
ARTICLE 1 DEFINITIONS

ARTICLE 2 GRANT OF RIGHTS; ALLIANCE MANAGEMENT
  2.1 Grants to Horizon
  2.2 Sublicenses
  2.3 Grants to AstraZeneca
  2.4 Retention of Rights
  2.5 No Implied Rights
  2.6 Restrictions
  2.7 Horizon Control in Horizon Territory
  2.8 Alliance Management

ARTICLE 3 TERRITORIAL RESTRICTIONS; COMPLIANCE
  3.1 Horizon Restrictions
  3.2 AstraZeneca Restrictions
  3.3 Compliance with Legal Requirements
  3.4 Compliance with Ethical Business Practices

ARTICLE 4 REGULATORY
  4.1 Regulatory Responsibilities
  4.2 Access to Regulatory Approvals and Documentation
  4.3 Pharmacovigilance Obligations
  4.4 Post-Closing Responsibility for Product

ARTICLE 5 RECORDS
  5.1 Records
  5.2 Review of Horizon Financial Records

ARTICLE 6 ASTRAZENECA PATENTS
  6.1 Maintenance and Prosecution of AstraZeneca Patents
6.2 Enforcement of AstraZeneca Patents

6.3 Infringement Claims by Third Parties

6.4 Invalidity or Unenforceability Defenses or Actions

6.5 Statements or Actions Pertaining to Esomeprazole or Nexium

ARTICLE 7 LICENSED TRADEMARKS

7.1 Use of Licensed Trademarks

7.2 Approval Procedures

7.3 Clearance, Registration, Prosecution and Maintenance of Licensed Trademarks

7.4 Enforcement and Defense of Licensed Trademarks

7.5 No Implied Rights

7.6 Other Trademarks

ARTICLE 8 LICENSED DOMAIN NAMES

8.1 Ownership and Goodwill

8.2 Registration and Maintenance

8.3 Control of Licensed Domain Name Websites

8.4 Country-Specific Traffic

8.5 Enforcement

ARTICLE 9 CONFIDENTIALITY AND NON-DISCLOSURE

9.1 General

9.2 Other Nexium Communications

9.3 Certain Permitted Esomeprazole and Nexium Disclosures

9.4 Press Releases

ARTICLE 10 DISCLAIMER OF WARRANTIES

ARTICLE 11 INDEMNITY
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<td>Counterparts</td>
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SCHEDULES

Schedule 1.29 Licensed Trademarks

- iv -
This License Agreement (this “Agreement”) is made and entered into effective as of November 22, 2013 (the “Effective Date”) by and between AstraZeneca AB, a Swedish corporation ("AstraZeneca"), and Horizon Pharma USA, Inc., a corporation organized and existing under the Laws of the State of Delaware (“Horizon”). AstraZeneca and Horizon are sometimes referred herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, AstraZeneca and Horizon are parties to that certain Asset Purchase Agreement, dated as of November 18, 2013 (the “Asset Purchase Agreement”), pursuant to which, effective as of the Closing, Horizon is purchasing from AstraZeneca certain assets related to the Product (as defined in the Asset Purchase Agreement) in the Horizon Territory (as defined in the Asset Purchase Agreement) and AstraZeneca is required to grant a license or right of reference and use to Horizon, and Horizon is required to take a license or right of reference and use, under certain intellectual property, regulatory data and approvals, to Exploit the Product and Other Products in the Horizon Territory; and

WHEREAS, following the Closing, Horizon will Control certain regulatory data and approvals with respect to the Product and is required to grant a right of reference and use to AstraZeneca, and AstraZeneca is required to take a right of reference, under such regulatory data and approvals with respect to the Product, to Exploit the Product and Other Products in the AstraZeneca Territory.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth and set forth in the Asset Purchase Agreement, the other Ancillary Agreements, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the meanings set forth in this Article 1 and capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed thereto in the Asset Purchase Agreement.

1.1 “AAA” has the meaning set forth in Section 13.2.2.

1.2 “Agreement” has the meaning set forth in the preamble hereto.

1.3 “Alliance Manager” has the meaning set forth in Section 2.8.

1.4 “Ancillary AstraZeneca Confidential Information” has the meaning set forth in Section 9.1.3.

1.5 “Ancillary Confidential Information” has the meaning set forth in
1.6 “Ancillary Disclosing Party” has the meaning set forth in Section 9.1.1.

1.7 “Ancillary Horizon Confidential Information” has the meaning set forth in Section 9.1.2.

1.8 “Ancillary Receiving Party” has the meaning set forth in Section 9.1.1.


1.10 “Arbitration Notice” has the meaning set forth in Section 13.2.2.

1.11 “Arbitrators” has the meaning set forth in Section 13.2.2.

1.12 “Asset Purchase Agreement” has the meaning set forth in the recitals hereto.

1.13 “AstraZeneca” has the meaning set forth in the preamble hereto.

1.14 “AstraZeneca Indemnitees” has the meaning set forth in Section 11.1.

1.15 “AstraZeneca Patents” has the meaning set forth in Section 6.1.

1.16 “Breaching Party” has the meaning set forth in Section 12.2.

1.17 “CCP” has the meaning set forth in Section 4.1.2.

1.18 “Dispute” has the meaning set forth in Section 13.2.1.

1.19 “Effective Date” has the meaning set forth in the preamble hereto.

1.20 “Ex-US Licensed Patents” means the Patent Rights that are the foreign equivalents of the Merck Patents, excluding any such Patent Rights included in the Manufacturing Technology.

1.21 “Existing Pediatric Study” means that certain study entitled [...***...].

1.22 “Government Official” means (a) any Person employed by or acting on behalf of a government, government-controlled agency or entity or public international organization, (b) any political party, party official or candidate, (c) any Person who holds or performs the duties of a public-sector appointment, office or position created by custom or
1.23 “Horizon” has the meaning set forth in the preamble hereto.

1.24 “Horizon Indemnites” has the meaning set forth in Section 11.2.

1.25 “Horizon Regulatory Documentation” means any and all Regulatory Documentation related to the Product or any Other Product, in each case, Controlled by Horizon or any of its Affiliates effective at any time as of or following the Closing, including the Purchased Regulatory Approvals and any other Regulatory Documentation included in the Purchased Assets.

1.26 “Licensed Intellectual Property” means the US Licensed Patents, the Ex-US Licensed Patents, the Licensed Know-How, the Licensed Copyrights, the Licensed Trademarks, the Licensed Domain Names and the Manufacturing Technology.

1.27 “Licensed Know-How” means (a) as of the Effective Date, any data, information and know-how that (i) is not generally known, (ii) are Controlled by AstraZeneca or its Affiliates and (iii) is used by or on behalf of AstraZeneca or its Affiliates as of the Effective Date for the Exploitation of the Product in the Horizon Territory or the research or development of the Product in the AstraZeneca Territory, excluding the Merck Know-How and (b) as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Know-How without violating the terms of any Merck Agreement, (i) the data, information and know-how described in clause (a) and (ii) the Merck Know-How used by or on behalf of AstraZeneca or its Affiliates as of the Effective Date for the Exploitation of the Product in the Horizon Territory provided that in either case ((a) or (b)), if such data, information or know-how becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 9.1), such data, information or know-how shall no longer be deemed Licensed Know-How, but excluding in either case ((a) or (b)) any data, information and know-how included in the Manufacturing Technology.

1.28 “Licensed Regulatory Documentation” means any and all Regulatory Documentation related to the Product or any Other Product, in each case, Controlled by AstraZeneca or any of its Affiliates as of and following the Closing, excluding the Regulatory Documentation included in the Purchased Assets.

1.29 “Licensed Trademarks” means (a) the Trademark VIMOVO and the other Trademarks and logos listed on Schedule 1.29 and (b) any variation or derivation of any of the Trademarks set forth in the foregoing clause (a) that are approved by AstraZeneca in accordance with the procedures set forth in Section 7.2.1 for use on or in connection with the Exploitation of the Product or any Other Product in the Horizon Territory.

1.30 “Manufacturing Technology” means (a) as of the Effective Date, all Patent Rights (including foreign equivalents of the Merck Patents) and all data, information and know-how that (i) with respect to data, information and know-how, is not generally known, (ii) are Controlled by AstraZeneca or any of its Affiliates as of the Effective Date and (iii) are used

- 3 -
by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Products or Other Products as of the Effective Date, excluding the Merck Patents and Merck Know-How and (b) as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Patents and Merck Know-How without violating the terms of any Merck Agreement, the Patent Rights, data, information and know-how described in clause (a) and any Merck Patents and Merck Know-How that are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Products or Other Products as of the Effective Date; provided, that in either case ((a) or (b)), if any data, information or know-how (but not, for clarity, Patent Rights) included in Manufacturing Technology becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 9.1), such data, information or know-how shall no longer be deemed Manufacturing Technology.

1.31 "Merck Net Sales" means, for any period of time, the total amount required to be recorded for such period by Horizon or any of its Affiliates or Sublicensees on its or their respective books and records in accordance with GAAP with respect to sales of Merck Product in the Horizon Territory for any use (whether in human medicine or otherwise) to its non-Affiliates after deducting (if not already deducted in the amount recorded) trade discounts, rebates, returns and allowances, retroactive price reductions or adjustments, and [***] of the amount recorded to cover cash discounts ("fast pay"), sales or excise taxes, transportation, and insurance charges.

1.32 “Notice” has the meaning set forth in Section 13.3.1.

1.33 “Notice Period” has the meaning set forth in Section 12.2.

1.34 “Other Esomeprazole Product” means any Other Product that contains Esomeprazole as an active ingredient.

1.35 “Party” and “Parties” each has the meaning set forth in the preamble hereto.

1.36 “Payment” has the meaning set forth in Section 3.4.1(b).

1.37 “Primary Licensed Domain Name” means vimovo.com.

1.38 “Product Label” means, with respect to the Product or any Other Product in the Horizon Territory, (a) the Regulatory Authority-approved full prescribing information for the Product or any Other Product, as applicable, including any required patient information and (b) all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for the Product or any Other Product, as applicable.

1.39 “Product Websites” has the meaning set forth in Section 8.3.

1.40 “Recipients” means, with respect to a Party, such Party’s and its Affiliates’ respective officers, employees, agents, attorneys, consultants, contractors, advisors and other representatives.

***Confidential Treatment Requested
1.41 “Representatives” has the meaning set forth in Section 3.4.1(b).

1.42 “Secondary Licensed Domain Names” means any Licensed Domain Name other than the Primary Domain Name.

1.43 “Senior Officer” means, with respect to AstraZeneca, its Vice President, Cornerstone and Commercial Excellence and with respect to Horizon, its Chief Executive Officer.

1.44 “Sublicensor” means a Third Party that is granted a sublicense (or further rights of reference and use) by Horizon under the grant in Section 2.1 or by AstraZeneca under the grant in Section 2.3, in either case, in accordance with Section 2.2.

1.45 “Term” has the meaning set forth in Section 12.1.

1.46 “Terminable Rights and Provisions” means (a) the licenses granted by AstraZeneca to Horizon under Section 2.1 with respect to the Licensed Trademarks and Licensed Domain Names only (but not, for clarity, with respect to any other Licensed Intellectual Property or Licensed Regulatory Documentation), (b) Article 7 and (c) Article 8.

1.47 “Third Party Claims” has the meaning set forth in Section 11.1.

1.48 “US Licensed Patents” means as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Patents without violating the terms of any Merck Agreement, the Merck Patents, excluding any Merck Patents included in the Manufacturing Technology.

2.1 Grants to Horizon. Subject to Section 2.4 and the other terms and conditions of the Asset Purchase Agreement and this Agreement, AstraZeneca (on behalf of itself and its Affiliates), in consideration of the amounts due under the Asset Purchase Agreement, hereby grants to Horizon and its Affiliates:

2.1.1 an exclusive (even as to AstraZeneca and its Affiliates), royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Copyrights, Licensed Trademarks, Licensed Domain Names, US Licensed Patents, and Licensed Know-How to Exploit the Product or any Other Product in the Field in the Horizon Territory;

2.1.2 an exclusive (even as to AstraZeneca and its Affiliates), royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture or have Manufactured the Product or any Other Product in the Field in the Horizon Territory;

2.1.3 a non-exclusive, royalty-free, non-transferable (except as provided
in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture and have Manufactured the Product or any Other Product in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in connection with the Exploitation of the Product or any Other Product in the Field in the Horizon Territory;

2.1.4 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Copyrights, Ex-US Licensed Patents, and Licensed Know-How to (a) perform research and development activities with respect to the Product or any Other Product in the AstraZeneca Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory, and (b) to export or import the Product or any Other Product in the AstraZeneca Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory; and

2.1.5 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) right of reference and use, with the right to grant further rights of reference and use in accordance with Section 2.2, under the Licensed Regulatory Documentation to (a) Manufacture, have Manufactured or Exploit the Product or any Other Product in the Field in the Horizon Territory, (b) Manufacture and have Manufactured the Product or any Other Product in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory, and (c) perform research and development activities with respect to, and export and import, the Product or any Other Product in the AstraZeneca Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the Horizon Territory.

All licenses granted under this Section 2.1 shall be perpetual and irrevocable except as otherwise provided in Article 12 with respect to the termination of the Terminable Rights and Provisions.

2.2 Sublicenses. Horizon shall have the right to grant sublicenses (or further rights of reference and use) under the licenses and rights of reference and use granted in Section 2.1, through multiple tiers of Sublicensees, and AstraZeneca shall have the right to grant sublicenses (or further rights of reference and use) under the licenses and rights of reference and use granted in Section 2.3, through multiple tiers of Sublicensees; provided, however, that any such sublicense granted by Horizon with respect to any Manufacturing Technology related to Esomeprazole under Section 2.1.2 or Section 2.1.3 shall be subject to AstraZeneca’s prior written consent, which consent may be granted or withheld in its sole discretion; provided, further, that AstraZeneca shall not condition, withhold or delay its consent to any such sublicense to be granted by Horizon or any of its Affiliates to any Third Party if, at the time of such proposed sublicense, such Third Party is supplying Esomeprazole to AstraZeneca or any of its Affiliates or any of its or their respective licensees or sublicensees. Notwithstanding the foregoing, AstraZeneca acknowledges and agrees that Horizon intends to grant [...***...]

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the Horizon Territory, and AstraZeneca hereby consents to such sublicense. AstraZeneca agrees that neither AstraZeneca nor any of its Affiliates shall claim (or assist a Third Party in claiming) that the further formulation or other processing of Esomeprazole by or on behalf of Horizon or its Affiliates or any Sublicensee in connection with the Manufacture of the Product or any Other Product in the Horizon Territory or in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in accordance with this Agreement, infringes or misappropriates any Patent Rights, information, data or know-how that are part of the Manufacturing Technology and that Horizon or its Affiliates or any Sublicensee shall have the right to formulate or otherwise process, or have a Third Party formulate or otherwise process on their behalf, any Esomeprazole from [...***... or any other Third Party to whom Horizon or any of its Affiliates grants a sublicense to any Manufacturing Technology related to Esomeprazole with AstraZeneca’s consent in connection with the Manufacture of the Product or any Other Product in the Horizon Territory or in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in accordance with this Agreement. Further, if AstraZeneca or any of its Affiliates assigns or transfers any Patent Rights that are part of the Manufacturing Technology, AstraZeneca or such Affiliate shall cause such assignee or transferee to be bound by the covenant set forth in the immediately foregoing sentence. Each Party granting a sublicense pursuant to this Section 2.2 shall (a) remain jointly and severally liable for the performance or non-performance of any such Sublicensee, and (b) provide to the other Party within 14 days after execution by the parties thereto a written notice setting forth in reasonable detail the nature of such sublicense and the identity of the Sublicensee, which written notice shall include a copy of such executed sublicense agreement; provided that the financial terms and any other commercially sensitive terms of any such sublicense agreement may be redacted to the extent not pertinent to an understanding of either Party’s obligations or benefits under this Agreement. The grant of any such sublicense shall not relieve the sublicensing Party of its obligations under this Agreement, except to the extent such obligations are performed by any such Affiliate or Sublicensee. Notwithstanding anything to the contrary herein, neither Party shall be responsible or liable for the other Party’s or its Affiliates’ (or their respective sub-sublicensees’) performance or exercise of any sublicense granted by the first Party to such other Party or its Affiliates under Section 2.1 or Section 2.3, as applicable.

2.3 Grants to AstraZeneca. Subject to the terms and conditions of this Agreement, Horizon (on behalf of itself and its Affiliates and sublicensees) hereby grants to AstraZeneca and its Affiliates:

2.3.1 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture or have Manufactured the Product or any Other Product in the Horizon Territory but solely for the exportation and use of such Product or Other Product in connection with the Exploitation of the Product or any Other Product in the Horizon Territory;

2.3.2 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) license, with the right to grant sublicenses in accordance with Section 2.2, under the Licensed Copyrights, US Licensed Patents, and Licensed Know-How to (a) perform research and development activities with respect to the Product or any Other Product in the Horizon Territory, and AstraZeneca hereby consents to such sublicense. AstraZeneca agrees that neither AstraZeneca nor any of its Affiliates shall claim (or assist a Third Party in claiming) that the further formulation or other processing of Esomeprazole by or on behalf of Horizon or its Affiliates or any Sublicensee in connection with the Manufacture of the Product or any Other Product in the Horizon Territory or in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in accordance with this Agreement, infringes or misappropriates any Patent Rights, information, data or know-how that are part of the Manufacturing Technology and that Horizon or its Affiliates or any Sublicensee shall have the right to formulate or otherwise process, or have a Third Party formulate or otherwise process on their behalf, any Esomeprazole from [...***... or any other Third Party to whom Horizon or any of its Affiliates grants a sublicense to any Manufacturing Technology related to Esomeprazole with AstraZeneca’s consent in connection with the Manufacture of the Product or any Other Product in the Horizon Territory or in the AstraZeneca Territory but solely for the exportation and use of such Product or Other Product in accordance with this Agreement. Further, if AstraZeneca or any of its Affiliates assigns or transfers any Patent Rights that are part of the Manufacturing Technology, AstraZeneca or such Affiliate shall cause such assignee or transferee to be bound by the covenant set forth in the immediately foregoing sentence. Each Party granting a sublicense pursuant to this Section 2.2 shall (a) remain jointly and severally liable for the performance or non-performance of any such Sublicensee, and (b) provide to the other Party within 14 days after execution by the parties thereto a written notice setting forth in reasonable detail the nature of such sublicense and the identity of the Sublicensee, which written notice shall include a copy of such executed sublicense agreement; provided that the financial terms and any other commercially sensitive terms of any such sublicense agreement may be redacted to the extent not pertinent to an understanding of either Party’s obligations or benefits under this Agreement. The grant of any such sublicense shall not relieve the sublicensing Party of its obligations under this Agreement, except to the extent such obligations are performed by any such Affiliate or Sublicensee. Notwithstanding anything to the contrary herein, neither Party shall be responsible or liable for the other Party’s or its Affiliates’ (or their respective sub-sublicensees’) performance or exercise of any sublicense granted by the first Party to such other Party or its Affiliates under Section 2.1 or Section 2.3, as applicable.
2.3.3 a non-exclusive, royalty-free, non-transferable (except as provided in Section 13.7) right of reference and use, with the right to grant further rights of reference and use in accordance with Section 2.2, under the Horizon Regulatory Documentation to (a) Manufacture, have Manufactured or Exploit the Product or any Other Product in the Field in the AstraZeneca Territory, (b) Manufacture and have Manufactured the Product or any Other Product in the Horizon Territory but solely for the exportation and use of such Product or Other Product in connection with the Manufacture and Exploitation of the Product or any Other Product in the AstraZeneca Territory, and (c) perform research and development activities with respect to, and export and import, the Product or any Other Product in the Horizon Territory solely in connection with the Manufacture and Exploitation of the Product or any Other Product in the AstraZeneca Territory.

2.4 Retention of Rights.

2.4.1 Except for the rights and licenses expressly granted to Horizon and Affiliates in this Agreement or in any other Ancillary Agreement, AstraZeneca, on behalf of itself and its Affiliates, retains all rights under the Licensed Intellectual Property and the Licensed Regulatory Documentation.

2.4.2 Except for the rights and licenses expressly granted to AstraZeneca and Affiliates in this Agreement or in any other Ancillary Agreement, (a) Horizon, on behalf of itself and its Affiliates, retains all rights under Horizon Regulatory Documentation and (b) Horizon, on behalf of its and its Affiliates, retains the exclusive right under (i) the Licensed Copyrights, Licensed Trademarks, Licensed Domain Names, US Licensed Patents, and Licensed Know-How to Exploit the Product or any Other Product in the Field in the Horizon Territory and (ii) the Manufacturing Technology, the Licensed Trademarks and the Licensed Copyrights to Manufacture or have Manufactured the Product or any Other Product in the Field in the Horizon Territory.

2.4.3 No rights shall be deemed granted by either Party to the other Party by implication, estoppel or otherwise with respect thereto.

2.4.4 In addition, AstraZeneca, on behalf of itself and its Affiliates, retains the non-exclusive right in the Horizon Territory under the Licensed Intellectual Property and Licensed Regulatory Documentation to perform its obligations under this Agreement, the Supply Agreement or Section 5.3 of the Asset Purchase Agreement.

2.4.5 Except as expressly granted herein, in the Asset Purchase Agreement or in any other Ancillary Agreement, (a) neither Party grants any right or license to any assets or rights, including intellectual property rights, of such Party and its Affiliates and (b) [...***...] or [...***...].

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2.5 No Implied Rights. For the avoidance of doubt, (a) Horizon and its Affiliates shall have no right, express or implied, except as expressly provided in Section 2.1 and elsewhere in this Agreement, the Asset Purchase Agreement, and the Ancillary Agreements with respect to (i) the Licensed Intellectual Property or the Licensed Regulatory Documentation, and (ii) [...***...]) and (b) AstraZeneca and its Affiliates shall have no right, express or implied, with respect to the Horizon Regulatory Documentation, except as expressly provided in Section 2.3 and elsewhere in this Agreement and in Section 2.3.3 of the Supply Agreement. For clarity, except for the licenses granted to Horizon and its Affiliates under the Licensed Trademarks and Licensed Domain Names, nothing herein grants either Party or any of its Affiliates the right to use or to register any Domain Name (including both gTLDs and ccTLDs) or any social media name, tag or handle or similar identifier that incorporates in whole or in part any of the trade names, corporate names and corporate logos of the other Party or the other Party’s Affiliates that are used by the other Party or any of the other Party’s Affiliates.

2.6 Restrictions.

2.6.1 Horizon shall not, and shall cause its Affiliates and Sublicensees not to, Exploit the Product or any Other Product for any indication other than (a) one or more indications for which NSAIDs alone are indicated, together with (b) the prevention, treatment or amelioration of, or decrease in the risk of, gastrointestinal side effects of NSAIDs in patients at risk of developing side effects associated with NSAID use, so long as such prevention, treatment or amelioration of, or decrease in the risk of, gastrointestinal side effects is described or referenced in the product prescribing information.

2.6.2 Without limiting the generality of Section 2.6.1, without the prior written consent of AstraZeneca (which consent may be granted or withheld in its sole discretion), Horizon shall not, and shall cause its Affiliates and Sublicensees not to:

(a) conduct any pre-clinical or clinical studies or any epidemiological, health economic or other similar studies with respect to any Other Esomeprazole Product;
(b) develop or seek Regulatory Approval for any Other Esomeprazole Product;
(c) develop or seek Regulatory Approval for the Product outside of the Field;
(d) refer to, or make any comparisons to, Nexium, any Nexium Trademark or the Nexium Business in advertising or promotional materials or otherwise (including any internet or social media campaigns);
(e) use any advertising or promotional campaign elements or phrases, logos, slogans or branding that are the same as or confusingly similar to those used with respect to Nexium anywhere in the world;

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(f) use the color purple or any phrase that includes the term “purple” to identify the Product or any Other Product;

(g) use any Trademark that is confusingly similar to any Nexium Trademark; or

(h) use any purple packaging or other trade dress with a purple color scheme with respect to the Product or any Other Product, including the physical appearance of the Product or any Other Product.

2.6.3 In the event that a Party intends to conduct any pre-clinical or clinical studies or any epidemiological, health economic or other similar studies with respect to the Product, other than the Existing Pediatric Study, such Party shall notify the other Party in writing of its intent to carry out such study and shall consider in good faith the other Party’s comments with respect to such proposed study.

2.7 **Horizon Control in Horizon Territory.** Subject to the terms of this Agreement, the Asset Purchase Agreement and the Supply Agreement, from and after the Effective Date, Horizon shall have the sole right and responsibility with respect to the Manufacture and Exploitation of Products and Other Products in the Horizon Territory.

2.8 **Alliance Management.** The Parties each acknowledge and agree that it would be beneficial to each to have a representative to act as an alliance manager (“Alliance Manager”) and shall appoint such a person promptly after the Effective Date. The Alliance Managers shall serve as a single point of contact within each Party and shall coordinate as necessary with respect to the Products and the Other Products from time to time. If a Party needs to access any information or documentation of the other Party or any of its Affiliates that is related to any Product or Other Product in order to comply with applicable Law or any Regulatory Authority requirement, to the extent such access is not otherwise provided under this Agreement or the Asset Purchase Agreement, the Alliance Managers shall coordinate to provide such first Party appropriate access to such information or documents to the extent necessary for such first Party or its Affiliate to comply with applicable Law or any Regulatory Authority requirement.

**ARTICLE 3**

**TERRITORIAL RESTRICTIONS; COMPLIANCE**

3.1 **Horizon Restrictions.** Horizon (a) shall, and shall cause its Affiliates and its and their respective Sublicensees and distributors to, distribute, market, promote, offer for sale and sell the Product and the Other Products only in the Horizon Territory, and (b) shall not, and shall not permit its Affiliates and its and their respective Sublicensees or distributors to, distribute, market, promote, offer for sale or sell the Product or any Other Product directly or indirectly to any Person for use in the AstraZeneca Territory. If Horizon or any of its Affiliates receives or becomes aware of the receipt by a Sublicensee or distributor of any orders for the Product or any Other Product in the AstraZeneca Territory, such Person shall refer such orders to AstraZeneca. Horizon shall cause its Affiliates and its and their respective Sublicensees and distributors to notify Horizon of any receipt of any orders for the Product or any Other Product in
3.2 **AstraZeneca Restrictions.** AstraZeneca (a) shall, and shall cause its Affiliates and its and their respective licensees, sublicensees and distributors to, distribute, market, promote, offer for sale and sell the Product and the Other Products only in the AstraZeneca Territory, and (b) shall not, and shall not permit its Affiliates and its and their respective licensees, sublicensees or distributors to, distribute, market, promote, offer for sale or sell the Product or any Other Product directly or indirectly to any Person for use in the Horizon Territory. If AstraZeneca or any of its Affiliates receives or becomes aware of the receipt by a licensee, sublicensee or distributor of any orders for the Product or any Other Product in the Horizon Territory, such Person shall refer such orders to Horizon. AstraZeneca shall cause its Affiliates and its and their respective licensees, sublicensees and distributors to notify AstraZeneca of any receipt of any orders for the Product or any Other Product in the Horizon Territory.

3.3 **Compliance with Legal Requirements.** Horizon shall conduct, and shall cause its Affiliates, Sublicensees, and Third Party subcontractors and distributors to conduct, all activities concerning the Product, any Other Product, the Licensed Intellectual Property and the Licensed Regulatory Documentation in compliance with all applicable Laws. AstraZeneca shall conduct, and shall cause its Affiliates, licensees, sublicensees, and Third Party subcontractors and distributors to conduct, all activities concerning the Product and any Other Product in compliance with all applicable Laws. In addition, each Party hereby certifies that it has not employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under United States Law, including 21 U.S.C. Section 335a (or any foreign equivalent thereof) or who is the subject of a conviction described in such section (or any foreign equivalent thereof), in connection with the Manufacture or Exploitation of the Product or any Other Product or the performance of any portion of its activities hereunder or pursuant hereto. Each Party shall notify the other Party in writing immediately if any such debarment or conviction occurs or comes to its attention or if any Litigation is pending or, to such Party’s knowledge, is threatened, relating to the debarment or conviction of such Party or any such Person, and shall, with respect to any Person so debarred or convicted promptly remove such Person from performing any activities in connection with the Exploitation of the Product or any Other Product or the performance of any portion of such Party’s activities hereunder or pursuant hereto.

3.4 **Compliance with Ethical Business Practices.**

3.4.1 **Anti-Bribery and Anti-Corruption Compliance.**

(a) Each Party acknowledges that the other Party’s corporate policy requires that such other Party’s business must be conducted within the letter and the spirit of the Law and consistent with good business ethics. By signing this Agreement, each Party agrees to conduct its activities under this Agreement (including, in the case of AstraZeneca, Manufacture, research, development, import and export of Products and Other Products in the Horizon Territory, and the Manufacture and Exploitation of Products and Other Products in the AstraZeneca Territory) in a manner that is consistent with Law, including Anti-Corruption Law, and good business ethics.
(b) Neither Party shall, or permit its Affiliates to, and each Party shall use its commercially reasonable efforts to not permit its Sublicensees, agents, contractors and other representatives to, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to give, or authorize the giving of anything of value (collectively, a “Payment”) to any Government Official in connection with the Manufacture or Exploitation of Products or Other Products where such Payment would constitute a violation of any Anti-Corruption Law. In addition, regardless of legality, neither Party shall make any Payment, directly or indirectly, to any Government Official in connection with the Manufacture or Exploitation of Products or Other Products if such Payment is for the purpose of influencing decisions or actions in connection with the Manufacture or Exploitation of Products or Other Products. Each Party acknowledges and agrees that none of the other Party, or any of its Affiliates or its or their respective officers, directors, employees, agents and representatives (collectively, “Representatives”) is authorized to waive compliance with the provisions of this Section 3.4.1(b) and that it shall be solely responsible for its compliance with the provisions of this Section 3.4.1(b) and the Anti-Corruption Laws irrespective of any act or omission of the other Party or any of its Affiliates or its or their respective Representatives.

3.4.2 Exclusions List. Horizon shall not use (and shall cause its Affiliates not to use) any Person (including any employee, officer, director, Sublicensee or Third Party contractor or distributor) who is (or has been) on the Exclusions List of the Office of Inspector General, U.S. Department of Health & Human Services, or who is (or has been) in violation of the terms hereof in connection with the Manufacture or Exploitation of Products or Other Products. Horizon certifies to AstraZeneca that, as of the Effective Date, Horizon has screened itself, and its officers and directors (and its Affiliates, Sublicensees and Third Party contractors and distributors and their respective officers and directors) against the Exclusions List of the Office of Inspector General, U.S. Department of Health & Human Services and that it has informed AstraZeneca whether Horizon, or any of its officers or directors (or any of its Affiliates, Sublicensees or Third Party contractors or distributors or any of their respective officers and directors) has been in violation of the terms hereof in connection with the performance of any activities hereunder. After the execution of this Agreement, Horizon shall promptly notify AstraZeneca in writing if any such violation comes to its attention.

ARTICLE 4
REGULATORY

4.1 Regulatory Responsibilities.

4.1.1 Notification of Label Changes.

(a) Horizon shall notify AstraZeneca in writing of any revisions to the Product Label for the Product or any Other Product in the Horizon Territory whether initiated by Horizon or requested by FDA within 10 days after such revision is approved by FDA, and such notice shall include the exact revised language for the applicable Product Label.
(b) AstraZeneca shall notify Horizon in writing of any revisions whether initiated by AstraZeneca or requested by any Regulatory Authority to (i) the Regulatory Authority approved full prescribing information for the Product or any Other Product in the AstraZeneca Territory, including any required patient information and all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for the Product or any Other Product in the AstraZeneca Territory or (ii) the Regulatory Authority approved full prescribing information for Nexium anywhere in the world, including any required patient information and all labels and other written, printed or graphic matter upon a container, wrapper or any package insert utilized with or for Nexium anywhere in the world, in either case (i) or (ii) that would reasonably be expected to impact the Product Label for the Product or any Other Product in the Horizon Territory within 10 days after such revision is initiated by AstraZeneca or requested by the applicable Regulatory Authority, as applicable. AstraZeneca shall also notify Horizon in writing of any such revisions within 10 days after such revision is approved by the applicable Regulatory Authority, and such notice shall include the exact revised language for the application revision.

(c) The Party notifying the other Party of any revisions to any Regulatory Authority-approved full prescribing information, including any required patient information or any labels and other written, printed or graphic matter upon a container, wrapper or any package insert pursuant to this Section 4.1.1, shall use commercially reasonable efforts to answer the other Party’s questions with respect to any such revision.

(d) For clarity, the Parties obligations under this Section 4.1.1 are in addition to any other notification obligations either Party has under the Transition Safety Data Exchange Agreement or the Post-Transition Safety Data Exchange Agreement.

4.1.2 If a legalized Certificate of Pharmaceutical Product (“CPP”) is required to renew any Regulatory Approval for a Product or Other Product in any country in the AstraZeneca Territory, upon AstraZeneca’s reasonable request with respect to timing, Horizon shall use commercially reasonable efforts to assist AstraZeneca in obtaining such CPP. AstraZeneca shall provide Horizon with reasonable advance notice of the need for any such CPP and such notice shall contain sufficient information and instructions as to minimize impact into Horizon’s normal business activities. The Alliance Managers shall coordinate with respect to any request for a CPP by AstraZeneca to ensure that such request is handled promptly and with reasonable care. Upon AstraZeneca’s request for any CPP, the Parties shall agree upon the process cost and timelines with respect thereto. AstraZeneca shall reimburse Horizon for all reasonable and documented or otherwise verifiable external and internal costs incurred in connection with processing or otherwise assisting AstraZeneca in obtaining any requested CPP, including the full time equivalent costs of the employees of Horizon involved in processing any requested CPP or otherwise assisting AstraZeneca in obtaining any requested CPP (which shall be calculated at a rate to be agreed to by the Parties), to the extent such costs do not exceed the costs agreed to by the Parties pursuant to the immediately preceding sentence. AstraZeneca shall reimburse Horizon for such costs within 45 days after receipt of an invoice and reasonable supporting documentation with respect to such costs.

4.1.3 Notwithstanding anything to the contrary in this Agreement, if Horizon is required by applicable Law to provide a Regulatory Authority any communication
that relates to [...***... and [...***...] as it [...***...] that [...***...] to [...***...].

4.2 Access to Regulatory Approvals and Documentation.

4.2.1 Upon Horizon’s reasonable request with respect to timing of delivery, AstraZeneca promptly shall (a) provide to Horizon, at Horizon’s cost and expense, copies of the Licensed Regulatory Documentation solely for purposes of exercising Horizon’s and its Affiliates’ rights under the grants in Section 2.1 and (b) provide to Horizon and to any specified Governmental Authority in the Horizon Territory a letter, in the form reasonably requested by Horizon, acknowledging that Horizon has the right of reference and use to any Licensed Regulatory Documentation as described under Section 2.1.5. Notwithstanding anything to the contrary contained in this Agreement, AstraZeneca shall not be required to disclose any information contained in the Licensed Regulatory Documentation or provide any such access to such information if such disclosure or access would, in AstraZeneca’s reasonable discretion, (x) violate (i) applicable Law or (ii) any binding agreement entered into by AstraZeneca prior to the Effective Date, including any confidentiality agreement to which AstraZeneca is a party (provided, that AstraZeneca shall use commercially reasonable efforts to obtain consent from any Third Party to any such binding agreement to enable AstraZeneca to disclose such information), (y) jeopardize any attorney/client privilege or other established legal privilege or (z) disclose any trade secrets; provided, that AstraZeneca shall provide Horizon with a general description of the type of any such information redacted or withheld by AstraZeneca to the extent that AstraZeneca is permitted to do so and keep Horizon informed of all efforts undertaken by AstraZeneca to enable AstraZeneca to disclose such redacted or withheld information to Horizon.

4.2.2 Upon AstraZeneca’s reasonable request with respect to timing of delivery, Horizon promptly shall (a) provide to AstraZeneca, at AstraZeneca’s cost and expense, copies of the Horizon Regulatory Documentation solely for purposes of exercising AstraZeneca’s and its Affiliates’ rights under the grants in Section 2.3 and (b) provide to AstraZeneca and to any specified Governmental Authority in the AstraZeneca Territory a letter, in the form reasonably requested by AstraZeneca, acknowledging that AstraZeneca has the right of reference to any Horizon Regulatory Documentation as described under Section 2.3.3. Notwithstanding anything to the contrary contained in this Agreement, Horizon shall not be required to disclose any information contained in the Horizon Regulatory Documentation or provide any such access to such information if such disclosure or access would, in Horizon’s reasonable discretion, (x) violate (i) applicable Law or (ii) any binding agreement entered into by Horizon prior to the Effective Date, including any confidentiality agreement to which Horizon is a party (provided, that Horizon shall use commercially reasonable efforts to obtain consent from any Third Party to any such binding agreement to enable Horizon to disclose such information), (y) jeopardize any attorney/client privilege or other established legal privilege or (z) disclose any ***Confidential Treatment Requested

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4.3 Pharmacovigilance Obligations.

4.3.1 Safety Data Exchange Agreement. Each Party shall duly and punctually perform all of its obligations under the Safety Data Exchange Agreement.

4.3.2 Safety Database. AstraZeneca shall set up, hold, and maintain (at AstraZeneca’s sole cost and expense) the global safety database for the Product and the Other Products. Each Party shall use commercially reasonable efforts to provide the other Party with information in its possession and control as necessary for each Party to comply with its pharmacovigilance responsibilities under this Agreement or the Safety Data Exchange Agreement, including, as applicable, any Adverse Events, from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies, and commercial experiences with the Product or any Other Product in the format specified in the Safety Data Exchange Agreement.

4.3.3 Esomeprazole Safety Data. Notwithstanding anything to the contrary in this Agreement, if Horizon is required by applicable Law to make any statements in an Adverse Event report or serious Adverse Event report pertaining to [***] the [***] to [***].

4.3.4 Medical and Other Inquiries. Except to the extent otherwise provided in this Agreement, the Asset Purchase Agreement (including the Transition Plan) or the Supply Agreement, from and after the Effective Date, Horizon (a) shall be responsible for, and shall handle and respond to, all customer complaints and inquiries (including medical and non-medical inquiries) related to the Product or any Other Product used, marketed, distributed or sold in the Horizon Territory, and (b) shall be responsible for, and shall conduct, all correspondence and communication with physicians and other health care professionals in the Horizon Territory relating to the Product or any Other Product.

4.4 Post-Closing Responsibility for Product. [***] shall not [***] without the prior written consent of [***], such consent not to be unreasonably conditioned, withheld or delayed, if [***] in the [***].

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ARTICLE 5
RECORDS

5.1 Records. Horizon shall, and shall cause its Affiliates and its and their respective Sublicensees to, keep complete and accurate financial books and records pertaining to the commercialization of Merck Products in the Horizon Territory, including books and records of Merck Net Sales of Merck Products, in sufficient detail to determine, calculate and verify Merck Net Sales of Merck Products in the Horizon Territory and the net present value of the projected Merck Net Sales of Merck Products in the Horizon Territory, in each case, from the Effective Date until AstraZeneca provides Horizon written notice that Horizon is no longer obligated to maintain such books and records. From and after the date set forth in such written notice, Horizon shall no longer be obligated to maintain financial books and records pertaining to the commercialization of Merck Products pursuant to this Section 5.1 and AstraZeneca (or its designee) shall no longer have the right to audit and examine Horizon’s financial books and records pursuant to Section 5.2. Horizon shall and shall cause its Affiliates and its and their respective Sublicensees to, retain such books and records under this Section 5.1 until the date AstraZeneca provides Horizon written notice that Horizon is no longer obligated to maintain such books and records. In the event that AstraZeneca no longer has any record keeping or reporting obligations to any Merck Party with respect to sales of Merck Products in the Horizon Territory, AstraZeneca shall promptly notify Horizon in writing, and Horizon’s obligations under this Section 5.1 shall automatically terminate effective upon the termination of such obligations of AstraZeneca to the Merck Parties.

5.2 Review of Horizon Financial Records. At the request of AstraZeneca, Horizon shall, and shall cause its Affiliates and its and their respective Sublicensees to, permit AstraZeneca (or its designee) or an independent auditor designated by AstraZeneca (or its designee), at reasonable times and upon reasonable notice, to audit and examine, and make copies or extracts of and from, the books, records and accounts of Horizon maintained pursuant to Section 5.1 for the purposes set forth in Section 5.1. As between the Parties, the cost of any such review or audit shall be borne by AstraZeneca. In the event that a Merck Party no longer has any right to audit, and AstraZeneca no longer has any obligation to audit, the books, records and accounts of Horizon maintained pursuant to Section 5.1, AstraZeneca shall promptly notify Horizon in writing, and AstraZeneca’s (including its designees and its or their independent auditors’) rights, and Horizon’s obligations, under this Section 5.2 shall automatically terminate, in each case, effective upon the termination of such rights of the Merck Parties or obligations of AstraZeneca to the Merck Parties.

ARTICLE 6
ASTRAZENECA PATENTS

6.1 Maintenance and Prosecution of AstraZeneca Patents. AstraZeneca shall have the sole right, but not the obligation, to prepare, file, prosecute and maintain (including with respect to related interference, re-issuance, re-examination, patent term extensions and opposition proceedings) the Merck Patents, the Ex-US Licensed Patents and any other Patent Rights included in the Manufacturing Technology (the “AstraZeneca Patents”), at AstraZeneca’s sole cost and expense. Horizon shall have no right to prepare, file, prosecute or maintain any AstraZeneca Patents. Horizon shall assist and cooperate with AstraZeneca as
AstraZeneca may reasonably request from time to time in connection with its activities set forth in this Section 6.1, at AstraZeneca’s sole cost and expense. Neither AstraZeneca nor any of its Representatives shall be liable to Horizon in respect of any act, omission, default or neglect on the part of any such Representative in connection with obtaining, prosecuting or maintaining an AstraZeneca Patent or otherwise exercising its rights under this Section 6.1. AstraZeneca will keep Horizon promptly informed of progress with regard to the preparation, filing, prosecution and maintenance of AstraZeneca Patents in the Horizon Territory.

6.2 Enforcement of AstraZeneca Patents.

6.2.1 Notice. If any AstraZeneca Patent is allegedly or actually infringed by a Third Party in a manner relating to the Product or any Other Product, the Party first having knowledge of such infringement shall promptly notify the other in writing, which notice shall set forth the facts of that infringement in reasonable detail.

6.2.2 AstraZeneca Patents. Subject to this Section 6.2.2, AstraZeneca shall have the sole right, but not the obligation, through counsel of its choosing, to control the prosecution of any infringement described in Section 6.2.1 relating to the AstraZeneca Patents [...***...]. Prior to commencing any prosecution of an infringement claim with respect to the AstraZeneca Patents hereunder, AstraZeneca shall notify Horizon of its intent to commence such prosecution, and if Horizon in good faith believes that the prosecution of any such infringement of the AstraZeneca Patents by AstraZeneca could have a material adverse effect on the AstraZeneca Patents in the Horizon Territory or Horizon’s rights thereunder, Horizon shall promptly notify AstraZeneca after receiving such notice of intent and the Parties shall discuss in good faith the appropriate actions to be taken in response to such infringement; provided, however, that if the Parties are unable to come to a mutually acceptable resolution, then AstraZeneca shall be entitled to undertake such prosecution in its sole discretion, taking Horizon’s concerns into good faith consideration. Horizon shall have no right to prosecute any infringement of any AstraZeneca Patents.

6.2.3 Enforcement Procedure; Costs and Recovery. If AstraZeneca brings an infringement action in accordance with this Section 6.2, Horizon shall cooperate fully with AstraZeneca in connection therewith, including furnishing powers of attorney, being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours, at AstraZeneca’s sole cost and expense. If AstraZeneca pursues such an infringement action, it shall consider in good faith any comments from Horizon and shall keep Horizon reasonably informed of any steps taken to preclude such infringement. Each Party shall bear its own costs and expenses relating to any enforcement action commenced pursuant to this Section 6.2. Any damages or other amounts collected shall be first allocated to reimburse the Parties for their costs and expenses in enforcing...

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the AstraZeneca Patents in order to make such recovery, which amounts shall be allocated *pro rata* based on the relative costs and expenses incurred by the Parties in connection with such enforcement if insufficient to cover the totality of such expenses. Any amount of recovery remaining after such reimbursement is made shall be retained by AstraZeneca.

6.3 Infringement Claims by Third Parties.

6.3.1 Defense of Third Party Claims. If a Third Party asserts that a Patent Rights or other intellectual property right (other than Trademarks or Domain Names, which shall be governed by Sections 7.4 and 8.5, respectively) owned or controlled by it is infringed by the Manufacture or Exploitation of the Product or any Other Product, the Party first obtaining knowledge of such a claim shall immediately provide the other Party notice of such claim along with the related facts in reasonable detail.

6.3.2 Horizon Territory. Horizon shall have the first right, but not the obligation, to control the defense of any claim described in Section 6.3.1 to the extent it relates to the Manufacture or Exploitation of the Product or any Other Product in the Horizon Territory; *provided* that Horizon shall not be entitled to assert a claim or counterclaim against such Third Party based on the AstraZeneca Patents in connection therewith without AstraZeneca’s prior written consent, in its sole discretion; and, *provided, further*, that prior to commencing any such claim or counterclaim hereunder, Horizon shall notify AstraZeneca of its intent to commence such claim or counterclaim, and if AstraZeneca in good faith believes that the assertion of any such claim or counterclaim by Horizon could have a material adverse effect on the AstraZeneca Patents in the AstraZeneca Territory or AstraZeneca’s rights thereunder or the Nexium Business, AstraZeneca shall promptly notify Horizon after receipt of such notice of intent and the Parties shall discuss in good faith the appropriate actions to be taken in response to such claim.

6.3.3 AstraZeneca Territory. AstraZeneca shall have the sole right, but not the obligation, to control the defense of any claim described in Section 6.3.1 to the extent it relates to the Manufacture or Exploitation of the Product or any Other Product in the AstraZeneca Territory.

6.3.4 Defense Procedure. The Party that does not control the defense of a claim under this Section 6.3 shall cooperate with the controlling Party, at the controlling Party’s reasonable request and expense, in any such defense and shall have the right, at its own expense, to be represented separately by counsel of its own choice in any such proceeding. If a Party is entitled to and brings a claim or counterclaim in accordance with this Section 6.3, the other Party shall cooperate fully with the claiming Party in connection therewith, including furnishing powers of attorney, being joined as a party plaintiff in such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any steps taken in connection with such defense, claim or counterclaim.
6.3.5 **Settlement of Third Party Claims.** The Party that controls the defense of a given claim pursuant to Section 6.3.2 or 6.3.3 also shall have the right to control settlement of such claim; *provided, however,* that (a) no settlement shall be entered into without the prior written consent of the other Party if such settlement would adversely affect or diminish the rights and benefits of the other Party under this Agreement, or impose any new obligations or adversely affect any obligations of the other Party under this Agreement and (b) in connection with any such settlement, if Horizon is the controlling Party, unless otherwise agreed in writing by AstraZeneca, Horizon shall only be entitled to grant a license or covenant not to sue under or with respect to the AstraZeneca Patents or Licensed Know-How, as applicable, to the extent provided in Section 2.2.

6.3.6 **Allocation of Costs.** All costs and expenses relating to any defense, settlement and judgments in Litigation commenced pursuant to this Section 6.3 with respect to (a) the Horizon Territory shall be borne by the Party controlling such Litigation in accordance with this Article 6 and (b) in the AstraZeneca Territory shall be borne by AstraZeneca. Any damages or other amounts collected shall be first allocated to reimburse the financially responsible Party (as set forth in the immediately preceding sentence) for its costs and expenses in making such recovery. Any amount of recovery remaining after such reimbursement is made shall be retained by the controlling Party under this Section 6.3.

6.4 **Invalidity or Unenforceability Defenses or Actions.** If a Third Party asserts, as a defense or as a counterclaim in any infringement action under Section 6.2 or claim or counterclaim asserted under Section 6.3, or in a declaratory judgment action or similar action or claim filed by such Third Party, in any such case, that any AstraZeneca Patent is invalid or unenforceable, then the Party pursuing such infringement action, or the Party first obtaining knowledge of such declaratory judgment action, as the case may be, shall promptly give written notice to the other Party. AstraZeneca shall have the sole right, but not the obligation, through counsel of its choosing, to defend against such action or claim. If AstraZeneca defends such action or claim, all costs and expenses of defending such action or claim shall be borne by AstraZeneca. Horizon shall assist and cooperate with AstraZeneca as AstraZeneca may reasonably request from time to time in connection with its activities set forth in this Section 6.4, including by providing access to relevant documents and other evidence and making its employees available at reasonable business hours, at AstraZeneca’s sole cost and expense. In connection with any such defense or claim or counterclaim, AstraZeneca shall consider in good faith any comments from Horizon and shall keep Horizon reasonably informed of any steps taken, and shall provide copies of all documents filed, in connection with such defense, claim or counterclaim.

6.5 **Statements or Actions Pertaining to Esomeprazole or Nexium.** Notwithstanding anything to the contrary in this Article 6, [...***...]

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7.1 Use of Licensed Trademarks.

7.1.1 Horizon hereby acknowledges AstraZeneca’s exclusive right, title and interest in and to the Licensed Trademarks, together with all goodwill associated therewith and all registrations and registration applications therefor, on a worldwide basis and acknowledges that nothing herein shall be construed to accord to Horizon or its Affiliates any rights in the Licensed Trademarks except for the license rights expressly conferred by this Agreement. Horizon shall not, and shall cause its Affiliates, Sublicensees and distributors not to, use in their respective businesses, any Trademark that is confusingly similar to or a colorable imitation of, misleading or deceptive with respect to or that dilutes any (or any part) of the Licensed Trademarks.

7.1.2 Horizon shall, and shall cause its Affiliates, Sublicensees and distributors to, (a) comply with all trademark usage guidelines, quality standards, business practices, methodology, policies and procedures and technical and operational specifications as may be reasonably specified by AstraZeneca from time to time or as may be imposed by applicable Law with respect to the manner of use of the Licensed Trademarks [...***...], (b) promptly make any changes to any Product Label, packaging with respect to any Product or any Other Product, Product (or any Other Product) inserts and advertising, marketing, promotional or other materials bearing any of the Licensed Trademarks as AstraZeneca may reasonably request to achieve compliance with clause (a), and (c) refrain from taking any action that endangers, destroys or similarly affects, in any material respect, the Licensed Trademarks or the value of the goodwill associated with the Licensed Trademarks.

7.1.3 Horizon shall not, and shall cause its Affiliates, Sublicensees and distributors not to, (a) directly or indirectly, at any time challenge AstraZeneca’s rights, title or interest in and to the Licensed Trademarks or in any registration or registration application therefor in any jurisdiction, (b) do or cause to be done or fail to do anything, the doing, causing or failure of which would contest or impair or in any way tend to impair the rights of AstraZeneca in and to the Licensed Trademarks or in any registrations or registration applications therefor in any jurisdiction, (c) represent to any Third Party that it has, in any jurisdiction, any ownership rights in or to the Licensed Trademarks or in any registration or registration application therefor or any other rights in the Licensed Trademarks other than the specific license rights conferred by this Agreement, or (d) register or attempt to register the Licensed Trademarks or any confusingly similar Trademark (including any translation or transliteration of any of the Licensed Trademarks or any colorable imitation thereof) as a Trademark with any Governmental Authority in its own name or in the name of any of its Affiliate or any Third Party in any jurisdiction.

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7.1.4 Horizon acknowledges and agrees that no ownership rights are vested or created in the Licensed Trademarks anywhere in the world by the licenses and other rights granted in this Agreement (including, for clarity, under Section 2.1 of this Agreement) and that all goodwill generated in connection with the use of the Licensed Trademarks by Horizon, its Affiliates, Sublicensees, and distributors shall inure solely for and to the benefit of AstraZeneca.

7.2 Approval Procedures.

7.2.1 During the Term, if Horizon desires to use any variation or derivative of an existing Licensed Trademark on, or in connection with the Exploitation of, the Product or any Other Product in the Horizon Territory, Horizon shall submit such variation or derivation to AstraZeneca for its approval, which approval may be granted or withheld in AstraZeneca’s sole discretion. If AstraZeneca approves such variation or derivation, then upon such approval by AstraZeneca, such variation or derivation shall be deemed a Licensed Trademark and subject to the terms hereof. AstraZeneca shall respond to each such submission within [***] after AstraZeneca’s receipt of each such request for approval. With respect to any variation or derivation of any existing Licensed Trademark that Horizon submits to AstraZeneca, Horizon shall be responsible for conducting a commercially reasonable trademark clearance search and assessing the availability of any such variation or derivation for use on, and registration for, the Product or any Other Product in the Horizon Territory and shall submit the results of such search and assessment to AstraZeneca when it submits such variation or derivation to AstraZeneca for its approval.

7.2.2 At AstraZeneca’s reasonable request with respect to timing of delivery, Horizon shall, and shall cause its Affiliates, Sublicensees and distributors to, furnish to AstraZeneca representative samples of all goods and all Product Labeling, Product packaging, Product inserts and advertising, marketing, promotional or other materials bearing any of the Licensed Trademarks for registration, renewal and quality control purposes, including web pages, brochures and stationery.

7.3 Clearance, Registration, Prosecution and Maintenance of Licensed Trademarks.

7.3.1 AstraZeneca shall be responsible for the registration, prosecution and maintenance of the Licensed Trademarks in the Horizon Territory. All registrations and applications therefor shall be filed, prosecuted, registered and maintained in the name, and for the benefit, of AstraZeneca. All costs and expenses of clearing, registering, prosecuting and maintaining the Licensed Trademarks in the Horizon Territory shall be borne solely by AstraZeneca. AstraZeneca shall (a) provide Horizon from time to time[***] a written report summarizing the current status of all applications and registrations for the Licensed Trademarks in the Horizon Territory; (b) notify Horizon promptly of, and consult with Horizon with respect to, any material, substantive issue or any opposition, cancellation, invalidity or other proceeding that may be raised or asserted against any application or registration for any Licensed Trademark within the Horizon Territory prior to taking any action in response thereto; and (c) consult with Horizon at least [***] prior to (i) taking any action to abandon or withdraw any application for any Licensed Trademark, or (ii)
permitting any registration for any Licensed Trademark to lapse, expire or be cancelled.

7.3.2 If AstraZeneca plans to cease, or ceases, the registration, prosecution and maintenance of a Licensed Trademark in the Horizon Territory, AstraZeneca shall notify Horizon in writing at least [...***... ] in advance of the due date of any action that is required with respect thereto and, in such event, Horizon may elect (but shall not be obligated), on written notice to AstraZeneca, at its sole cost and expense, to assume responsibility for and control over such registration, prosecution and maintenance in the name of Horizon. All registrations and applications therefor shall be filed, prosecuted, registered and maintained in the name, and for the benefit, of Horizon. AstraZeneca shall execute such powers of attorney or other instruments and shall take such other actions as Horizon may reasonably request to permit Horizon to file and prosecute any registration application and to maintain, renew, enforce and defend any registration for any such Licensed Trademarks in the Horizon Territory.

7.4 Enforcement and Defense of Licensed Trademarks. Horizon shall have the first right, but not the obligation, to enforce and defend the Licensed Trademarks in the Horizon Territory, including (a) after consultation with AstraZeneca, defending against any alleged, threatened or actual claim by a Third Party that the use of the Licensed Trademarks in the Horizon Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or copyright of any Third Party or constitutes unfair trade practices or any other like offense, or any other claims as may be brought by a Third Party against a Party in connection with the use of or relating to the Licensed Trademarks with respect to the Product or any Other Product in the Horizon Territory and (b) taking such action as Horizon, after consultation with AstraZeneca, deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of, or unfair trade practices or any other like offense relating to, the Licensed Trademarks by a Third Party in the Horizon Territory; provided that if Horizon plans to cease, or ceases, any action with respect to the enforcement or defense of any of the Licensed Trademarks in the Horizon Territory, Horizon shall notify AstraZeneca in writing at least [... ***... ] in advance of the due date of any action that is required with respect thereto and, in such event, AstraZeneca may elect (but shall not be obligated), on written notice to Horizon, to assume responsibility for and control over such enforcement or defense or to take any such action in its own name or in the name of Horizon. Notwithstanding the foregoing, as long as Horizon is Exploiting the Product or any Other Product under the Licensed Trademarks, if Horizon reasonably determines that initiating a suit or taking other action to enforce or defend any of the Licensed Trademarks in the Horizon Territory pursuant to this Section 7.4 is not in the best interests of the Licensed Trademarks in the Horizon Territory and Horizon so notifies AstraZeneca in writing (which notice shall include a reasonably detailed description of Horizon’s reasons for not initiating suit or taking other action to enforce or defend any of the Licensed Trademarks in the Horizon Territory pursuant to this Section 7.4), then AstraZeneca may not enforce or defend any such Licensed Trademarks pursuant to this Section 7.4. Each enforcing or defending Party shall bear its own costs and expenses relating to any enforcement action or defense commenced pursuant to this Section 7.4 and any settlements and judgments with respect thereto. Any damages or other amounts recovered in any such proceeding shall be retained by the Party controlling such proceeding. Each Party shall provide to the other Party all reasonable assistance requested by the other Party in connection with any such action, defense, claim or suit under this Section 7.4, at such other Party’s cost and expense. Horizon shall obtain

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AstraZeneca’s written consent before entering into any compromise, settlement or stipulation with respect to any such action, defense, claim or suit (such consent not to be unreasonably withheld or delayed). In no event shall Horizon take any position or submit any argument with respect to such action, defense, claim or suit that would be reasonably expected to materially endanger, lessen, impair or undermine the Licensed Trademarks or AstraZeneca’s rights therein or AstraZeneca’s corresponding Trademark rights outside the Horizon Territory. Each Party, at the other Party’s cost and expense, shall execute such powers of attorney or other instruments and shall take such other actions as the other Party may reasonably request as necessary to permit the other Party to assume responsibility for and control over the enforcement or defense of the Licensed Trademarks as permitted hereunder.

7.5 **No Implied Rights.** Except as expressly provided in this Article 7, Horizon shall have no right to register, maintain, prosecute, enforce or defend the Licensed Trademarks.

7.6 **Other Trademarks.** Horizon shall have the right to Exploit the Product and any Other Product in the Horizon Territory under a Trademark that is not a Licensed Trademark; provided, that such other Trademark is not confusingly similar to any Licensed Trademark (including any translation or transliteration of any Licensed Trademark or any colorable imitation of any Licensed Trademark).

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**ARTICLE 8**

**LICENSED DOMAIN NAMES**

8.1 **Ownership and Goodwill.** Horizon acknowledges that it acquires no right, title or interest in the Licensed Domain Names other than the rights expressly set forth in this Agreement. Horizon shall not at any time do or suffer to be done any act that would materially impair AstraZeneca’s proprietary rights in or to the Licensed Domain Names, and Horizon agrees not to directly or indirectly contest or aid in contesting the ownership of the Licensed Domain Names, or to take any action whatsoever in derogation of AstraZeneca’s claimed rights therein. Horizon agrees and acknowledges that any and all rights and goodwill arising from use of the Licensed Domain Names by Horizon or its Affiliates or permitted sublicensees shall inure exclusively to the benefit of AstraZeneca.

8.2 **Registration and Maintenance.** AstraZeneca shall (a) at its own expense, maintain the Primary Licensed Domain Name and (b) if requested in writing by Horizon and at Horizon’s expense, maintain the Secondary Licensed Domain Names. Neither Party shall intentionally take, or fail to take, any action that may reasonably be expected to jeopardize the use, value, validity, or enforceability of any Licensed Domain Name; provided, that unless Horizon requests in writing that AstraZeneca maintain a Secondary Licensed Domain Name at Horizon’s expense, AstraZeneca may allow the registration for such Secondary Licensed Domain Name to lapse.

8.3 **Control of Licensed Domain Name Websites.** AstraZeneca hereby grants Horizon the sole right to administer, manage and control the content of any website associated with, and use, the Licensed Domain Names (the “*Product Websites*”) under the terms of this Agreement. At Horizon’s request, AstraZeneca shall use the technical contact and
server information provided by Horizon for the Licensed Domain Names. Horizon may ask from time to time that such information be further revised or updated, and AstraZeneca shall, within a reasonable amount of time, contact the domain name registrar and revise the information accordingly. AstraZeneca shall not change the technical contact or server information for the Licensed Domain Names or take any action to direct Internet traffic to any of the Licensed Domain Names to any servers or IP addresses other than those identified by Horizon. AstraZeneca may, from time to time, change the registrar with whom AstraZeneca has contracted to manage its domain name portfolio. Horizon shall assist and cooperate with AstraZeneca, the old registrar or the new registrar in any way necessary to effectuate such a change of registrar. Horizon shall be responsible for the content of the Product Websites and shall ensure that all Product Websites comply with all applicable Law.

8.4 Country-Specific Traffic.

8.4.1 Horizon shall use commercially reasonable efforts to cause traffic to the Licensed Domain Names that originates within a country outside the Horizon Territory, to be re-directed to such ccTLD as AstraZeneca may designate in writing.

8.4.2 AstraZeneca shall use commercially reasonable efforts to cause traffic to vimovoglobal.com, or any other Domain Name used by or on behalf of AstraZeneca or its Affiliates in connection with Exploitation of the Products in more than one country of the AstraZeneca Territory, that originates within a country outside the AstraZeneca Territory, to be re-directed to such ccTLD as Horizon may designate in writing.

8.4.3 Among other techniques that the Parties may mutually agree for re-directing traffic is the placement of a hyperlink on the homepage of the generic “.com” top-level Licensed Domain Names or other domain names noted in Section 8.4.2, as applicable, which hyperlink shall be placed in a manner, form and style mutually agreeable to the Parties.

8.5 Enforcement. If Horizon becomes aware of any use, trafficking, or registration of a Licensed Domain Name other than by or on behalf of Horizon or its Affiliates or Sublicensees pursuant to this Agreement or of any use, trafficking, or registration a confusingly similar domain name, Horizon shall promptly notify AstraZeneca of such use or trafficking or registration. AstraZeneca may take any action and institute legal, administrative or other proceedings relating to the use, trafficking, or registration of such Licensed Domain Names as AstraZeneca, in its sole discretion, deems fit. Horizon shall execute any and all documents and to do such acts as may be reasonably necessary to carry out such proceeding or Litigation, including becoming a nominal party to any legal action. If AstraZeneca fails to take any action within [...***...] days after notification of such use, trafficking or registration, or notifies Horizon that it will not take any action, then Horizon may take any action and institute legal, administrative or other proceedings relating to such use, trafficking or registration as Horizon, in its sole discretion, deems appropriate. AstraZeneca agrees to execute any and all documents and to do such acts as may be reasonably necessary to carry out such proceeding or Litigation, including becoming a nominal party to any legal action. Each Party shall bear its own costs and expenses relating to any enforcement action commenced pursuant to this Section 8.5 and any settlements and judgments with respect thereto.

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ARTICLE 9
CONFIDENTIALITY AND NON-DISCLOSURE

9.1 General

9.1.1 All Ancillary Confidential Information provided by one Party (or its Recipients or Affiliates) (collectively, the “Ancillary Disclosing Party”) to the other Party (or its Recipients or Affiliates) (collectively, the “Ancillary Receiving Party”) shall be subject to and treated in accordance with the terms of this Section 9.1. As used in this Section 9.1, “Ancillary Confidential Information” means (a) all information disclosed to the Ancillary Receiving Party by the Ancillary Disclosing Party in connection with any Ancillary Agreement, including all information with respect to the Ancillary Disclosing Party’s licensors, licensees or Affiliates and (b) all memoranda, notes, analyses, compilations, studies and other materials prepared by or for the Ancillary Receiving Party to the extent containing or reflecting the information in the preceding clause (a). Notwithstanding the foregoing, Ancillary Confidential Information shall not include information that, in each case as demonstrated by competent written documentation:

(a) was already known to the Ancillary Receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure by the Ancillary Disclosing Party;
(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Ancillary Receiving Party;
(c) became generally available to the public or otherwise part of the public domain after its disclosure to the Ancillary Receiving Party other than through any act or omission of the Ancillary Receiving Party in breach of this Agreement;
(d) is subsequently disclosed to the Ancillary Receiving Party by a Third Party without obligations of confidentiality with respect thereto; or
(e) is subsequently independently discovered or developed by the Ancillary Receiving Party without the aid, application or use of Confidential Information or Ancillary Confidential Information.

9.1.2 All Ancillary Confidential Information obtained by AstraZeneca (or its Affiliates or Recipients) from Horizon (or its Affiliates or Recipients) and all Ancillary Confidential Information relating solely to the Product Business (other than Ancillary Confidential Information relating to (x) the Licensed Intellectual Property, the Ex-US Licensed Patents or the Licensed Regulatory Documentation, (y) the Pozen Original Agreement or the Pozen ROW Agreement or (z) the Merck Parties or the Merck Patents), the Purchased Assets and the Assumed Liabilities (the “Ancillary Horizon Confidential Information”) shall be deemed to be Ancillary Confidential Information disclosed by Horizon to AstraZeneca for purposes of this Section 9.1 and shall be used by AstraZeneca solely as required for any AstraZeneca Permitted Purpose, and for no other purpose. During the Term and for a period of five years thereafter, AstraZeneca shall not disclose, or permit the disclosure of, any of the Ancillary
9.1.3 All Ancillary Confidential Information obtained by Horizon (or its Affiliates or Recipients) from AstraZeneca (or its Affiliates or Recipients) other than the Ancillary Horizon Confidential Information (the "Ancillary AstraZeneca Confidential Information") shall be used by Horizon solely as required for any Horizon Permitted Purpose, and for no other purpose. During the Term and for a period of five years thereafter, Horizon shall not disclose, or permit the disclosure of, any of the Ancillary AstraZeneca Confidential Information to any Person except (x) those Persons to whom such disclosure is necessary in connection with a Horizon Permitted Purpose or (y) in connection with any due diligence or disclosure obligations under any financing arrangement or equity offering pursuant to obligations of confidentiality and non-use no less stringent than those set forth in this Section 9.1. Horizon shall treat, and will cause its Affiliates and the Recipients of Horizon or any of its Affiliates to treat, Ancillary AstraZeneca Confidential Information as confidential, using the same degree of care as Horizon normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

9.1.4 In the event either Party is requested pursuant to, or required by, applicable Law to disclose any of the other Party’s Ancillary Confidential Information (i.e., Ancillary AstraZeneca Confidential Information or Ancillary Horizon Confidential Information, as applicable), it will notify the other Party in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party’s sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Ancillary Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, provided that such Party furnishes only that portion of the Ancillary Confidential Information which such Party is advised by an opinion of its counsel is legally required and such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Ancillary Confidential Information.

9.1.5 Nothing in this Section 9.1 shall be construed as preventing or in any way inhibiting either Party from complying with applicable Law governing activities and obligations undertaken pursuant to this Agreement, the Asset Purchase Agreement or any other Ancillary Agreement in any manner which it reasonably deems appropriate.

9.2 Other Nexium Communications. Except as expressly provided in Sections 4.1.2, 4.3.4 and 9.3 hereof, the Asset Purchase Agreement or any Ancillary Agreement, without [...] prior written consent, [...] shall not make, and shall prohibit its Affiliates, Sublicensees, Third Party contractors, and agents from [...] or [...]
9.3 Certain Permitted Esomeprazole and Nexium Disclosures. Within 30 days after the Effective Date, the Parties shall mutually agree in good faith on a written document specifying [... *** ...], and the [... *** ...] to be [... *** ...] that is not [... *** ...].

9.4 Press Releases. [... *** ...] to the [... *** ...].

ARTICLE 10
DISCLAIMER OF WARRANTIES

EACH PARTY ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN THE ASSET PURCHASE AGREEMENT OR THE SUPPLY AGREEMENT, THE OTHER PARTY HAS MADE NO REPRESENTATION OR WARRANTY WHATSOEVER AND SUCH PARTY HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING ANY WARRANTY OF QUALITY, FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, CONDITION OF THE ASSETS, AS TO THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF ANY PERSON OR AS TO ANY OTHER MATTER IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREBY.

ARTICLE 11
INDEMNITY

11.1 Indemnification of AstraZeneca. Subject to this Article 11, Horizon shall indemnify, defend and hold harmless AstraZeneca and its Affiliates, and their respective officers, directors, employees and agents (collectively, “AstraZeneca Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Litigation by Third Parties (collectively, “Third Party Claims”) arising from or occurring as a result of: (a) any breach by Horizon of any term of this Agreement; (b) the fraud, gross negligence or willful misconduct on the part of any Horizon Indemnitees in the performance of Horizon’s obligations under this Agreement or (c) the Manufacture or Exploitation of the Product by or on behalf of Horizon, its Affiliates and Sublicensees (but excluding the Manufacture or Exploitation of Product or any Other Product by or on behalf of AstraZeneca or its Affiliates pursuant to the Supply Agreement, the Transition Plan (as defined in the Asset Purchase Agreement) or pursuant to any sublicense granted by Horizon to AstraZeneca under the this Agreement or any Ancillary Agreement), except, in each case ((a), (b) and (c)), to the extent of

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11.2 Indemnification of Horizon. Subject to this Article 11, AstraZeneca shall indemnify, defend and hold harmless Horizon and its Affiliates, and their respective officers, directors, employees and agents (collectively, “Horizon Indemnites”) from and against any and all Losses incurred by them in connection with any and all Third Party Claims arising from or occurring as a result of: (a) any breach by AstraZeneca of any term of this Agreement; (b) the fraud, gross negligence or willful misconduct on the part of any AstraZeneca Indemnitee in the performance of AstraZeneca’s obligations under this Agreement; (c) the Manufacture or Exploitation of the Product or any Other Product by or on behalf of AstraZeneca, its Affiliates and sublicensees (but excluding the Manufacture of Product under the Supply Agreement), except, in each case (a), (b) and (c), to the extent of those Losses for which Horizon has an obligation to indemnify any AstraZeneca Indemnitees pursuant to Section 11.1 or pursuant to the Supply Agreement, as to which Losses each Party shall indemnify the other Party and the AstraZeneca Indemnites or the Horizon Indemnites, as applicable, to the extent of its liability for such Losses.

11.3 Indemnification Procedures. All indemnification claims in respect of Horizon or any Horizon Indemnites shall be made solely by Horizon and all indemnification claims in respect of AstraZeneca or any AstraZeneca Indemnitee shall be made solely by AstraZeneca and, in each case, shall be governed by Section 7.2.2 of the Asset Purchase Agreement. Notwithstanding anything herein to the contrary, the Parties’ respective indemnification obligations under this Article 11 shall not apply to any Losses for which such Party is entitled to indemnification under the Asset Purchase Agreement (excluding for this purpose, application of the limitations in Section 7.3 of the Asset Purchase Agreement).

11.4 Limitation on Damages and Liability. EXCEPT IN CIRCUMSTANCES OF FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT BY A PARTY OR ITS AFFILIATES, LICENSEES, SUBLICENSEES OR DISTRIBUTORS, AND EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 9, AND WITHOUT LIMITING THE PARTIES’ RIGHTS UNDER SECTION 11.1 OR 11.2 WITH RESPECT TO THIRD PARTY CLAIMS, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL, MULTIPLE, PUNITIVE OR CONSEQUENTIAL DAMAGES, OR FOR LOST PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF OR WITH RESPECT TO THIS AGREEMENT, EVEN IF THAT PARTY HAS BEEN PLACED ON NOTICE OF THE POSSIBILITY OF SUCH DAMAGES.

11.5 Insurance. As of the Effective Date, Horizon shall have and maintain adequate insurance coverage, which policies shall be in effect during the Term and shall include products liability coverage and comprehensive general liability insurance of not less than […] ***...]; provided that if any such policy is held on a claims-made basis, such policy shall be maintained throughout the Term and for a period of […] ***...] thereafter. All insurers
providing such policies shall have an AM Best (A-) or higher rating. Horizon shall provide AstraZeneca with certificates of insurance evidencing that the policies required to be maintained by Horizon hereunder are in full force and effect annually and, upon AstraZeneca’s request, copies of such policies shall be provided. Should any of the policies be cancelled, terminated or otherwise materially altered before the expiration date thereof, notice will be delivered in accordance with the policy provisions in writing to AstraZeneca.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until terminated in accordance with this Article 12 (such period, the “Term”).

12.2 Termination for Material Breach. In the event that either Party (the “Breaching Party”) breaches any of its material obligations under Section 2.6, Section 3.3, Section 3.4, Article 7 or Article 8, the other Party may terminate the Terminable Rights and Provisions upon 60 days’ prior written notice (such 60-day period, the “Notice Period”) to the Breaching Party, specifying the breach and its claim of right to terminate; provided, that the termination of the Terminable Rights and Provisions shall not become effective at the end of the Notice Period if (a) the Breaching Party cures such breach during the Notice Period or (b) such breach cannot be cured during the Notice Period and the Breaching Party commences and diligently pursues actions to cure such breach within the Notice Period, in which case the Breaching Party shall have an additional 90-day period to cure such breach before such termination becomes effective.

12.3 Mutual Agreement. This Agreement or the Terminable Rights and Provisions may be terminated upon the mutual written agreement of Horizon and AstraZeneca at any time.

12.4 Consequences of Termination.

12.4.1 Termination of Terminable Rights and Provisions. Upon any termination of the Terminable Rights and Provisions pursuant to Section 12.2 or Section 12.3, (a) the licenses granted by AstraZeneca to Horizon under Section 2.1 solely with respect to the Licensed Trademarks and Licensed Domain Names, any sublicenses related thereto entered into by Horizon pursuant to Section 2.2 and Articles 7 and 8, in each case, at AstraZeneca’s option, shall terminate in their entirety and (b) the licenses granted by AstraZeneca to Horizon under Section 2.1 with respect to the US Licensed Patents, Ex-US Licensed Patents, Licensed Know-How, Licensed Regulatory Documentation and the Manufacturing Technology, the licenses granted by Horizon to AstraZeneca under Section 2.3 and all other provisions of this Agreement (other than those provisions referenced in the preceding clause (a)) shall remain in full force and effect.

12.4.2 Termination of Agreement. Upon the termination of this Agreement pursuant to Section 12.3, all of the licenses granted by the Parties under Article 2, and any sublicenses related thereto entered into by either Party as permitted hereunder, and all
other rights and obligations of this Agreement (subject to those rights and obligations that survive as set forth in Section 12.4.5 of this Agreement), shall terminate in their entirety.

12.4.3 **Discontinued Use of Trademarks.** Upon any termination described in Section 12.4.1 or Section 12.4.2, Horizon shall, and shall cause its Affiliates, Sublicensees and distributors to discontinue all use of the Licensed Trademarks (including in connection with all Product Labels, packaging with respect to the Product or any Other Product, Product (or any Other Product) inserts and advertising, marketing, promotional or other materials bearing any of the Licensed Trademarks) and Licensed Domain Names promptly, but in any event, within 90 days after any such termination.

12.4.4 **Accrued Rights.** The termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination. Such termination shall not relieve a Party from obligations that are expressly indicated to survive the termination of this Agreement.

12.4.5 **Survival.** Without limiting the foregoing, Sections 2.4, 2.5, 5.1 (to the extent required under the Merck Agreements), 5.2 (to the extent required under the Merck Agreements), this Section 12.4 and ARTICLE 9, ARTICLE 10, ARTICLE 11 (provided that Section 11.5 survives only for as long as provided in Section 11.5), and ARTICLE 13 shall survive the termination of this Agreement for any reason.

ARTICLE 13
MISCELLANEOUS

13.1 **Governing Law, Jurisdiction, Venue and Service.**

13.1.1 **Governing Law.** This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of Law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction.

13.1.2 **Jurisdiction.** Subject to Section 13.2 and 13.12, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

13.1.3 **Venue.** Subject to Section 13.2 and 13.12, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.
13.1.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 13.3.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

13.2 Dispute Resolution.

13.2.1 Except as provided in Section 13.12, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of 10 Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

13.2.2 If such Senior Officers are unable to resolve any such Dispute within such 10-Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 13.2.2 upon written notice to the other Party (an “Arbitration Notice”) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the “Arbitrators”). Each of Horizon and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made later than 30 days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Horizon and the Arbitrator chosen by AstraZeneca, but in no event later than 30 days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association (“AAA”) (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, USA, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within 15 days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

13.2.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 13.2, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 13.2.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that
prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses) or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 13.2.3 is pending under this Agreement, the Parties shall continue to comply with all terms and provisions of this Agreement. All arbitration proceedings and decisions of the Arbitrator under this 13.2 shall be deemed Confidential Information of both Parties under Section 5 of the Asset Purchase Agreement. For clarity, nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

13.3 Notices.

13.3.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a “Notice”) shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 13.3.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 10 days’ prior to such address taking effect in accordance with this Section 13.3. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.

13.3.2 Address for Notice.

If to AstraZeneca, to:
AstraZeneca AB
Pepparredslunden 1
S-431 83 Mölndal
Attention: President
Facsimile: +46 31 7763871

with a copy (which shall not constitute notice) to:
AstraZeneca AB
Pepparredslunden 1
S-431 83 Mölndal
Attention: Senior Counsel and Lead, Legal Dept.
Facsimile: +46 31 7763871
and to:
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004
Facsimile: (202) 662-6291
Attention: John Hurvitz
Michael J. Riella

If to Horizon, to:
Horizon Pharma USA, Inc.
520 Lake Cook Road, Suite 520
Deerfield, Illinois 60015
USA
Facsimile: 847-572-1372
Attention: Chief Executive Officer
with a copy (which shall not constitute notice) to:
Cooley LLP
4401 Eastgate Mall
San Diego, California 92121
USA
Facsimile: 858-550-6420
Attention: L. Kay Chandler, Esq.

13.4 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Horizon Indemnitees and AstraZeneca Indemnitees under Article 11, they shall not be construed as conferring any rights on any other Persons.

13.5 Waiver and Non-Exclusion of Remedies. 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 shall 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 any Party of any right hereunder or of the failure to perform or of a breach by the other Party shall 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. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.

13.6 Expenses. Except as otherwise specified herein or in the Asset Purchase Agreement or in any other Ancillary Agreement, each Party shall bear any costs and expenses incurred by it with respect to the transactions contemplated herein.

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13.7 Assignment. Except as expressly set forth in this Agreement, neither Party shall have the right or the power to assign, in whole or in part, any of its rights, or delegate the performance of any of its obligations, under this Agreement without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld, conditioned or delayed, and any assignment or delegation of this Agreement or any of such rights or obligations without such authorization shall be void and of no effect; provided, however, that either Party may assign the Agreement, in whole or in part, to an Affiliate without the prior written authorization of the other Party; and provided, further, that either Party shall have the right to assign this Agreement, in whole or in part, in connection with a merger or other acquisition of the capital stock or all or substantially all of the assets of such assigning Party, without the prior written authorization of the other Party, subject to providing the other Party with written notice thereof within 30 days after such assignment or delegation. Any permitted assignment or delegation hereunder by a Party shall not relieve such Party of any of its obligations under this Agreement (whether by operation of law or otherwise), unless, with respect an assignment to a Third Party, such assignee agrees in writing to assume such Party’s obligations under this Agreement, in which case such Party shall be relieved of its obligations hereunder from and after the effective date of such assignment and assumption. Subject to the foregoing, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

13.8 Use of Affiliates, Third Party Subcontractors. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates, or to subcontract any of its rights or obligations under this Agreement to any Third Party, without authorization of the other Party. For clarity this shall not limit the provisions of Section 2.2 with respect to Sublicensees.

13.9 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

13.10 Independent Contractors. In the exercise of their respective rights, and the performance of their respective obligations, under this Agreement, the Parties are, and shall remain, independent contractors. Nothing in this Agreement shall be construed to constitute the Parties as partners, joint venturers, or participants in a joint enterprise or undertaking, or to constitute either of the Parties as the agent of the other Party for any purpose whatsoever. Neither Party shall bind, or attempt to bind, the other Party hereto to any contract or the performance of any other obligation, or represent to any Third Party that it is authorized to enter into any contract or binding obligation on behalf of the other Party hereto.

13.11 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 shall be fully severable, (b) this Agreement shall 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 shall remain in full force and effect and shall 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 shall be added automatically as a part of this
13.12 **Equitable Relief.** The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

13.13 **English Language.** This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

13.14 **Counterparts.** This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

13.15 **Entire Agreement.** This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Asset Purchase Agreement and the other Ancillary Agreements, contain the entire agreement between the Parties with respect to the transactions contemplated hereby and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

13.16 **Construction.** Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall 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 does not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article, Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,” “hereto,” “hereby,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted
successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto; and (g) references to monetary amounts are denominated in United States Dollars.

[Signature page follows]

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

ASTRAZENECA AB
By: /s/ Jan-Olof Jacke
Name: Jan-Olof Jacke
Title: President

HORIZON PHARMA USA, INC.
By: /s/ Timothy P. Walbert
Name: Timothy P. Walbert
Title: President and Chief Executive Officer

[Signature Page to License Agreement]
## Licensed Trademarks

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<td>App 77726998 Reg 3914867</td>
<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
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<td>App 77670350 Reg 3941225</td>
<td>(Class 5) pharmaceutical preparations and substances for the treatment of pain and inflammation</td>
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</tbody>
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SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT ("Agreement") is made and entered into effective as of November 22, 2013 (the “Effective Date”), by and between ASTRAZENECA LP, a Delaware limited partnership ("AstraZeneca"), having offices at 1800 Concord Pike, Wilmington, Delaware 19803, and Horizon Pharma USA, Inc., a Delaware corporation ("Horizon"), having an office at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015. AstraZeneca and Horizon each may be referred to herein individually as a “Party,” or collectively as the “Parties.”

REcITALS

A. AstraZeneca 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. Horizon and AstraZeneca AB, an Affiliate of AstraZeneca, are parties to that certain (i) Asset Purchase Agreement dated as of November 18, 2013 (as may be amended, the “Asset Purchase Agreement”) under which, among other things, effective as of the Closing (as defined in the Asset Purchase Agreement), Horizon is purchasing from AstraZeneca AB certain assets relating to Products (as defined in the Asset Purchase Agreement) in the Field (as defined in the Asset Purchase Agreement) in the Horizon Territory (as defined in the Asset Purchase Agreement) and (ii) License Agreement of even date herewith (as may be amended, the “License Agreement”), under which, among other things, effective as of the Closing (as defined in the Asset Purchase Agreement), Horizon is obtaining an exclusive license to certain of AstraZeneca AB’s intellectual property for the purpose of manufacturing, developing and commercializing Products in the Field in the Horizon Territory.

C. AstraZeneca desires to supply to Horizon, and Horizon desires to obtain from AstraZeneca, on a transitional basis the Supplied Products (as defined herein) on the terms and conditions set forth herein.

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, AstraZeneca and Horizon hereby agree as follows:

AGREEMENT

1. DEFINITIONS

When used in this Agreement, capitalized terms have the meanings as defined below and throughout this Agreement and capitalized terms used but not otherwise defined herein have the respective meanings ascribed thereto in the Asset Purchase Agreement.

1.1 “AAA” has the meaning assigned to it in Section 14.3.2.

1.2 “Agreement” has the meaning assigned to it in the preamble hereto.
1.3 “API” means micronized Esomeprazole magnesium trihydrate and Naproxen as further described in the applicable Product Specifications.

1.4 “Arbitration Notice” has the meaning assigned to it in Section 14.3.2.

1.5 “Arbitrators” has the meaning assigned to it in Section 14.3.2.

1.6 “Asset Purchase Agreement” has the meaning assigned to it in the recitals.

1.7 “AstraZeneca” has the meaning assigned to it in the preamble hereto.

1.8 “AstraZeneca Indemnitee” has the meaning assigned to it in Section 12.2 (Indemnification by Horizon).

1.9 “Bailment Agreement” means that certain Bailment Agreement executed and delivered by the Parties on the Effective Date.

1.10 “Bailment Product” means any Supplied Product delivered to Horizon prior to the Bailment Product Transfer Date.

1.11 “Bailment Product Transfer Date” has the meaning set forth in the Bailment Agreement.

1.12 “Breaching Party” has the meaning as defined in Section 11.2 (Termination for Material Breach).

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

1.14 “Dispute” has the meaning assigned to it in Section 14.3.1.

1.15 “Commercialization” means all activities relating to the marketing, promotion, advertising, selling and distribution of Supplied Product in the Horizon Territory, including preparing advertising and promotional materials, sales force training and all interactions and activities regarding the commercialization of Supplied Product and the maintenance of Regulatory Approvals.

1.16 “Effective Date” has the meaning assigned to it in the preamble hereto.

1.17 “EMA” means the European Medicines Agency, or any successor agency thereto.

1.18 “Existing Regulatory Approval” means NDA# 22-511.

1.19 “Existing Product” means that certain product containing non-enteric coated Esomeprazole and enteric-coated Naproxen that is the subject of the Existing Regulatory Approval in the Horizon Territory, which product is currently known as VIMOVO™ including all dosage strengths thereof.

1.20 “Firm Forecast” has the meaning assigned to it in Section 3.1.3.
1.21 “Forecast” has the meaning assigned to it in Section 3.1.2.

1.22 “Force Majeure Event” has the meaning assigned to it in Section 14.5.

1.23 “Horizon” has the meaning assigned to it in the preamble hereto.

1.24 “Horizon Indemnitee” has the meaning assigned to it in Section 12.1 (Indemnification by AstraZeneca).

1.25 “Horizon Intellectual Property” means (a) any data, information and know-how that (i) is not generally known, (ii) is Controlled by Horizon or its Affiliates as of the Effective Date or during the Term and (iii) is necessary or useful for AstraZeneca to Manufacture the Supplied Products hereunder; (b) any Patent Right that (i) is Controlled by Horizon or its Affiliates as of the Effective Date or during the Term and (ii) is necessary or useful for AstraZeneca to Manufacture the Supplied Products hereunder; (c) any Horizon Marks; and (d) any Licensed Trademark.

1.26 “Horizon Marks” means the trade names, corporate names and corporate logos of Horizon or Horizon’s Affiliates that are used by Horizon or any of Horizon’s Affiliates in connection with the Supplied Product.

1.27 “Horizon Regulatory Documentation” has the meaning assigned to it in the License Agreement.

1.28 “Initial Forecast” has the meaning assigned to it in Section 3.1.1.

1.29 “Initial Purchase Orders” has the meaning assigned to it in Section 3.2.1.

1.30 “Indirect Taxes” has the meaning assigned to it in Section 4.3.2 (Indirect Taxes).

1.31 “License Agreement” has the meaning assigned to it in the preamble hereto.

1.32 “Licensed Trademarks” has the meaning assigned to it in the License Agreement.

1.33 “Manufacturing Process” has the meaning assigned to it in Section 7.3 (Manufacturing Process).

1.34 “Manufacture” and “Manufacturing” means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of the Supplied Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.

1.35 “Manufacturing Technology” means (a) as of the Effective Date, all Patent Rights and all data, information and know-how that (i) with respect to data, information and know-how, is not generally known, (ii) are Controlled by AstraZeneca or any of its Affiliates as
of the Effective Date and (iii) are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Supplied Products as of the Effective Date and (b) as of the date, if any, that AstraZeneca or any of its Affiliates may grant a license to Horizon under the Merck Patents and Merck Know-How without violating the terms of any Merck Agreement, the Patent Rights, data, information and know-how described in clause (a) and any Merck Patents and Merck Know-How that are used by or on behalf of AstraZeneca or its Affiliates for the Manufacture of Supplied Products as of the Effective Date; provided, that in either case ((a) or (b)), if any data, information or know-how (but not, for clarity, Patent Rights) included in Manufacturing Technology becomes publicly disclosed (other than as a result of any disclosure by Horizon in breach of its obligations under Section 5.5 of the Asset Purchase Agreement), such data, information or know-how shall no longer be deemed Manufacturing Technology.

1.36 "Minimum Batch Quantity" means (a) with respect to the Supplied Product in the form of 500/20mg tablets in 60-count bottles, [...] bottles; (b) with respect to the Supplied Product in the form of 375/20mg tablets in 60-count bottles, [...] bottles; and (c) with respect to the Supplied Product in the form of 500/20mg tablets in 6-count bottles, [...] bottles.

1.37 "Non-Breaching Party" has the meaning assigned to it in Section 11.2 (Termination for Material Breach).

1.38 "Notice" has the meaning assigned to it in Section 14.4 (Notice Requirements).

1.39 "Notice Period" has the meaning assigned to it in Section 11.2 (Termination for Material Breach).

1.40 "Package" and "Packaging" mean the acts of packaging and labeling the Existing Product in bulk form into Supplied Product.

1.41 "Packaging Technology" means all Manufacturing Technology that is necessary or useful for the packaging and labeling of the Existing Product in bulk form into Supplied Product and set forth on Schedule 1.41.

1.42 "Party" and "Parties" each has the meaning assigned to it in the preamble hereto.

1.43 "Pass-Through Affiliate" means, with respect to a Pass-Through Supply Agreement, any Affiliate of AstraZeneca that is party to such Pass-Through Supply Agreement.

1.44 "Pass-Through Supply Agreements" means those agreements set forth on Schedule 1.44.

1.45 "Pass-Through Supply Vendor" means the party to a Pass-Through Supply Agreement other than AstraZeneca or a Pass-Through Affiliate.


1.47 "Payments" has the meaning assigned to it in Section 4.3.1 (Payments).
1.48 “Product Labeling” means (a) the full prescribing information for a Supplied Product approved by the applicable Regulatory Authority in the Horizon Territory, 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 a Supplied Product in the Horizon Territory.

1.49 “Product Specifications” means the specifications for the Supplied Product contained in the applicable Regulatory Approval and any specifications mutually agreed to by the Parties established in connection with the Supplied Product and changes to such specifications made at the request of a Regulatory Authority in the Horizon Territory or by mutual agreement of the Parties from time to time, including the specifications set forth on Schedule 1.49.

1.50 “Purchase Order” has the meaning assigned to it in Section 3.2.3.

1.51 “Quality Agreement” has the meaning assigned to it in Section 6.1 (Quality Agreement).

1.52 “Raw Materials” has the meaning assigned to it in Section 7.1 (Raw Materials).

1.53 “Recall” has the meaning set forth in the Quality Agreement.

1.54 “SKU” means, with respect to any Supplied Product, the stock keeping unit number identifying the individual presentation of such Supplied Product.

1.55 “Sublicense” means a Third Party that is granted a sublicense by Horizon under the grant in Section 2.1 of the License Agreement, in accordance with Section 2.2 of the License Agreement.

1.56 “Subsequent Purchase Order” has the meaning assigned to it in Section 3.2.3.

1.57 “Supplied Product” means the Existing Product in analyzed, released, final, packaged and labeled form, including all Product Labeling, ready for Commercialization in the Field in the Horizon Territory, as further described in the Product Specifications. The Supplied Product does not include HUD blister packs.

1.58 “Technology Recipient” has the meaning assigned to it in Section 2.3.1 (Technology Transfer).

1.59 “Technology Transfer Notice” has the meaning assigned to it in Section 2.3.1 (Technology Transfer).

1.60 “Term” has the meaning assigned to it in Section 11.1 (Term).

1.61 “Third Party” means any entity other than AstraZeneca, Horizon, or any of their respective Affiliates.

1.62 “Third Party Claim” has the meaning assigned to it in Section 12.1 (Indemnification of AstraZeneca).
1.63 "Transfer Price" has the meaning assigned to it in Section 4.1 (Transfer Price).

2. SUPPLY OF SUPPLIED PRODUCTS.

2.1 Supply by AstraZeneca. During the Term, subject to the terms and conditions of this Agreement, AstraZeneca will Manufacture or have Manufactured and supply or have supplied to Horizon such quantities of Supplied Products, including samples, as requested by Horizon for use by Horizon and its Sublicensees in connection with activities with respect to Supplied Products in the Horizon Territory, including Exploitation activities in the Horizon Territory.

2.2 Supply Transition. AstraZeneca or its applicable Pass-Through Affiliate will coordinate with each Pass-Through Supply Vendor to enable such Pass-Through Supply Vendor to supply the Supplied Products, or any component thereof, for the benefit of Horizon solely for use in the Horizon Territory without breaching any of the terms of the applicable Pass-Through Supply Agreement (including by entering into any necessary side letters or amending the applicable Pass-Through Supply Agreement, in each case in accordance with Section 14.1 (AstraZeneca’s Third Party Manufacturers)). Without limiting the foregoing, promptly after the Effective Date, AstraZeneca will cause AstraZeneca AB to deliver a side letter in substantially the form of Exhibit A to Patheon Inc. and Patheon Pharmaceuticals Inc.

2.3 Technology Transfer.

2.3.1 Horizon shall have the right, at any time during the Term, to provide notice to AstraZeneca requesting transfer to Horizon or its designated Third Party manufacturer (the “Technology Recipient”) of all Packaging Technology (the “Technology Transfer Notice”). Promptly following the date of such Technology Transfer Notice, the Parties shall work together to agree to a plan for transitioning the Packaging Technology to the Technology Recipient, and each Party shall use commercially reasonable efforts to perform its obligations under such plan in accordance with the timelines set out therein. Such plan shall provide for the transfer by AstraZeneca to the Technology Recipient, at Horizon’s expense, all Packaging Technology; provided, however, that AstraZeneca shall provide up to [***] of technology transfer services at no cost to Horizon in connection with the transfer of the Packaging Technology to Horizon or the Technology Recipient (and in providing reasonable assistance in connection therewith). In the event that Horizon desires additional technology transfer services with respect to the transfer of the Packaging Technology beyond the [***] of assistance provided above, at Horizon’s reasonable request and upon the payment of [***] to AstraZeneca, AstraZeneca shall provide up to [***] of additional technology transfer services, provided that AstraZeneca’s other Manufacturing operations are not disrupted by the provision of such additional assistance.

2.3.2 In no event shall AstraZeneca be required to transfer the Packaging Technology to more than one Technology Recipient. Horizon (or the Technology Recipient at Horizon’s direction) shall obtain and make available such information, personnel, products, materials, services, facilities and other resources, and take such other actions, as are reasonably necessary or useful to enable AstraZeneca to transfer the Packaging Technology to the Technology Recipient, including those set forth in the technology transfer plan to be agreed to by

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the Parties. Horizon acknowledges that the timely and successful transfer of the Packaging Technology to the Technology Recipient depends on the provision of information, personnel, products, materials, services, facilities and other resources by or on behalf of Horizon or the taking of certain actions by or on behalf of Horizon. Horizon acknowledges and agrees that AstraZeneca provides no assurances or guarantee that the Packaging Technology may be successfully transferred to the Technology Recipient.

2.3.3 Limited License. Horizon, on behalf of itself and its Affiliates, hereby grants to AstraZeneca and its Affiliates a non-exclusive, royalty-free, fully paid-up non-transferable (except as provided in Section 14.8) license under the Horizon Intellectual Property and a right of reference and use under the Horizon Regulatory Documentation, with the right, to grant further licenses and sublicenses or rights of reference and use, in each case, to the extent necessary for AstraZeneca and its Affiliates to perform their obligations hereunder.

3. FORECASTS AND PURCHASE ORDERS.

3.1 Forecasts.

3.1.1 Horizon’s written rolling, non-binding (except as set forth in Section 3.1.3) forecast of its and its Sublicensees’ anticipated requirements for Supplied Product in the Horizon Territory broken out on a month-by-month basis by SKU (in multiples of Minimum Batch Quantities) for the twelve-month period beginning January 1, 2014 (the “Initial Forecast”) is attached as Schedule 3.1.1.

3.1.2 Beginning on December 5, 2013, Horizon shall provide AstraZeneca, on or before the [***] day of each calendar month during the Term, with a written rolling, non-binding (except as set forth in Section 3.1.3) forecast of its and its Sublicensees’ anticipated requirements for Supplied Product in the Horizon Territory broken out on a month-by-month basis by SKU (in multiples of Minimum Batch Quantities), for the shorter of the twelve (12)-month period beginning with such calendar month and the remainder of the Term (each, a “Forecast”, and together with the Initial Forecast, the “Forecasts”).

3.1.3 The first (1st) [***] months of each Forecast shall be binding on Horizon (each, a “Firm Forecast”) and may not be changed without AstraZeneca’s written consent (which may be withheld in its sole discretion). The forecasted quantity of each Supplied Product SKU for each of the [***] months of a given Forecast shall not be more than [***] or less than [***] of the forecasted quantity for such Supplied Product SKU for such month in the immediately preceding Forecast.

3.2 Purchase Orders.

3.2.1 Horizon shall order Supplied Product by submitting written purchase orders to AstraZeneca pursuant to the terms of this Section 3.2.

3.2.2 Horizon’s binding written purchase orders to AstraZeneca specifying the quantities of each Supplied Product SKU ordered by Horizon for delivery during December 2013 and each month during the first Calendar Quarter of 2014 (the “Initial Purchase Orders”) are

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3.2.3 Subject to Section 3.2.2, at least [***...] prior to the first (1st) day of each calendar month during the Term, Horizon shall submit to AstraZeneca a binding written purchase order to AstraZeneca, specifying the quantities of each Supplied Product SKU to be delivered to Horizon and its Sublicensees during such month, which quantities shall be the Minimum Batch Quantity for the applicable Supplied Product SKU, or a multiple thereof (each, a “Subsequent Purchase Order”, and together with the Initial Purchase Orders, the “Purchase Orders”).

3.2.4 AstraZeneca shall make each delivery of Supplied Product in the quantity and during the applicable month specified for it on Horizon’s Purchase Order [***...]. In the event that the quantity of Supplied Product delivered by AstraZeneca differs from the quantity requested in the applicable Purchase Order, Horizon shall pay AstraZeneca for the quantity of Supplied Products delivered, rather than the quantity ordered, to the extent that the quantity delivered is not more than [***...] of the quantity required in the Purchase Order. The quantity of each Supplied Product SKU specified in any Purchase Order submitted by Horizon to AstraZeneca for delivery in the applicable month shall be the quantity of such Supplied Product SKU forecasted by Horizon in the Firm Forecast for such month. Any Purchase Order for Supplied Product submitted by Horizon to AstraZeneca shall reference this Agreement and shall be governed exclusively by the terms contained herein. The Parties hereby agree that the terms and conditions of this Agreement shall supersede any term or condition in any order, confirmation or other document furnished by Horizon or AstraZeneca that is in any way inconsistent with these terms and conditions.

4. Transfer Price and Taxation.

4.1 Transfer Price. Horizon will pay AstraZeneca the transfer price set forth on Schedule 4.1 (the “Transfer Price”) for Supplied Products supplied by AstraZeneca to Horizon and its Sublicensees under this Agreement.

4.2 Invoices; Method of Payments.

4.2.1 AstraZeneca shall invoice Horizon for the aggregate Transfer Price of: (a) each delivery of Supplied Products that are not Bailment Products, at the time of such delivery and (b) each delivery of Bailment Products, any time after the Bailment Product Transfer Date.

4.2.2 All payments due hereunder to AstraZeneca shall be paid to AstraZeneca in U.S. Dollars not later than [***...] days following the date of the applicable invoice but not earlier than the date of delivery, unless such delivery of Supplied Product is rejected in accordance with the provisions of Section 6.2.1 (Rejection of Non-Conforming Supplied Products). All amounts due hereunder will be paid in United States Dollars by check sent to such address as may be designated in writing by AstraZeneca from time to time during the Term.

4.2.3 If AstraZeneca does not receive payment of any sum due to it on or before

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the due date, simple interest will thereafter accrue on the sum due beginning on the [...***...] Business Day after the due date until the date of payment at the per annum rate of the then-current [...***...] quoted by Citibank in New York City plus [...***...] basis points, or the maximum rate allowable by applicable Law, whichever is lower.

4.3 Taxes

4.3.1 The amounts payable by Horizon to AstraZeneca pursuant to this Agreement (“Payments”) shall not be reduced on account of any Taxes unless required by applicable Law. AstraZeneca alone shall be responsible for paying any and all Taxes (other than withholding Taxes required to be paid by Horizon levied on account of, or measured in whole or in part by reference to, any Payments it receives. Horizon shall deduct or withhold from the Payments any Taxes that it is required by applicable Law to deduct or withhold. Notwithstanding the foregoing, if AstraZeneca is entitled under any applicable Tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, it may deliver to Horizon or the appropriate Governmental Authority (with the assistance of Horizon 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 or to relieve Horizon of its obligation to withhold Tax, and Horizon shall apply the reduced rate of withholding, or dispense with the withholding, as the case may be, provided that Horizon has received evidence, in a form reasonably satisfactory to Horizon, of AstraZeneca’s delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, Horizon withholds any amount, it shall pay to AstraZeneca the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to AstraZeneca proof of such payment within sixty (60) days following that payment.

4.3.2 “Indirect Taxes” means value added taxes, sales taxes, consumption taxes and other similar taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, Horizon shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by AstraZeneca in respect of those Payments. AstraZeneca shall issue invoices for all amounts payable under this Agreement consistent with Indirect Tax requirements and irrespective of whether the sums may be netted for settlement purposes.

5. Delivery. AstraZeneca will deliver Supplied Products to Horizon in such quantities and during the applicable month as are specified in Purchase Orders subject to the terms and conditions of this Agreement. Deliveries shall be made [...***...] (Incoterms 2012) [...***...]. For clarity, [...***...] shall be responsible for the freight and insurance costs of delivery of the Supplied Products [...***...]. Except with respect to the Bailment Product, title and risk of loss for the Supplied Products shall [...***...] in accordance with this Section 5. Title and risk of loss with respect to the Bailment Product shall be governed by the Bailment Agreement.
6. QUALITY ASSURANCE; ACCEPTANCE.

6.1 Quality Agreement. Concurrently with execution of this Agreement, the Parties will enter into an agreement that details the quality assurance obligations of each Party with respect to the Manufacture and supply of Supplied Products under this Agreement (the “Quality Agreement”). Each Party shall perform its obligations under the Quality Agreement in accordance with the terms and conditions thereof. In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the provisions of the Quality Agreement shall govern.

6.2 Acceptance and Rejection.

6.2.1 Rejection of Non-Conforming Supplied Products. Horizon may reject any delivery (or portion thereof) of Supplied Product pursuant to the terms of the Quality Agreement.

6.2.2 Cost of Replacement of Rejected Product. If any delivery of Supplied Product is rejected by Horizon pursuant to the provisions of the Quality Agreement, [...***...]. If only a portion of a delivery is rejected, [...***...].

6.2.3 Return of Rejected Product. If a delivery or partial delivery is rejected by Horizon pursuant to the provisions of the Quality Agreement and there is a determination pursuant to Section 9.1 of the Quality Agreement that such Supplied Product fails to conform to any warranty set forth in Section 9.1 (Supplied Product Warranty), Horizon shall return to AstraZeneca at AstraZeneca’s request and expense (or, at the election of AstraZeneca, destroy at AstraZeneca’s cost and provide evidence of such destruction to AstraZeneca) any such rejected Supplied Product. AstraZeneca shall (a) credit the original invoice in respect of the rejected Supplied Product, and (b) adjust the invoice to Horizon for any Supplied Product that was not rejected, payment of which is due in accordance with the terms of the original invoice. Except as set forth in Section 12.1 (Indemnification by AstraZeneca), this Section 6.2.3 (Return of Rejected Product) shall be Horizon’s sole remedy if AstraZeneca supplies Horizon Supplied Product that fails to conform to any warranty set forth in Section 9.1 (Supplied Product Warranty).

6.2.4 Supply of Replacement Product. During the pendency of any rejection discussions AstraZeneca shall use commercially reasonable efforts to supply Horizon with additional Supplied Product, which Horizon shall purchase on the same terms as the Supplied Product that is the subject of the rejection discussions.

7. MANUFACTURE OF SUPPLIED PRODUCT.

7.1 Raw Materials. AstraZeneca shall be responsible for obtaining and storing, at no cost to Horizon (subject to Section 4.1 (Transfer Price)), all materials required for the Manufacture of Supplied Products including all API, raw materials, components and other

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ingredients, and all Product Labeling and containers, wrappers and other packaging materials (collectively, “Raw Materials”) required for the Manufacture of the Supplied Products hereunder. AstraZeneca shall have the right to change any source of Raw Materials; provided, however, that any change to the source of Raw Materials that would require approval by, or notification to, a Regulatory Authority (other than the annual report to the FDA for the Existing Product) shall be subject to the prior written approval of Horizon, such approval not to be unreasonably conditioned, withheld or delayed.

7.2 Manufacture of Supplied Product. AstraZeneca will Manufacture (to the extent AstraZeneca Manufactures), and will use its commercially reasonable efforts to cause the Pass-Through Supply Vendors to Manufacture, Supplied Products in accordance with the Product Specifications, cGMPs and applicable Law.

7.3 Costs of Changes to Product Specifications and Manufacturing Process. The procedures governing changes to the Product Specifications or the process or procedures used to Manufacture the Supplied Product (the “Manufacturing Process”) shall be set forth in the Quality Agreement. If any change to the Product Specifications or Manufacturing Process is proposed by AstraZeneca, then AstraZeneca shall bear any expenses of implementing such change. For changes to the Product Specifications or Manufacturing Process proposed by Horizon (including any change that is required solely by a Regulatory Authority in the Horizon Territory), Horizon promptly shall reimburse AstraZeneca for all reasonable internal and external costs incurred by AstraZeneca or any Pass-Through Affiliate (including any and all costs AstraZeneca or any Pass-Through Affiliate must pay to a Pass-Through Supply Vendor) in connection with the implementation of any such change.

7.4 Shelf Life. Supplied Products will have a remaining shelf life of at least [***...] months from the date of delivery, unless otherwise agreed by the Parties in writing, such agreement not to be unreasonably conditioned, withheld or delayed.

7.5 Supplied Product Shortfall. AstraZeneca shall use commercially reasonable efforts to avoid shortfalls in supply of Supplied Products based on the Forecasts provided by Horizon. In the event AstraZeneca is unable to supply to Horizon, in whole or in part, Supplied Products requested for any reason (except to the extent caused by Horizon), then AstraZeneca shall promptly notify Horizon, in writing, of such shortage, or potential shortage, or inability to timely supply Supplied Product and, if possible, the date when AstraZeneca will again be able to supply Supplied Product. AstraZeneca will use commercially reasonable efforts to remedy any shortfall of Supplied Product as soon as practicable and AstraZeneca will allocate its available production capacity at its facility located at [***...] for the production of Supplied Product in a manner proportional to the utilization of AstraZeneca and Horizon, respectively, of such capacity in the prior [***...] period and will allocate such Supplied Product on a proportional basis with respect to remaining shelf-life as well; provided, that in connection with any such shortfall, AstraZeneca shall not be required to supply Supplied Product from its own inventories or from orders for Supplied Product for the AstraZeneca Territory ordered pursuant to the [***...] Agreement or to incur any capital or other expenditures in connection therewith.

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8. REGULATORY.

8.1 Regulatory Compliance. AstraZeneca shall comply with all regulatory requirements with respect to Manufacture and supply of Supplied Product imposed by applicable Law upon AstraZeneca as the Manufacturer of the Supplied Product.

8.2 Recall of Supplied Product. The procedures governing Recall of Supplied Product shall be set forth in the Quality Agreement. In the event that any Supplied Product is Recalled in the Horizon Territory, Horizon shall be responsible for all costs and expenses related to such Recall and shall reimburse AstraZeneca or its applicable Pass-Through Affiliate for any out-of-pocket expenses incurred in connection with any such Recall, including any amounts payable to any Pass-Through Supply Vendors with respect thereto. Notwithstanding the foregoing, to the extent a Recall results from the nonconformance of Supplied Product supplied by AstraZeneca hereunder with each warranty set forth in Section 9.1 (Supplied Product Warranty), AstraZeneca shall reimburse Horizon for all out-of-pocket expenses incurred by Horizon with respect to such Recall.

9. REPRESENTATIONS AND WARRANTIES.

9.1 Supplied Product Warranty. AstraZeneca represents and warrants that, as of the date of delivery, all Supplied Product delivered hereunder will (a) be Manufactured by AstraZeneca in accordance with all applicable Regulatory Approvals, cGMPs and other applicable Law; (b) conform to the Product Specifications at the time of delivery; (c) have a remaining shelf life of at least [...***...] months from the date of delivery, unless otherwise agreed by the Parties in writing; (d) at the time of delivery, be free and clear of any pledges, liens, charges, security interests, leases, title retention agreements, mortgages, restrictions, development or similar agreements, easements, rights-of-way, title defects, options, or adverse claims or encumbrances of any kind or character whatsoever, and (e) be supplied in accordance with the Quality Agreement [...***...].

9.2 Other AstraZeneca Representations and Warranties. AstraZeneca represents and warrants to Horizon that (a) Schedule 9.2(a) sets forth all Third Party manufacturers engaged by AstraZeneca and its Affiliates to Manufacture or supply Supplied Products, including API and other Raw Materials used to Manufacture Supplied Products, (b) neither AstraZeneca nor any Affiliate, in any capacity, in connection with the Manufacture of Supplied Products, 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, and (c) neither AstraZeneca nor any Affiliate, in any capacity, in connection with the Manufacture of the Supplied Product has received in the past [...***...] years or is currently subject to a Warning Letter (as defined in the Act) with respect to any facility Manufacturing Supplied Product. AstraZeneca shall, or shall cause its Pass-Through Affiliates to, provide Horizon with the benefit of any warranties with respect to the subject matter in clauses (b) and (c) that AstraZeneca or its ***Confidential Treatment Requested
Pass-Through Affiliates obtained from the Pass-Through Supply Vendors with respect to the Manufacture of Supplied Products (or components thereof) under the Pass-Through Supply Agreements, and AstraZeneca shall use commercially reasonable efforts to pursue or cause the applicable Pass-Through Affiliate to use commercially reasonable efforts to pursue all remedies available to AstraZeneca or the applicable Pass-Through Affiliate under the Pass-Through Supply Agreement for any breach of any such warranties.

9.3 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.

9.4 Disclaimer of Warranties. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTIONS 9.1 (ASTRAZENECA WARRANTIES), SECTION 9.2 (RECIPROCAL REPRESENTATIONS AND WARRANTIES) OR IN THE ASSET PURCHASE AGREEMENT, EACH PARTY MAKES NO REPRESENTATIONS AND GRANTS NO WARRANTIES WITH RESPECT TO THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND ASTRAZENECA AND HORIZON 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.

9.5 Other Covenants.

9.5.1 Each Party shall comply with all applicable Law in performing its obligations under this Agreement.

9.5.2 AstraZeneca shall not employ, contract with, or retain any person directly or indirectly to perform any services under this Agreement if such a person (a) is under investigation by the FDA for debarment or is presently debarred by the FDA pursuant to 21 U.S.C. § 335a or its successor provisions, or (b) has a disqualification hearing pending or has been disqualified by the FDA pursuant to 21 C.F.R. § 312.70 or its successor provisions. If, during the Term, AstraZeneca or any person employed or retained by it to perform under this Agreement (excluding any Pass-Through Supply Vendor) (i) comes under investigation by the FDA for a debarment action or disqualification, (ii) is debarred or disqualified, or (iii) engages in any conduct or activity that could lead to any of the above-mentioned disqualification or debarment actions, AstraZeneca shall immediately notify Horizon of same; provided AstraZeneca shall use commercially reasonable efforts to require the same or similar obligations from its Pass-Through Supply Vendors and shall provide Horizon with the benefit of any warranties with respect to the subject matter.
9.5.3 AstraZeneca has and will maintain (or, as applicable, will use commercially reasonable efforts to cause the applicable Pass-Through Supply Vendors to maintain) during the Term all government permits, including, health, safety and environmental permits, necessary for the conduct of the activities that it undertakes pursuant to this Agreement.

9.5.4 As between AstraZeneca and Horizon, Horizon shall be responsible for ensuring that the Product Specifications shall comply with all applicable Regulatory Approvals, cGMPs and other applicable Law.

10. CONFIDENTIALITY

10.1 General. The rights and obligations of the Parties with respect to Confidential Information disclosed by or on behalf of one Party to the other Party hereunder shall be governed by the terms of Section 9.1 of the License Agreement.

11. TERM and TERMINATION

11.1 Term. The term of this Agreement will commence as of the Effective Date and, unless earlier terminated in accordance with this Section 11 (Term and Termination), will expire on December 31, 2014 (the “Term”).

11.2 Termination for Material Breach. In the event that either Party (the “Breaching Party”) is 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 by ninety (90) days’ prior written notice (such ninety (90)-day period, 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). It is understood that termination pursuant to this Section 11.2 (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 Section 14.3 (Dispute Resolution) to resolve the dispute for which termination is being sought and is diligently pursuing such procedure, including any arbitration following therefrom, the termination shall become effective only if and when such dispute is finally resolved through such dispute resolution procedure. This Section 11.2 (Termination for Material Breach) defines exclusively the Parties’ right to terminate in case of any material breach of this Agreement.

11.3 Other Termination by Horizon. Horizon may terminate this Agreement at any time at will upon one hundred twenty (120) days prior written notice to AstraZeneca. In addition, Horizon may terminate this Agreement immediately upon written notice to AstraZeneca if (a) the Existing Regulatory Approval is suspended for any reason or (b) any Regulatory Authority provides a Warning Letter (as defined in the Act) or other official documentation expressing major and significant concerns from a regulatory perspective with
11.4 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 sixty (60) days after the filing thereof.

11.5 Termination of License Agreement. This Agreement shall automatically terminate upon expiration or termination of the License Agreement.

11.6 Consequences of Expiration and Termination.

11.6.1 Upon expiration or termination of this Agreement, except as set forth in this Section 11.6 or Section 11.7, all obligations of the Parties under this Agreement will terminate immediately. The use by either Party 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.

11.6.2 Upon expiration or termination of this Agreement (a) all unfilled Purchase Orders shall be cancelled; provided, that if Horizon terminates this Agreement pursuant to Section 11.2, at its option, Horizon may require that all unfilled Purchase Orders be delivered in accordance with the terms of this Agreement and (b) Horizon shall promptly pay to AstraZeneca (i) the cost of AstraZeneca’s then existing inventory of Raw Materials that cannot otherwise be used in the business of AstraZeneca or returned to the vendor without additional costs and the cost that AstraZeneca or any Pass-Through Affiliate is required to pay to a Pass-Through Supply Vendor with respect to such Pass-Through Supply Vendor’s then existing inventory of Raw Materials that cannot otherwise be used in the business of such Pass-Through Supply Vendor or returned to the vendor without additional costs and (ii) the applicable Transfer Price for all work in process and finished Supplied Product Manufactured but not then delivered by AstraZeneca to Horizon; provided all such Raw Materials, work in process, and finished Supplied Product Manufactured but not then delivered by AstraZeneca to Horizon, shall be delivered to Horizon or its designee within thirty (30) days.

11.7 Surviving Obligations. 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 2.3 (Technology Transfer) (only for six (6) months after the end of the Term), 9.4 (Disclaimer of Warranties), 10 (Confidentiality), 11.6 (Consequences of Expiration)
12. INDEMNIFICATION AND INSURANCE

12.1 Indemnification by AstraZeneca. Subject to this Article 12, AstraZeneca shall indemnify, defend and hold harmless Horizon and its Affiliates, and its and their respective licensors, licensees, officers, directors, employees and agents (collectively, “Horizon Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Litigation by Third Parties (collectively, “Third Party Claims”) arising from or occurring as a result of: (a) the gross negligence or willful misconduct of any AstraZeneca Indemnitee or (b) the breach by AstraZeneca of any warranty, representation, covenant or agreement made by AstraZeneca in this Agreement, in each case, except to the extent such Losses result from the gross negligence or willful misconduct of any Horizon Indemnitee or the breach by Horizon of any warranty, representation, covenant or agreement made by Horizon in this Agreement, as to which Losses each Party shall indemnify the other Party and the AstraZeneca Indemnitees or the Horizon Indemnitees, as applicable, to the extent of its liability for such Losses.

12.2 Indemnification by Horizon. Subject to this Article 12, Horizon shall indemnify, defend and hold harmless AstraZeneca and its Affiliates, and its and their respective officers, directors, employees and agents (collectively, “AstraZeneca Indemnitees”) from and against any and all Losses incurred by them in connection with any and all Third Party Claims arising from or occurring as a result of: (a) the Exploitation or Manufacture of any Supplied Product by Horizon, its Affiliates or any of their respective Sublicensees, (b) the gross negligence or willful misconduct of any Horizon Indemnitee, or (c) the breach by Horizon of any warranty, representation, covenant or agreement made by Horizon 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, as to which Losses each Party shall indemnify the other Party and the AstraZeneca Indemnitees or the Horizon Indemnitees, as applicable, to the extent of its liability for such Losses.

12.3 Indemnification Procedures. All indemnification claims in respect of Horizon or any Horizon Indemnitees shall be made solely by Horizon and all indemnification claims in respect of AstraZeneca or any AstraZeneca Indemnitee shall be made solely by AstraZeneca and, in each case, shall be governed by Section 7.2 of the Asset Purchase Agreement. Notwithstanding anything herein to the contrary, the Parties’ respective indemnification obligations under this Article 12 shall not apply to any Losses for which such Party is entitled to indemnification under the Asset Purchase Agreement (excluding for this purpose, application of the limitations in Section 7.3 of the Asset Purchase Agreement).

12.4 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.
13. LIMITATION OF LIABILITY

13.1 Except in circumstances of fraud, gross negligence or willful misconduct by a party or its affiliates, licensees, sublicensees or distributors, and without limiting the parties’ rights under Section 12.1 or 12.2 with respect to third party claims, neither party nor any of its affiliates shall be liable for special, indirect, incidental, multiple, punitive or consequential damages, or for lost profits, revenue or income, diminution in value or loss of business opportunity, whether in contract, warranty, negligence, tort, strict liability or otherwise, arising out of or with respect to this agreement, even if that party has been placed on notice of the possibility of such damages.

13.2 Notwithstanding anything to the contrary in this agreement, with respect to any losses or damages under this agreement that arise out of any act or omission of any pass-through supply vendor, astraZeneca shall not be liable to horizon (or any horizon indemnitee) for any losses (whether grounded in contract, tort or otherwise) in an amount greater than any amounts recovered by astraZeneca or its pass-through affiliates under the applicable pass-through supply agreement with respect to such act or omission to the extent applicable to the supplied product (or component thereof) in the horizon territory; provided that astraZeneca shall use its reasonable best efforts to pursue all reasonable remedies and causes of action available under the applicable pass-through supply agreement with respect to such act or omission against any such pass-through supply vendor in accordance with the terms of the applicable pass-through supply agreement.

14. MISCELLANEOUS

14.1 AstraZeneca’s Third Party Manufacturers. The parties acknowledge and agree that astraZeneca plans to use the pass-through supply vendors in connection with the supply of supplied products under this agreement and that astraZeneca’s obligations, and horizon’s rights, under this agreement are subject to the terms and conditions of the applicable pass-through supply agreements. astraZeneca shall not amend any pass-through supply agreement in a manner that materially and adversely affects horizon’s rights under this agreement and the quality agreement nor terminate any such pass-through supply agreement if such termination materially and adversely affects horizon’s rights under this agreement, in either case, without prior written consent of horizon, such consent not to be unreasonably conditioned, withheld or delayed.

14.2 Governing Law, Jurisdiction, Venue and Service.

14.2.1 Governing Law. This agreement shall be governed by and construed in
accordance with the Laws of the State of New York, excluding any conflicts or choice of Law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive Law of another jurisdiction.

14.2.2 Jurisdiction. Subject to Section 14.3 and 14.13, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial.

14.2.3 Venue. Subject to Section 14.3 and 14.13, the Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

14.2.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 14.4 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any court.

14.3 Dispute Resolution.

14.3.1 Except as provided in Section 14.13, if a dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of 10 Business Days. Any final decision mutually agreed to by the Senior Officers in writing shall be conclusive and binding on the Parties.

14.3.2 If such Senior Officers are unable to resolve any such Dispute within such 10-Business Day period, either Party shall be free to institute binding arbitration in accordance with this Section 14.3.2 upon written notice to the other Party (an “Arbitration Notice”) and seek such remedies as may be available. Upon receipt of an Arbitration Notice by a Party, the applicable Dispute shall be resolved by final and binding arbitration before a panel of three (3) experts with relevant industry experience (the “Arbitrators”). Each of Horizon and AstraZeneca shall promptly select one Arbitrator, which selections shall in no event be made later than thirty (30) days after the notice of initiation of arbitration. The third Arbitrator shall be chosen promptly by mutual agreement of the Arbitrator chosen by Horizon and the Arbitrator chosen by AstraZeneca, but in no event later than thirty (30) days after the date that the last of such Arbitrators was appointed. The Arbitrators shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery; provided that the Arbitrators shall permit such discovery as they deem necessary

18.
to permit an equitable resolution of the Dispute. The arbitration shall be administered by the American Arbitration Association ("AAA") (or its successor entity) in accordance with the then current Commercial Rules of the American Arbitration Association including the Procedures for Large, Complex Commercial Disputes (including the Optional Rules for Emergency Measures of Protection), except as modified in this Agreement. The arbitration shall be held in New York, New York, USA, and the Parties shall use reasonable efforts to expedite the arbitration if requested by either Party. The Arbitrators shall, within fifteen (15) days after the conclusion of the arbitration hearing, issue a written award and statement of decision describing the essential findings and conclusions on which the award is based, including the calculation of any damages awarded. The decision or award rendered by the Arbitrators shall be final and non-appealable, and judgment may be entered upon it in accordance with applicable Law in the State of New York or any other court of competent jurisdiction. The Arbitrators shall be authorized to award compensatory damages, but shall not be authorized to reform, modify or materially change this Agreement or any other agreements contemplated hereunder.

14.3.3 Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 14.3, and shall pay an equal share of the fees and costs of the Arbitrators and all other general fees related to any arbitration described in Section 14.3.3; provided, however, the Arbitrators shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for its reasonable counsel fees, costs and disbursements (including expert witness fees and expenses, photocopy charges, or travel expenses) and/or the fees and costs of the Arbitrators. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in Section 14.3.3 is pending under this Agreement, the Parties shall continue to comply with all terms and provisions of this Agreement. All arbitration proceedings and decisions of the Arbitrator under this 14.3 shall be deemed Confidential Information of both Parties under Section 10. For clarity, nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

14.4 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a "Notice") shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in this Section 14.4 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least five (5) days prior to such address taking effect in accordance with this Section 14.4. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.
14.5 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement if such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any
Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) (each, a “Force Majeure Event”). The non-performing Party shall notify the other Party of such Force Majeure Event within thirty (30) days after such occurrence by giving written notice to the other Party stating the nature of the Force Majeure Event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

14.6 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Horizon Indemnitees and AstraZeneca Indemnitees under Article 12, they shall not be construed as conferring any rights on any other Persons.

14.7 Waiver and Non-Exclusion of Remedies. 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 shall 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 of any right hereunder or of the failure to perform or of a breach by the other Party shall 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.

14.8 Assignment. Except as expressly set forth in this Agreement, neither Party shall have the right or the power to assign, in whole or in part, any of its rights, or delegate the performance of any of its obligations, under this Agreement without the prior written authorization of the other Party, which authorization shall not be unreasonably withheld, conditioned or delayed, and any assignment or delegation of this Agreement or any of such rights or obligations without such authorization shall be void and of no effect; provided, however, that either Party may assign the Agreement, in whole or in part, to an Affiliate without the prior written authorization of the other Party; and provided, further, that either Party shall have the right to assign this Agreement, in whole or in part, in connection with a merger or other acquisition of the capital stock or all or substantially all of its assets, without the prior written authorization of the other Party. Any permitted assignment or delegation hereunder by a Party shall not relieve such Party of any of its obligations under this Agreement (whether by operation of law or otherwise), unless, with respect an assignment to a Third Party, such assignee agrees in writing to assume such Party’s obligations under this Agreement, in which case such Party shall be relieved of its obligations hereunder from and after the effective date of such assignment and assumption. Subject to the foregoing, this Agreement shall be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

14.9 Use of Affiliates. Either Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates without authorization of the other Party. For clarity, AstraZeneca is permitted to perform its obligations hereunder using any Pass-Through Supply Vendor.
14.10 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

14.11 Independent Contractors. In the exercise of their respective rights, and the performance of their respective obligations, under this Agreement, the Parties are, and shall remain, independent contractors. Nothing in this Agreement shall be construed to constitute the Parties as partners, joint venturers, or participants in a joint enterprise or undertaking, or to constitute either of the Parties as the agent of the other Party for any purpose whatsoever. Neither Party shall bind, or attempt to bind, the other Party hereto to any contract or the performance of any other obligation, or represent to any Third Party that it is authorized to enter into any contract or binding obligation on behalf of the other Party hereto.

14.12 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 shall be fully severable, (b) this Agreement shall 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 shall remain in full force and effect and shall 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 shall 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.

14.13 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

14.14 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.15 Counterparts. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

14.16 Entire Agreement. This Agreement, together with the Schedules and Exhibits
expressly contemplated hereby and attached hereto, the Ancillary Agreements, the Confidentiality Agreement and the other agreements, certificates and
documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the
entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings,
promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof. In the event of any
inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

14.17 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any
gender shall 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 does not limit the generality of any description preceding such term. The language of this Agreement shall
be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise
specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article,
Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) “hereof,”
“hereto,” “hereby,” “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any
particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any
amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto;
(f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed
or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of
reference thereto; and (g) references to monetary amounts are denominated in United States Dollars.

[Remainder of page intentionally left blank. Signature page follows.]
IN WITNESS WHEREOF, the Parties have executed this SUPPLY AGREEMENT by their respective authorized representatives as of the date first written above.

HORIZON PHARMA USA, INC.  AstraZeneca LP

By: /s/ Timothy P. Walbert  By: /s/ Steve Mohr
Name: Timothy P. Walbert  Name: Steve Mohr
Title: President and Chief Executive Officer  Title: Deputy General Counsel, North America and US General Counsel

SIGNATURE PAGE TO SUPPLY AGREEMENT
SCHEDULE 1.41

PACKAGING TECHNOLOGY

[...***...]

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SCHEDULE 1.44

PASS-THROUGH SUPPLY AGREEMENTS

[...***...]

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SCHEDULE 1.49

PRODUCT SPECIFICATIONS

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## SCHEDULE 3.1.1

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### SCHEDULE 3.2.2

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## SCHEDULE 4.1

### TRANSFER PRICES

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***Confidential Treatment Requested***
SCHEDULE 9.2(A)

THIRD PARTY MANUFACTURERS

[...***...]

***Confidential Treatment Requested
EXHIBIT A

PATHEON SIDE LETTER

(SEE ATTACHED)
Dear Patheon Legal Services Department:

Reference is made to that certain Manufacturing Services Agreement dated as of March 30, 2010 (the “Patheon Agreement”), by and between AstraZeneca LP (“AZLP”), on the one hand, and Patheon Inc. and Patheon Pharmaceuticals Inc. (collectively, “Patheon”), on the other hand.

Horizon Pharma USA, Inc. (“Horizon”) and AstraZeneca AB (“AZAB”) have executed an asset purchase agreement pursuant to which, among other things, AZAB transfers, assigns and licenses to Horizon all rights of AZAB and its affiliates to that certain product containing non-enteric coated Esomeprazole and enteric-coated Naproxen that is the subject of NDA #22-511 in the United States (“Vimovo”), and other pharmaceutical products that contain gastroprotective agents in a single fixed combination oral solid dosage form with non-steroidal anti-inflammatory drugs in the United States and its territories and possessions (the “Divestiture”).

In connection with the Divestiture, AZLP, will supply Vimovo in finished packaged form to Horizon solely for sale in the United States until December 31, 2014. After December 31, 2014, Horizon will be responsible for obtaining Vimovo for sale in the United States. In order to facilitate Horizon’s obtaining its own supply of Vimovo for sale in the United States, notwithstanding any agreement between AZLP or any of its affiliates and Patheon to the contrary, AZLP hereby waives any restriction on Patheon using, and authorizes Patheon to use, the equipment described on Schedule A to manufacture Vimovo for Horizon and its affiliates, licensees and sublicensees solely for sale in the United States. Except for the express waiver and authorization set forth in the immediately preceding sentence, this letter shall not limit or otherwise affect the rights or obligations of AZLP or Patheon under the Patheon Agreement or any other agreement between AZLP and Patheon.
AZLP and Patheon agree not to modify or amend the Patheon Agreement, or enter into a separate agreement pertaining to Vimovo, if such modification or amendment or separate agreement would alter or conflict with the provisions of this letter.

The foregoing provisions of this letter are for the benefit of Horizon and may be enforced by Horizon.

The terms and conditions of this letter, including its existence, are subject to the confidentiality provisions of the Patheon Agreement.

This letter shall be governed by and construed in accordance with the Laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this letter to the substantive law of another jurisdiction.

Please sign below to indicate your acknowledgement of this letter and return it to the undersigned.
Best regards,

AstraZeneca LP

By: /s/ Steve Mohr  
Steve Mohr  
Deputy General Counsel, North America and US General Counsel

Acknowledged:

Patheon Inc.

By: /s/ Jason Conner  
Name: Jason Conner  
Title: VP, Legal & Assistant General Counsel  
November 25, 2013

Patheon Pharmaceuticals Inc.

By: /s/ Francis P. McCune  
Name: Francis P. McCune  
Title: Secretary  
November 25, 2013

Horizon Pharma USA, Inc.

By: /s/ Timothy P. Walbert  
Timothy P. Walbert  
President and Chief Executive Officer  
November 22, 2013
1. The following manufacturing equipment AZ Tech MP 7 Train 2 is proposed for Naproxen/Esomeprazole tablets.

<table>
<thead>
<tr>
<th>Process Step</th>
<th>375mg Tablets Equipment</th>
<th>500mg Tablets Equipment</th>
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<tr>
<td>High Shear Granulation</td>
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<td>Quadro Comil U20</td>
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<tr>
<td>Fluid Bed Dry</td>
<td>GEA MP7</td>
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<td>Quadro Comil U20</td>
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<tr>
<td>Mill</td>
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<td>Comil 196S</td>
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<tr>
<td>Blend</td>
<td>75 CF V-Blender</td>
<td>75 CF V-Blender</td>
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<tr>
<td>Compress</td>
<td>Fette 3090</td>
<td>Fette 3090</td>
</tr>
<tr>
<td>Coating (Multi-step)</td>
<td>60” Coating Pan</td>
<td>60” Coating Pan</td>
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<tr>
<td>Printing</td>
<td>Hartnett</td>
<td>Hartnett</td>
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<tr>
<td>Inspection</td>
<td>Viswell</td>
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1.2 The following manufacturing equipment New Tech Train 1 is proposed for Naproxen / Esomeprazole tablets

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<tr>
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<th>500mg Tablets Equipment</th>
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<td>75 CF V-Blender</td>
<td>75 CF V-Blender</td>
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<td>60” Coating Pan</td>
<td>60” Coating Pan</td>
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<tr>
<td>Printing</td>
<td>Hartnett</td>
<td>Hartnett</td>
</tr>
<tr>
<td>Inspection</td>
<td>Viswell</td>
<td>Viswell</td>
</tr>
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AMENDED AND RESTATED
COLLABORATION AND LICENSE AGREEMENT FOR THE UNITED STATES

by and between

POZEN INC.

and

ASTRAZENECA AB

November 18, 2013
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## SCHEDULES

- **Schedule 1.43** – Licensed Patents
- **Schedule 1.83** – Vimovo Trademarks
- **Schedule 8.1.3** – Market Reduction Example
THIS AMENDED AND RESTATED COLLABORATION AND LICENSE AGREEMENT FOR THE UNITED STATES (the “Agreement”) is made and entered into as of November 18, 2013 (the “Amended and Restated 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 (“Licensee”). POZEN and Licensee each may be referred to herein individually as a “Party,” or collectively as the “Parties.”

RECITALS

A. WHEREAS, POZEN and Licensee are parties to that certain Collaboration and License Agreement, dated as of August 1, 2006 and as amended as of September 6, 2007, October 1, 2008 and September 16, 2013 (as amended, the “Original Agreement”);

B. WHEREAS, Licensee is in discussions with Horizon Pharma USA, Inc. (“Horizon”) to divest Licensee’s (and its Affiliates’) rights to Products (as defined below) in the United States (such transaction, the “Divestiture”); and

C. WHEREAS, to facilitate the proposed Divestiture, Licensee and POZEN desire to amend and restate the terms of the Original Agreement in two separate agreements: (a) this Agreement, which contains the terms and conditions pursuant to which Licensee (or its assignee) will have a license to POZEN’s intellectual property to manufacture, develop and commercialize the Products (as defined below) in the United States, which will be assigned to Horizon in connection with the Divestiture, and (b) another agreement that contains the terms and conditions pursuant to which Licensee (or its designee) will have a license to POZEN’s intellectual property to manufacture, develop and commercialize the Products throughout the world outside of the United States and Japan (the “ROW 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 Licensee 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 **“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.

1.2 **“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.

1.3 **“Amended and Restated Effective Date”** has the meaning set forth in Section 12.1.

1.4 **“Amended and Restated Execution Date”** has the meaning set forth in the preamble.

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 **“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 in the Territory.

1.7 **“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 (i) 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; or (ii) any merger, consolidation, sale of stock, sale or transfer of all or substantially all of the assets, or other similar transaction permitted under Section 15.1 (Assignment).

1.8 **“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.

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

1.10 **“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:
1.11 “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.

1.12 “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.

1.13 “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 [...***...]( [...***...] ) [...***...] of POZEN’s voting securities.

1.14 “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.

1.15 “Commercial Launch” means the nationwide commercial sale, promotion and distribution of POZEN Product in the Territory following receipt of Marketing Approval in the Territory.

1.16 “Commercialization” means all activities relating to the manufacture, marketing, promotion, advertising, selling and distribution of Product in 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.

1.17 “Commercialized POZEN Product” has the meaning set forth in Section 12.8 (Formulation Technology).

1.18 “Competing Product” means, with respect to a particular Product being Commercialized by Licensee or any of its Affiliates or Sublicensees in the Territory, a product being marketed by or on behalf of a Third Party (other than a Sublicensee) in the Territory containing at least [...***...] that are [...***...] those in the [...***...] and are [...***...].
1.19 “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.

1.20 “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 in the Territory, including, without limitation, preparing and conducting pre-clinical testing, toxicology testing, human clinical studies, regulatory affairs.

1.21 “Diligent Efforts” means, with respect to the Development, Manufacture or Commercialization by Licensee of a product, at any given time as the case may be, efforts and resources reasonably used by Licensee or its Affiliates (giving due consideration to relevant industry standards) for Licensee’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 or the Three-Party Agreement), the extent of market exclusivity, patent protection, cost to develop the product, promotable claims, and health economic claims.

1.22 “Divestiture” has the meaning set forth in the recitals.

1.23 “Duexis” means the pharmaceutical product containing ibuprofen and famotidine in a single fixed combination dosage form, which product is being commercialized as of the Amended and Restated Effective Date by Horizon or its Affiliates in the Territory as Duexis®.

1.24 “Effective Date” means the date on which the Original Agreement became effective pursuant to the terms thereof.

1.25 “Esomeprazole” means that certain pharmaceutical compound with the name (5-methoxy-2-\{(S)-(4-methoxy-3,5-dimethylpyridin-2-yl)methyl\}sulfanyl\}-1H-benzimidazole), including any [...***...].

1.26 “Execution Date” means August 1, 2006.

1.27 “FDA” means the United States Food and Drug Administration, or any successor agency thereto.

1.28 “Field of Use” means the treatment of human diseases and conditions by means of a pharmaceutical product.

1.29 “First Commercial Sale” means, with respect to a Product, the date on which Licensee 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 the Territory (including, without limitation, sale in an individual state or similar sub-national political subdivision in which Marketing Approval may be received); provided, that with respect to the

***Confidential Treatment Requested

- 4 -
Initial Pozen Product, “First Commercial Sale” means July 6, 2010. 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.

1.30 “Formulation Technology” means any Know-How Controlled by Licensee in the Licensee Inventions that are used by Licensee in the manufacture, use, sale or import of the formulation of a Commercialized POZEN Product, and any Patents Controlled by Licensee claiming such Licensee 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.

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

1.32 “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.

1.33 “Horizon” has the meaning set forth in the recitals.

1.34 “IND” means an Investigational New Drug Application filed with the FDA pursuant to 21 CFR § 312.20.

1.35 “Indirect Tax” means value added taxes, sales taxes, consumption taxes and other similar taxes.

1.36 “Initial POZEN Product” means the POZEN Product containing non-enteric coated Esomeprazole and enteric-coated Naproxen that is the subject of NDA #22-511.

1.37 “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.

1.38 “Joint Invention” means any Invention that is conceived jointly by one or more employees, agents, or independent contractors of Licensee or its Affiliate(s) and one or more employees, agents, or independent contractors of POZEN or its Affiliate(s).


1.40 “JSC” has the meaning set forth in Section 2.1.2 (Joint Steering Committee).

1.41 “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.
1.42 “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 in the Territory and that is Controlled by POZEN or any of its Affiliates as of the Effective Date or during the Term.

1.43 “Licensed Patents” means: (a) the Patents set forth on Schedule 1.43, and any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, or extensions of such Patents, (b) any Patents in the Territory 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), and (c) all other Patents in the Territory 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 in the Territory. Notwithstanding anything in this Section 1.43 to the contrary, Licensed Patents shall not include any Patents Controlled by POZEN with Valid Claims that do not cover any Product (e.g., any Patents with Valid Claims solely directed to any product containing acetyl salicylic acid).

1.44 “Licensed Technology” means the Licensed Patents and the Licensed Know-How.

1.45 “Licensee House Marks” means any trademarks, trade names, domain names, or other names or marks used or registered by Licensee or its Affiliates at any time during the Term to identify itself.

1.46 “Licensee Invention” means any Invention that is conceived solely by one or more employees, agents, or independent contractors of Licensee or its Affiliate(s).

1.47 “Manufacture” means all activities related to the manufacturing of a Product, or any ingredient thereof, in the Territory, 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.

1.48 “Market Reduction” has the meaning set forth in Section 8.1.3 (Rate Step Down for Competing Product Entrants).

1.49 “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 the Territory, that are necessary or useful to be obtained prior to the manufacture or Commercialization of a Product in the Territory. For purposes of clarification, “Marketing Approval” in the U.S. shall have the same meaning as NDA Approval in the U.S.
1.50 “Naproxen” means that certain pharmaceutical compound with the chemical name (S)-6-methoxy-(alpha)-methyl-2-naphthaleneacetic acid, including any [...***...].

1.51 “NDA” means a New Drug Application filed with the FDA as described in 21 CFR § 314.

1.52 “NDA Approval” means receipt of a letter from the FDA approving an NDA.

1.53 “Net Sales” means with respect to any Product, the gross amounts recognized by Licensee, its Sublicensees or its Affiliates from Third Party customers for sales of a Product in the Territory, less the following deductions made by Licensee (to the extent not already taken by Licensee in the Product invoice or in amounts recognized), its Sublicensees or its Affiliates in arriving at net sales as reported in the Licensee 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 Licensee statutory accounts; and

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

Net Sales shall be calculated using Licensee’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 8.1 (Royalties) shall be determined as follows:

\[
\frac{A}{A+B} \times \text{Net Sales of the Combination Product, where:}
\]

\[
A = \text{Standard Sales Price of the ready-for-sale form of the Product if sold separately from the Combination Product in question, in the Territory.}
\]

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\[ B = \text{Standard Sales Price of the ready-for-sale form of a product containing the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the Territory.} \]

If (a) the other therapeutically active ingredient(s) in such Combination Product are not sold separately in the Territory, 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 the Territory 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 the Territory of the other therapeutically active ingredient(s) in the Combination Product and \( C \) is the Standard Sales Price in the Territory of the Combination Product. If 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. If the Product in the Combination Product is marketed in the Territory, 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 \( [\ldots] \) of the Standard Sales Price of the Product sold outside of such Combination Product in the Territory.

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:

\[
\frac{A}{A+B} \times \text{Net Sales of the Product Set, where:}
\]

\[ A = \text{Standard Sales Price of the Product if sold separately from the Product set in question, in the Territory.} \]

\[ B = \text{The total of the Standard Sales Prices of all products in the Product Set other than the Product, in the Territory.} \]

1.54 “Nexium” means AstraZeneca AB’s and its Affiliates’ products containing Esomeprazole as the sole active ingredient in any presentation form.

1.55 “Nexium Business” means AstraZeneca AB’s and its Affiliates’ development and commercialization activities pertaining to Esomeprazole and Esomeprazole based products.

1.56 “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).

1.57 “Original Agreement” has the meaning set forth in the recitals.

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1.58 “Patent Challenge” has the meaning set forth in Section 9.9.

1.59 “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.

1.60 “Post-Approval Failure” means: (a) a mandatory withdrawal or recall of a Product by a Regulatory Authority, or (b) any voluntary withdrawal or recall of a Product 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 Licensee’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 in the Territory shall not be considered a Post-Approval Failure for purposes of this Agreement.

1.61 “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.

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

1.63 “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 in the Territory without a license from POZEN of the Licensed Patents, infringe one or more Valid Claims of the Licensed Patents.

1.64 “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 Licensee or its Affiliates during the Term, but in each case excluding Duexis. For the avoidance of doubt, “Product” does not include any product containing acetyl salicylic acid (including salts and derivatives thereof).

1.65 “Product Labeling” means (a) the full prescribing information for a POZEN Product approved by the applicable Regulatory Authority in the Territory, 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 in the Territory.

1.66 “Product Trademarks” means (a) the VIMOVO Trademarks and (b) any other trademarks, trade dress (including packaging design), logos, slogans, domain names and designs, whether or not registered in a country or territory, selected by Licensee and used to identify or promote a POZEN Product, but excluding any POZEN House Marks and Licensee House Marks.
1.67 “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 Licensee or its Affiliates in connection with any promotion of the Initial POZEN Product hereunder in the Territory, but excluding Product Labeling.

1.68 “PT” means Licensee’s product team operating pursuant to Licensee’s instructions for product teams for the Initial POZEN Product in the Territory with representatives of Licensee having expertise in the areas of research & development, marketing, regulatory, intellectual property, finance, toxicology, and other areas.

1.69 “PT Chair” will have the meaning set forth in Section 2.2.1 (PT).

1.70 “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 European Medicines Agency, or any successor agency thereto, and any national regulatory authority in any EU country.

1.71 “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 the Territory. Regulatory Materials include, without limitation, INDs and NDAs, and amendments and supplements for any of the foregoing, and applications for pricing and reimbursement approvals.

1.72 “ROW Agreement” has the meaning set forth in the recitals.

1.73 “ROW Party” has the meaning set forth in Section 7.4(b).

1.74 “Royalty Term” has the meaning set forth in Section 8.1.2 (Royalty Term).

1.75 “Standard Sales Price” means, as reported by IMS (or ACNielsen in the case of over-the-counter products) in the Territory, 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.
1.76 “Sublicense Agreement” means any agreement under which Licensee 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.

1.77 “Sublicensee” means any Third Party that has entered into a Sublicense Agreement.

1.78 “Term” has the meaning assigned to it in Section 12.2 (Term).

1.79 “Territory” means the United States.

1.80 “Third Party” means any entity other than POZEN, Licensee, or any of their respective Affiliates.

1.81 “Third Party Royalties” means upfront, commercialization milestone, royalty and any other similar payments paid by Licensee or any Licensee Affiliate or Sublicensee to any Third Party in consideration for a license to a Blocking Patent for the Development or Commercialization of POZEN Products in the Territory.

1.82 “Three-Party Agreement” means that certain letter agreement of even date herewith by and among AstraZeneca AB, POZEN and Horizon.

1.83 “Vimovo Trademarks” means the trademark VIMOVO and the other trademarks and logos listed on Schedule 1.83 and any variations thereof.

1.84 “U.S.” or “United States” means the United States of America and its possessions and territories.

1.85 “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 [...***...][...***...]) years 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 Product Team. Within twenty (20) days after the Amended and Restated Effective Date, the Parties will appoint representatives to the PT in accordance with the terms of this Section 2.1 and convene the first PT meeting. The PT will coordinate and oversee the Commercialization of the Initial POZEN Product hereunder. The purposes of the PT will be, with respect to the Initial POZEN Product only, to develop Licensee’s marketing plans for the Initial POZEN Product in the Territory. The PT 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 Amended and Restated Effective Date, the Parties will create a joint steering committee
(the “JSC”) to provide strategic guidance to the PT in decisions pertaining to the Initial POZEN Product in the Territory. The purposes of the JSC will be to resolve disputes of the PT. 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 PT.

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

(b) Chairpersons. The product director designated by Licensee for the Initial POZEN Product will chair the PT (“PT Chair”).

(c) Meetings. The PT will hold meetings when called by the PT Chair. Meetings may be held in person or by means of telecommunication (telephone, video, or web conference). Face-to-face PT meetings that require POZEN attendance will be convened on an as-needed basis as mutually agreed by Licensee and POZEN, but in any event, at least twice per annum. The location of these meetings, will be based on business requirements and determined by mutual agreement between Licensee and POZEN. Following any PT meeting, the PT Chair will be responsible for preparing and issuing minutes of such meeting within fifteen (15) Business Days thereafter. When POZEN has participated in the meeting, such minutes will not be finalized until a representative of the PT 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 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 PT 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 PT and JSC will not have any power to amend this Agreement. 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 PT and JSC.

2.3 **Decision-Making.**

2.3.1 **PT Decisions.** Subject to the terms of this Section 2.3 (Decision-Making), the PT will act by decision of the PT 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 […] Business Days 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 Commercialization of the Initial POZEN Product in the Territory), 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 

[...***...][...***...]) Business Days 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 [...***...][...***...]) Business Day period, then the Chief Executive Officer or designee of Licensee will have the final decision-making authority with respect to disagreement relating to any and all matters.

2.3.4 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).

2.4 Operating Principles. Promptly after the Amended and Restated Effective Date, the Parties will agree in writing on operating principles to guide the conduct of the PT and JSC. To the extent there is any conflict between such operating principles and the terms and conditions of the Agreement, then the Agreement will control.

3. [INTENTIONALLY OMITTED]

4. REGULATORY MATTERS

4.1 Responsibilities. Licensee shall have the sole right at its own expense to (a) seek any Marketing Approval for Products in the Territory, including Marketing Approval for claims not obtained in the initial NDA Approval for the Initial POZEN Product, and (b) prepare or make any filings or submissions to, or otherwise communicate with, any Regulatory Authority in the Territory regarding Products. For clarity, Licensee shall own all Marketing Approvals and Regulatory Materials pertaining to Products in the Territory. Without limiting the foregoing, as owner of the NDA Approval for the Initial POZEN Product, Licensee will be the sole owner of all data exclusivity protection related to the Initial POZEN Product in the Territory as provided by Applicable Law.

4.2 Access to Filings. Licensee 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 in the Territory, 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 in the Territory, review of such materials by the relevant Regulatory Authority in the Territory, and Marketing Approvals received for the Initial POZEN Product in the Territory.

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4.3.2 Communications. Except as may be required by Applicable Law, only Licensee will communicate regarding POZEN Products, including the Initial POZEN Product, with any Regulatory Authority in the Territory. If POZEN is required to make such a communication by a Regulatory Authority, then POZEN will [...***...].

4.4 Exchange of Know-How; Information Sharing. As of the Amended and Restated Effective Date, each Party has provided to the other Party copies of all 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 outstanding of any study reports, all to the extent reasonably required for a Party to perform its obligations under this Agreement. Each Party will provide to the other Party copies of any Know-How that comes into its possession on or after the Amended and Restated Effective 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 a Party to perform its obligations under this Agreement. In addition, 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 in the Territory, 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 to comply with Applicable Law, [...***...].

4.5 Regulatory Audits. If a Regulatory Authority in the Territory 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. Licensee will have the right upon request (which request shall not be unreasonably withheld) to have a representative observe such inspection or audit with respect to a POZEN facility, or a facility under contract with POZEN. 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. **Confidential Treatment Requested**

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4.6.1 Licensee will maintain and will be the recognized holder of the safety database for AE and SAE reports related to POZEN Products in the Territory. 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 in the Territory.

4.6.2 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 in the Territory 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.

4.7 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 under this Agreement.

5. DEVELOPMENT AND COMMERCIALIZATION

5.1 Development and Commercialization. As between the Parties, Licensee will be solely responsible for the Development and Commercialization of POZEN Products in the Territory during the Term.

5.2 Regulatory Obligations. Licensee will own and maintain all regulatory filings and Marketing Approvals in the Territory for POZEN Products, including all INDs and NDAs for the Initial POZEN Product. As between the Parties, but subject to [...***...], Licensee will be solely responsible for all activities in connection with maintaining Marketing Approvals required for the Commercialization and manufacture of POZEN Products in the Territory, including communicating and preparing and filing all reports (including Adverse Event reports) with the applicable Regulatory Authorities in the Territory.

5.3 Performance; Diligence. Licensee will use Diligent Efforts to Commercialize a POZEN Product in the Territory. The foregoing Diligent Efforts requirement will apply only to one POZEN Product in the Territory, irrespective of the number of POZEN Products Licensee elects to Develop and Commercialize, and Licensee may elect to fulfill its Diligent Efforts obligation in the Territory in respect to any POZEN Product of its choice in the exercise of its reasonable and good faith judgment. Licensee will have the right to Develop and Commercialize Products during the Term in the Territory, for so long as Licensee is using Diligent Efforts to Commercialize at least one POZEN Product in accordance with this Section 5.3, it being understood that the Parties intend for Licensee to focus its initial efforts on the Commercialization of the Initial POZEN Product in the Territory.

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5.4 Threatened Removal. In the event that any governmental authority threatens or initiates any action to remove any POZEN Product from the market in the Territory, Licensee will promptly notify POZEN of such communication. Any voluntary recall or withdrawal of any POZEN Product in the Territory will be at Licensee’s sole discretion and expense. Before Licensee initiates a recall or withdrawal in the Territory, 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 of any POZEN Product in the Territory, Licensee will implement any necessary action, with assistance from POZEN as reasonably requested by Licensee.

5.5 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 in the Territory 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.

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

5.6.1 Responsibilities. As between the Parties, Licensee will select all Product Trademarks for use on or in connection with POZEN Products in the Territory, will be the sole owner of the Product Trademarks in the Territory and, except with respect to the Vimovo Trademarks, which are addressed in the last sentence of this Section 5.6.1, will be responsible for the filing, prosecution, maintenance and defense of all registrations of the Product Trademarks in the Territory, and will be responsible for the payment of any costs relating to filing, prosecution, maintenance and defense of the Product Trademarks in the Territory. The Parties acknowledge and agree that AstraZeneca AB (or its Affiliate) is the sole owner of any Vimovo Trademark that may be used by Licensee in connection with POZEN Products in the Territory pursuant to a separate agreement between Licensee and AstraZeneca AB, and that the filing, prosecution, maintenance and defense of all registrations of the Vimovo Trademarks in the Territory shall be governed by the terms of such separate agreement.

5.6.2 Use. Licensee 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.

5.6.3 Licensee Marks. Licensee reserves all rights in the Licensee House Marks. POZEN acknowledges Licensee’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 Licensee House Mark.
5.6.4 POZEN Marks. POZEN reserves all rights in the POZEN House Marks not expressly granted to Licensee in this Agreement. Licensee 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 Licensee any rights in such trademarks except as expressly provided herein. Licensee further acknowledges that its use of the POZEN House Marks will not create in Licensee 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. Licensee agrees not to use or file any application to register any trademark or trade name that is confusingly similar to any POZEN House Mark.

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

5.7 Commercial Supply. Licensee will be solely responsible, at its own expense, for the Manufacture and supply of Licensee’s entire requirements of supplies of POZEN Product for Commercialization in the Territory.

6. [INTENTIONALLY OMITTED]

7. LICENSES

7.1 Licensed Technology. Subject to the terms and conditions of this Agreement, POZEN hereby grants to Licensee 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, Licensee 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 Licensee 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. Licensee 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. Licensee 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). Licensee 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 Section 11 (Confidentiality), 14 (Limitation of Liability), 8.2

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7.4 Reservation of Rights; No Implied Licenses.

(a) 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 Licensee or any of its Affiliates, and likewise Licensee 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.

(b) Licensee understands that POZEN has retained rights to the Products outside the Territory and has licensed such rights to a Person under the ROW Agreement (the “ROW Party”).

7.5 Restrictive Covenant. Licensee 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 Licensee 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 Licensee 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 Licensee to compensate POZEN if Licensee so exploits such products.

8. FINANCIAL TERMS

8.1 Royalties.
8.1.1 Royalty Rate. Subject to the terms and conditions of this Agreement, Licensee will pay to POZEN royalties based on the aggregate annual Net Sales of Products sold by Licensee, its Affiliates or Sublicensees, at the rate of 10% of aggregate Net Sales of Products sold in the Territory.

8.1.2 Royalty Term. Licensee acknowledges that it will continue to enjoy substantial benefit from its license under, and the transfer to Licensee of certain elements of, the Licensed Technology pursuant to this Agreement (including the Licensed Know-How and the regulatory data to be provided to Licensee pursuant to this Agreement) as well as from Licensee’s own development of technology derived from the practice of such license and Licensee’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 the Territory. Accordingly, subject to the terms of Section 8.1.3 (Rate Step Down for Competing Product Entrants), Licensee’s royalty payment obligations under this Section 8.1 (Royalties) will commence upon First Commercial Sale of a Product in the Territory and will expire 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 the Territory, and (ii) ten (10) years after the First Commercial Sale of such Product in the Territory (such period ending at the later of the periods set forth in clause (i) and (ii) above, the “Royalty Term”).

8.1.3 Rate Step Down For Competing Product Entrants. With respect to any particular Product in the Territory, 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 during such Calendar Quarter will be reduced to [***] percent ([***]%). Such reduced royalty rates will continue in effect, on a Product-by-Product basis, until expiration of the applicable Royalty Term. As used in this Section 8.1.3, the term “Market Reduction” of a Product in a Calendar Quarter occurs when (i) the cumulative share achieved by Competing Products for such Product commercialized by Third Parties in such [***] of the [***] in the Territory of the Product and Competing Products and (ii) the sales of the Product(s) in such [***] are reduced by [***] to the [***] in which the [***] of a Competing Product occurred. The example set forth in Schedule 8.1.3 illustrates the application of this Section 8.1.3.

8.1.4 Third Party Payments. If Licensee or a Sublicensee determines that a license to certain Third Party technology is reasonably necessary for the successful Development, Manufacture or Commercialization of a Product in the Territory, then Licensee 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), Licensee (or Sublicensee, if applicable) will negotiate the terms on which such a Third Party license would be granted to Licensee 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 Licensee with respect to a Product pursuant to Section 8.1 (Royalties) shall be subject to a reduction by Licensee in an ***Confidential Treatment Requested
amount equal to […***…] (% of the amount of […***…] that are […***…] under such […***…] in the […***…] for the […***…] of such […***…] during the […***…]; provided, that (i) […***…] of the […***…] of such […***…] pursuant to […***…] for such […***…], and (ii) if such […***…] is a […***…] (i.e., […***…] for such […***…]). For clarity, and notwithstanding anything to the contrary in this Agreement, AstraZeneca AB and its Affiliates 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.

8.1.5 […***…].

8.2 Payments and Sales Reporting.

8.2.1 Sales Reporting. Licensee will provide POZEN, within […***…] of the end of each Calendar Quarter, with a report setting forth, on a Product-by-Product basis, the amount of gross sales of each Product in the Territory, a calculation of Net Sales and a calculation of the amount of royalty payment due on such Net Sales, provided that Licensee 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 Licensee has such reports available for its own internal purposes. If any payment reduction is claimed by Licensee under this Agreement from the full royalty rates set forth in Section 8.1 (Royalties), then the report will set forth in detail the claimed reduction and the related facts.

8.2.2 Payment Timing. Licensee will make royalty payments to POZEN within […] days of the last day of each Calendar Quarter for which such payments are due under Section 8.1 (Royalties).

8.2.3 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: 
Receiving bank address: 
ABA routing number (1): 
SWIFT BIC address (2): 
For credit to the account of: 

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8.2.4 Currency. All payments required under this Article 8 shall be made in U.S. Dollars.

8.2.5 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 [***…]% over the then-current [***…] quoted by Citibank in New York City, or the maximum rate allowable by Applicable Law, whichever is lower.

8.3 Records; Audit. Licensee 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 Licensee for a period of [***…] calendar years 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 Licensee, for the sole purpose of verifying the accuracy of the financial reports furnished by Licensee pursuant to this Agreement. Any such auditor will not disclose Licensee’s Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Licensee or the amount of payments due by Licensee under this Agreement. Any amounts shown to be owed but unpaid will be paid within [***…] days from the accountant’s report, plus interest (as set forth in Section 8.2.5 (Late Payments)) from the original due date. Any amounts determined to be overpaid will be refunded within [***…] days 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 [***…]% (***…%), in which case Licensee will bear the full cost of such audit.

8.4 Taxes.

8.4.1 General. The royalties, milestones and other amounts payable by one Party to the other Party pursuant to this Agreement or the Three-Party 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 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 ***Confidential Treatment Requested
appropriate governmental authorization) at least [...] days 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 [...] days following that payment.

8.4.2 Indirect Taxes. Notwithstanding anything contained in Section 8.4.1 (General), this Section 8.4.2 (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 the 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. POZEN will provide a copy of all proposed filings at least [...] days in advance of the filing date and will consider in good faith the requests and suggestions of Licensee with respect to filing and prosecuting the Licensed Patents and will keep Licensee 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 Licensee of such intention to abandon (which notice will, in any event, be given no later than [...] days 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), and Licensee will have the right to assume responsibility for such Licensed Patent. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, Licensee will have no right to assume responsibility for such Patent as provided under this Section 9.1 should POZEN decide to abandon such Patent.

9.2 Prosecution and Maintenance of Joint Patents. Licensee will be responsible for the preparation, filing, prosecution and maintenance of Joint Patents, at its own expense. Licensee will provide to POZEN a copy of all proposed filings at least [...] days 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 Licensee desires to abandon any Joint Patent, Licensee will provide reasonable prior written notice to POZEN of such intention to abandon (which notice will, in any event, be given no later than [...] days 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), 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, Licensee will own all Licensee

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Inventions, POZEN will own all POZEN Inventions, and Joint Inventions will be owned jointly by Licensee and POZEN; provided, however, that during the Term of this Agreement: (i) neither POZEN nor Licensee shall [...***…] 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. The Parties acknowledge and agree that AstraZeneca AB owns all AstraZeneca Inventions (as defined in the Original Agreement) conceived under the Original Agreement in the performance of activities undertaken pursuant to the Original Agreement solely by employees, agents, or independent contractors of AstraZeneca AB, its Affiliates or sublicensees prior to the Amended and Restated Effective Date.

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. 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 in the Territory claiming or disclosing such Inventions, and to enable the other Party to apply for and to prosecute patent applications in the Territory; 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. Licensee and POZEN will each, within [...***…] ([…***…]) Business Days of learning of any alleged or threatened infringement of the Licensed Patents or Joint Patents, notify the other Party in writing. [...***…] will have the first right, but not the obligation, to prosecute any such infringement. If [...***…] does not commence an infringement action against the alleged or threatened infringement (i) within [...***…] ([…***…]) days following the detection of the alleged infringement, or (ii) [...***…] ([…***…]) Business Days before the
time limit, if any, set forth in appropriate laws and regulations for filing of such actions, whichever comes first, then [...] will so notify [...] promptly, and [...] may commence litigation with respect to the alleged or threatened infringement at its own expense. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, [...] will have no right to prosecute any infringement of such Patent under this Section 9.6.1. Notwithstanding anything in this Section 9.6.1 to the contrary, [...] shall not have the right to prosecute an infringement action under this Section 9.6.1 unless such action involves a Product.

9.6.2 Challenge by Third Parties. Licensee and POZEN will each notify the other Party in writing within [...] ( [...] ) Business Days 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. [...] will have the first right, but not the obligation, to defend any such challenge. If [...] does not commence Diligent Efforts to defend against the alleged or threatened challenge (i) within [...] ( [...] ) days following the detection of the alleged challenge, or (ii) [...] ( [...] ) Business Days 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 [...] will so notify [...] promptly, and [...] may take action with respect to the alleged or threatened challenge at its own expense. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, [...] will have no right to defend any challenge of such Patent under this Section 9.6.2.

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 affect 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 [...] will be [...] and subject to [...] set forth in [...] ;
and (b) settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought by [...***...] will be [...***...].

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. [...***...] 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, [...***...] will keep [...***...] reasonably informed of all material developments in connection with any such claim, suit, or proceeding; provided, that if [...***...] is named as a defendant in any such claim, suit or proceeding, that [...***...] 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, [...***...] agrees to provide [...***...] with copies of all pleadings filed in such action and to allow [...***...] 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 Licensee 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, Licensee 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, Licensee will use Diligent Efforts to promptly list and maintain with the applicable
Regulatory Authorities in the Territory 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. [...***...].

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 Licensee decides not to bring infringement proceedings against the entity making such a certification with respect to any such Licensed Patents, Licensee will give notice to POZEN of its decision not to bring suit within [...] ([...***...]) Business Days after receipt of notice of such certification (or, if the time period permitted by law is less than [...] ([...***...])) Business Days, within [...] of the time period permitted by law for Licensee to commence such action). POZEN 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. For clarity, any Patent with Valid Claims solely directed to any product containing acetyl salicylic acid (including salts and derivatives thereof) is not a Licensed Patent; therefore, Licensee will have no right to bring infringement proceedings of such Patent under this Section 9.10.2. Notwithstanding anything in this Section 9.10.2 to the contrary, Licensee shall not have the right to bring an infringement proceeding under this Section 9.10.2 unless such proceeding involves a POZEN Product.

9.11 Patent Marking. Any POZEN Product marketed and sold by Licensee 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 Licensee as of the Amended and Restated Execution Date and the Amended and Restated Effective Date that POZEN is the sole and exclusive owner of the Licensed Patents and has the right to perform its obligations hereunder and to grant to Licensee the rights and licenses set forth in this Agreement in and to the Licensed Technology.

10.2 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
10.3 DISCLAIMER OF WARRANTY. EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTIONS 10.1 (POZEN WARRANTIES) AND 10.2 (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.

10.4 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 [***...]. Without limiting Licensee’s rights under this Agreement or otherwise, in case of any breach of this 10.4 (POZEN Non-Compete), Licensee will notify POZEN and, if such breach is not cured by POZEN within [***...][***...]) days after receipt of such notice, [***...].

10.5 Other Covenants.

10.5.1 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 Licensee under this Agreement.

10.5.2 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. “Confidential Information” means information, 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, communicated by a Party (a “Disclosing Party”) to the other
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 [...] years 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
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 within [...***...](...***...) Business Days 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 [...***...](...***...) days 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 in the Territory (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 [...***...](...***...) days 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.

11.5 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.

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***Confidential Treatment Requested***
11.6.1 On or after the Amended and Restated Effective Date of this Agreement at a mutually agreed time, each Party (including, for clarity, Horizon as assignee of Licensee in connection with the Divestiture) 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 [...***...][...***...]) Business Days prior to the date on which such Party plans to release such Public Disclosure, and in any event will submit such drafts at least [...***...]) prior to the release of such Public Disclosure, and will review and consider in good faith any comments provided in response.

11.6.2 If a Party is unable to comply with the foregoing [...***...]) 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 existing or potential Third Party investors, lenders or acquirors or, in the case of Licensee, to existing or 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 Amended and Restated Effective Date. This Agreement (other than this Section 12.1, which is binding and effective as of the Amended and Restated Execution Date), shall not become effective unless and until the closing of a Divestiture occurs (the date of such closing, the “Amended and Restated Effective Date”), and upon the Amended and Restated Effective Date this Agreement and all of its terms and provisions shall be automatically effective and binding on both Parties. The Original Agreement shall not be amended and restated or otherwise superseded by this Agreement until the Amended and Restated Effective Date. If the Amended and Restated Effective Date has not occurred by December 31, 2013, then this Agreement, including this Section 12.1, shall terminate and be of no further force and effect. For
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 the Territory (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 by ninety (90) days 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). 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. If a Post-Approval Failure occurs in the Territory, Licensee may, at its option, terminate the Agreement in its entirety; provided, that written notice of termination must be delivered to POZEN within sixty (60) days following such Post-Approval Failure.

12.5 Consequences of Expiration and Termination.

12.5.1 Effect of Expiration. Upon expiration (but not earlier termination) of the Term pursuant to Section 12.2 (Term), Licensee will have a non-exclusive, irrevocable, perpetual, 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 in the Territory.

12.5.2 Effect of Termination. 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. If either Party terminates
this Agreement, all rights and licenses granted by POZEN to Licensee and all obligations of Licensee and POZEN under this Agreement will terminate immediately.

12.6 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”).

12.7 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. Each Party agrees that the other Party, as licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under Title 11. POZEN hereby grants to Licensee and all Affiliates of Licensee, effective upon any breach of this Agreement caused by the rejection of this Agreement by POZEN under Section 365 of Title 11 or otherwise, a right of access and to obtain possession of and to benefit from the following items to the extent Controlled by POZEN relating to the Licensed Technology or POZEN Products: (i) copies of research data, (ii) laboratory samples, (iii) formulas, (iv) laboratory notes and notebooks, (v) data and results related to clinical trials, (vi) clinical and pre-clinical research data and results, and (vii) any IND, NDA or other regulatory filing or approval related to a POZEN Product in the Territory, all of which constitute “embodiments” of intellectual property pursuant to Section 365(n) of Title 11, and (viii) copies or examples of all other embodiments of the Licensed Technology. POZEN agrees not to interfere with Licensee 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 Licensee 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 Licensee or its Affiliates to exercise such rights and licenses in accordance with this Agreement. Each party agrees and acknowledges that all payments by Licensee to POZEN payable under this Agreement other than royalty payments pursuant to Section 8.1 (Royalties) and commercialization milestone payments under the Three-Party Agreement do not constitute “royalties” within the meaning of Section 365(n) of Title 11 or relate to licenses of intellectual property hereunder.

12.8 Formulation Technology. If Licensee 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, Licensee agrees to grant to POZEN, and does hereby grant effective automatically upon such termination, (a) a perpetual, irrevocable, non-exclusive license or sublicense under the Formulation Technology, with the right to grant sublicenses and authorize the grant of sublicenses to the extent provided in this Section 12.8, to make, have made, use, sell, offer for
sale, and import POZEN Products in the Territory and (b) a perpetual, irrevocable, non-exclusive license or sublicense, as applicable, under the Formulation Technology, with the right to grant sublicenses and authorize the grant of sublicenses to the extent provided in this Section 12.8, to Develop and Manufacture (but not sell or otherwise Commercialize) POZEN Products outside the Territory solely in support of the Development or Commercialization of the POZEN Products in the Territory; provided, that nothing herein gives POZEN any right or license under any other intellectual property rights Controlled by Licensee, regardless of whether such rights are necessary in order to exploit the Formulation Technology pursuant to this Section 12.8. 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 POZEN Product Commercialized by Licensee in the Territory at the time of such termination (a “Commercialized POZEN Product”) in the Territory, POZEN may grant such sublicense upon notice to Licensee, but without obtaining Licensee’s consent, and (ii) for any sublicense relating to POZEN Products other than Commercialized POZEN Products in the Territory, POZEN may grant such sublicense with Licensee’s prior written consent (such consent not to be unreasonably withheld, conditioned or delayed).

12.9 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 8.1 (Royalties), 8.2 (Payments and Sales Reporting), 8.3 (Records; Audits), 9.2 (Prosecution and Maintenance of Joint Patents), 9.3 (Ownership of Inventions), 10.3 (Disclaimer of Warranty), 11 (Confidentiality), 12.5 (Consequences of Expiration and Termination), 12.7 (Effect of Bankruptcy), 12.8 (Formulation Technology), 12.9 (Survival), 13 (Indemnification and Insurance), 14 (Limitation of Liability), and 15 (Miscellaneous) will survive any termination or expiration of this Agreement (other than a termination pursuant to Section 12.1).

13. INDEMNIFICATION AND INSURANCE

13.1 Indemnification by POZEN. POZEN hereby agrees to save, defend and hold Licensee and its Affiliates and their respective directors, officers, employees and agents (each, a “Licensee 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 Licensee 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 Licensee Indemnitee or the breach by Licensee of any warranty, representation, covenant or agreement made by Licensee in this Agreement.

13.2 Indemnification by Licensee. Licensee 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 Licensee, its Affiliates or any of their respective Sublicensees, (ii) the gross negligence or willful misconduct
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 Licensee); 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 [...] days 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), 10.4 (POZEN NON-COMPETE), 11 (CONFIDENTIALITY), AND 13 (INDEMNIFICATION AND INSURANCE) OF THIS AGREEMENT.

15. MISCELLANEOUS

15.1 Assignment.

15.1.1 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. Except as set forth in that certain side letter agreement between POZEN and AstraZeneca AB dated September 16, 2013, 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.

15.1.2 In the event that POZEN desires to sell all or a part of its rights to receive payments under this Agreement, then upon POZEN’s written request, Licensee shall enter into a consent in substantially the form of the Consent Agreement attached hereto as Schedule 15.1.2 with respect to such transaction.

15.2 Termination of Certain Rights Upon POZEN Change of Corporate Control. POZEN shall promptly notify Licensee 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 Licensee will have the right, exercisable by written notice to POZEN or its successor in interest given within [...] ([...***...]) days after Licensee receives written notice from POZEN of the completion of such Change of Corporate Control: (a) to terminate [...] ([...***...]) established pursuant to this Agreement; and (b) to terminate its obligation to make [...] ([...***...]) to POZEN pursuant to this Agreement other than [...] ([...***...]) and as reasonably required to [...] ([...***...])

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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 [...***…] Business Days 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 [...***…] Business Days 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. 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.

15.5 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:
DLA Piper LLP (US)
51 John F. Kennedy Parkway, Suite 120
Short Hills, New Jersey 07078
USA
Attention: Andrew P. Gilbert
Facsimile: (973) 520-2575

If to Licensee, to:
AstraZeneca AB
SE-431 83
Mölndal
Sweden
Attention: Manager Legal Department Mölndal
Facsimile: +46 31 776 38 71

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 that certain side letter between POZEN and AstraZeneca AB, dated

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September 16, 2013, and the Three-Party Agreement, 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.

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 (including Horizon), 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.

15.14 Assignment to Horizon. POZEN acknowledges that, in connection with the Divestiture, AstraZeneca AB will assign this Agreement to Horizon, effective as of the Amended and Restated Effective Date, and that, notwithstanding Section 15.1, AstraZeneca AB may assign this Agreement to Horizon in connection with the Divestiture without the prior written consent of POZEN. Without limiting any provision of the Three-Party Agreement, from and after the Amended and Restated Effective Date, all references to “Licensee” in this Agreement, other than references to Licensee in connection with anticipated actions to be taken by AstraZeneca AB as Licensee in connection with the Divestiture, shall automatically be deemed references to Horizon.

15.15 Amendment and Restatement. This Agreement, together with the ROW Agreement, constitutes an amendment and restatement of the Original Agreement effective from and after the Amended and Restated Effective Date. All rights or obligations owing under the Original Agreement, or based on facts or events occurring or existing prior to the Amended and Restated Effective Date, shall be governed by the Original Agreement. As of the Amended and Restated Effective Date, the Original Agreement is hereby amended, supplemented, modified and restated in its entirety as described herein and in the ROW Agreement. For clarity, in no event shall this Section 15.15 or any other provision in this Agreement be deemed to limit or otherwise affect the agreements made by AstraZeneca AB, Horizon and POZEN in the Three-Party Agreement or that certain side letter agreement between POZEN and AstraZeneca AB dated September 16, 2013 with respect to each party’s respective liability in connection with the Original Agreement, this Agreement or the ROW Agreement.

[Remainder of page intentionally left blank. Signature page follows.]
IN WITNESS WHEREOF, the Parties have executed this Amended and Restated Collaboration and License Agreement for the United States by their respective authorized representatives as of the date first written above.

POZEN INC.
By: /s/ John R. Plachetka
Name: John R. Plachetka
Title: Chairman, President and CEO

ASTRAZENECA AB (publ)
By: /s/ Jan-Olof Jacke
Name: Jan-Olof Jacke
Title: President

[Signature Page to Pozen US Agreement]
## Licensed Patents

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Schedule 8.1.3

Market Reduction Example

For Products sold in the Territory:

[...***...]

***Confidential Treatment Requested
CONSENT AGREEMENT

This Consent Agreement (this “Consent”) is made and entered into as of [_____] the Effective Date by and between POZEN Inc., a Delaware corporation (“Sponsor”), and [AstraZeneca AB, a corporation organized under the laws of Sweden][Horizon Pharma USA, Inc., a Delaware corporation] (“Counterparty”). Sponsor and Counterparty are parties to the Amended and Restated Collaboration and License Agreement for [Outside] the United States effective as of November 2013, and any amendments thereto (collectively, the “Agreement”). As of the Effective Date, Sponsor is considering a transaction to sell all or part of its rights to receive payments under Sections [8.2, 9.6.4 and 12.6.4(b)(i) of the Agreement and paragraph 5 of that certain letter agreement by and among Sponsor, Counterparty and Horizon Pharma USA dated November 2013, as well as certain related information rights under Sections 8.3 and 8.4 of the Agreement and certain recovery rights under Section 8.5 of the Agreement] [8.1 and 9.6.4 of the Agreement and paragraph 5 of that certain letter agreement by and among Sponsor, Counterparty and AstraZeneca AB dated November 2013, as well as certain related information rights under Sections 8.2 and 8.3 of the Agreement and certain recovery rights under Section 8.4 of the Agreement] (collectively, “Rights”; such contemplated transaction, the “Transaction”). In connection with the Transaction, Sponsor is requesting Counterparty to give its consent under the Agreement to certain matters, as set forth below. Capitalized terms not otherwise defined herein shall have the meaning ascribed to them in the Agreement.

1. Assignability. Notwithstanding Section 15.1.2 of the Agreement, Counterparty hereby consents and agrees that in connection the Transaction, Sponsor may sell, assign, pledge as security, contribute, convey, grant or otherwise transfer (collectively, “assign”) all or any part of the Rights to any one person or entity (whether or not an affiliate of Sponsor) other than a Competitor without the prior written consent of Counterparty in accordance with the terms of this Consent. In addition, such person or entity (an “Assignee”) of Sponsor may likewise assign such Assignee’s Rights to any one person or entity (whether or not Sponsor or an affiliate of Sponsor) other than a Competitor without the prior written consent of Counterparty, it being understood and agreed that, all times, there shall only be one single person or entity that holds the Rights (other than Sponsor) and constitutes an “Assignee.” “Competitor” shall mean any Person, other than Sponsor or its subsidiaries and affiliates, that is in the business of researching, developing or commercializing therapeutics primarily for rheumatoid arthritis and osteoarthritis pain indications or any company ranked in the top 10 pharmaceutical companies in the United States based on IMS-reported pharmaceutical sales for the preceding calendar year (or any of such company’s subsidiaries or controlled affiliates).

2. Payment Direction; Reports. Following the consummation of the Transaction, Sponsor shall remain responsible for the performance of its obligations and the exercise of its rights under the Agreement, however, Counterparty agrees that, upon written notice from Sponsor (or any direct or indirect permitted Assignee contemplated by Section 1 above), Counterparty shall deliver any future payments contemplated by the Agreement, together with
any royalty or other reports or statements contemplated by the Agreement (“Reports”) to the Assignee, in accordance with the directions in such written notice; provided copies of Reports are also simultaneously sent to the Sponsor.

3. **Prospective Assignee Confidentiality.** Notwithstanding Section 11 of the Agreement, Counterparty consents and agrees that Sponsor, in connection with the Transaction, may disclose Confidential Information to its advisors, affiliates, agents, assignees, auditors, bankers, co-investors, contractors, counsel, directors, employees, financing parties, insurance providers, investors, lenders, managers, members, officers, partners, sublicensees, trustees or other representatives or any third party that has, or proposes to have, an interest (whether direct or indirect) in the Rights (each, a “Recipient”), provided that each such Recipient (a) is not a Competitor and (b) shall agree to keep such Confidential Information confidential on reasonable and customary terms pursuant to a non-disclosure agreement between Sponsor (or an affiliate of Sponsor) and such Recipient, which non-disclosure agreement shall, among other things, provide that (i) if such Recipient is not a prospective Assignee identified by the Company or a holder of a debt or equity interests therein (a “Prospective Assignee”), the term of such non-disclosure agreement shall extend for a period of 24 months from the date of such nondisclosure agreement, (ii) if such Recipient is a Prospective Assignee, the term of such non-disclosure agreement shall extend for a period of 24 months from the date such Prospective Assignee notifies Sponsor that it ceases to have an interest in the Transaction, (iii) such Recipient shall use any Confidential Information so disclosed only to evaluate, enter into, monitor or enforce the Transaction, (iv) upon expiration of such non-disclosure agreement, such Recipient promptly shall destroy the Confidential Information or return the Confidential Information to Sponsor, as directed by Sponsor, provided that in each case an appropriate person within such Recipient’s organization may retain one copy of such Confidential Information subject to the provisions hereof if required to comply with internal record retention policies or regulatory considerations, and (v) Counterparty shall be treated as a third party beneficiary of such non-disclosure agreement and shall have the right to enforce any provision of such non-disclosure agreement against such Recipient. For the avoidance of doubt, the term “Confidential Information” shall include unredacted copies of the Agreement, all royalty reports provided by Counterparty pursuant to Section [8.3.1][8.2.1] of the Agreement, and material notices and correspondence received by Sponsor relating to or involving the Agreement that affect the Rights.

4. **Final Assignee Confidentiality.** If Sponsor consummates the Transaction, Sponsor shall cause the Assignee to agree, pursuant to the definitive documentation for the Transaction, to be bound by confidentiality provisions in substantially the same form and substance as those confidentiality provisions contained in Section 11 of the Agreement (with such Counterparty being treated as a third party beneficiary of such provisions to the same extent as is contemplated by clause (v) of Paragraph 3 hereof).

5. **Consent Concerning Additional Disclosures.** Counterparty hereby consents to and agrees that Sponsor may disclose to its advisors, including its consulting firm, L.E.K. Consulting (“LEK”), and the Sponsor, its advisors and/or LEK may in turn disclose to Prospective Assignees (who are not Competitors and who have agreed to the confidentiality obligations set forth in Paragraph 3 hereof), the following information provided to Sponsor by Counterparty: (i) the anticipated launch dates of commercial sales of Vimovo by Counterparty in countries outside the United States; (ii) information pertaining to the Counterparty’s new US
sales model for Vimovo implemented in 2012; (iii) historical information relating to the ratio of Vimovo gross sales to net sales; and (iv) information relating to Counterparty’s promotional plan for Vimovo and strategy regarding Medicare Part D.

6. **Termination.** Unless a definitive agreement with respect to the Transaction has been executed prior to the first anniversary of the Effective Date, this Consent shall automatically terminate as of the first anniversary of the Effective Date.

   Except as supplemented hereby, all terms and provisions of the Agreement shall remain in full force and effect. This Consent may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same agreement. An executed signature page of this Consent delivered by facsimile transmission or in PDF format via email shall be as effective as an original executed signature page. This Consent shall be governed by the laws of the State of New York without regard to any choice of law principles thereof that would cause the application of the laws of a different jurisdiction.

POZEN INC.

By: ____________________________
Name: __________________________
Title: ____________________________

[ASTRAZENECA AB (publ)][HORIZON PHARMA USA, INC.] 

By: ____________________________
Name: __________________________
Title: ____________________________
Master Manufacturing Services Agreement

October 31, 2013
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MASTER MANUFACTURING SERVICES AGREEMENT

THIS MASTER MANUFACTURING SERVICES AGREEMENT (the “Agreement”) is made as of October 31, 2013 (the “Effective Date”) BETWEEN:

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware

(“Patheon”),

- and -

Horizon Pharma Inc.,
a corporation existing under the laws of the State of Delaware

(“Client”).

THIS AGREEMENT WITNESSES THAT in consideration of the rights conferred and the obligations assumed herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound the parties agree as follows:

ARTICLE 1

STRUCTURE OF AGREEMENT AND INTERPRETATION

1.1 Master Agreement.

This Agreement establishes the general terms and conditions under which Patheon or any Affiliate of Patheon may perform Manufacturing Services for Client or any Affiliate of Client, at the manufacturing site where the Affiliate of Patheon resides. This “master” form of agreement is intended to allow the parties, or any of their Affiliates, to contract for the manufacture of multiple Products through Patheon’s global network of manufacturing sites through the issuance of site specific Product Agreements without having to re-negotiate the basic terms and conditions contained herein.

1.2 Product Agreements.

This Agreement is structured so that a Product Agreement may be entered into by the parties for the manufacture of a particular Product or multiple Products at a Patheon manufacturing site. Each Product Agreement will be governed by the terms and conditions of this Agreement unless the parties to the Product Agreement expressly modify the terms and conditions of this Agreement in the Product Agreement. Unless otherwise agreed by the parties, each Product Agreement will be in the general form and contain the information set forth in Appendix 1 hereto.
1.3 Definitions

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

“Active Materials”, “Active Pharmaceutical Ingredients” or “API” means the materials listed in a Product Agreement on Schedule D;

“Active Materials Credit Value” means the value of the Active Materials for certain purposes of this Agreement, as set forth in a Product Agreement on Schedule D;

“Actual Annual Yield” or “AAAY” has the meaning specified in Section 2.2(a);

“Affiliate” means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party to this Agreement, by stock ownership or otherwise; or

(b) a business entity which is controlled by a party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party to this Agreement;

For this definition, “control” means the ownership of shares carrying at least a majority of the votes for the election of the directors of a corporation;

“Annual Product Review Report” means the annual product review report prepared by Patheon as described in Title 21 of the United States Code of Federal Regulations, Section 211.180(e);

“Annual Report” means the annual report to the FDA prepared by Client regarding the Product as described in Title 21 of the United States Code of Federal Regulations, Section 314.81(b)(2);

“Annual Volume” means the minimum volume of Product to be manufactured in any Year of this Agreement as set forth in Schedule B;

“Applicable Laws” means (i) for Patheon, the Laws of the State of Ohio [or local jurisdiction for Patheon Affiliate], being the jurisdiction where the Manufacturing Site is located; and (ii) for Client and the Products, the Laws of all jurisdictions where the Products are manufactured, distributed, and marketed as these are agreed and understood by the parties in this Agreement;

“Authority” means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal;

“Bill Back Items” means the expenses for all third party supplier fees for the purchase or use of columns, standards, tooling, non-standard pallets, PAPR or PPE suits (where applicable), RFID tags and supporting equipment, and other project-specific items necessary for Patheon to perform the Manufacturing Services, and which are not included as Components;

“Breach Notice” will have the meaning specified in Section 8.2(a);
“Business Day” means a day other than a Saturday, Sunday or a day that is a statutory holiday in the United States;
“cGMPs” means, as applicable, current good manufacturing practices as described in:
(a) Division 2 of Part C of the Food and Drug Regulations (Canada);
(b) Parts 210 and 211 of Title 21 of the United States’ Code of Federal Regulations; and
(c) EC Directive 2003/94/EC,
together with the latest Health Canada, FDA and EMEA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;
“Client Intellectual Property” means Intellectual Property generated or derived by Client before entering into this Agreement or during any Term of this Agreement, or by Patheon while performing any Manufacturing Services or otherwise generated or derived by Patheon in its business which Intellectual Property is specific to, integral or dependent upon, Client’s Active Material or Product;
“Client Property” will have the meaning specified in Section 8.4(e);
“Client-Supplied Components” means those Components to be supplied by Client or that have been supplied by Client;
“CMC” has the meaning specified in Section 7.8(c);
“Components” means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture the Products in accordance with the Specifications, other than the Active Materials;
“Confidentiality Agreement” means the agreement about the non-disclosure of confidential information between Patheon and Client dated September 27, 2013;
“Deficiencies” has the meaning specified in Section 7.8(d);
“Deficiency Notice” has the meaning specified in Section 6.1(a);
“Delivery Date” means the date scheduled for shipment of Product under a Firm Order as set forth in Section 5.1(d);
“EMA” means the European Medicines Agency;
[“Equipment” will have the meaning ascribed to it in {the Capital Equipment Agreement related to this MSA if any}]”
“FDA” means the United States Food and Drug Administration;
“Firm Orders” has the meaning specified in Section 5.1(b);
"Force Majeure" will have the meaning specified in Section 13.7;

"Health Canada" means the section of the Canadian Government known as Health Canada and includes, among other departments, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

"Initial Product Term" has the meaning specified in Section 8.1;

"Initial Set Exchange Rate" means as of the Effective Date of a Product Agreement, the initial exchange rate set forth in the Product Agreement to convert one unit of the billing currency into the Patheon Manufacturing Site local currency, calculated as the daily average interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the 90 day period immediately preceding the Effective Date as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

"Initial Term" has the meaning specified in Section 8.1;

"Intellectual Property" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"Invention" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable;

"Inventory" means all inventories of Components and work-in-process produced or held by Patheon for the manufacture of the Products but, for greater certainty, does not include the Active Materials;

"Late Delivery" has the meaning specified in Section 5.5;

"Laws" means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Authority;

"Manufacturing Services" means the manufacturing, quality control, quality assurance, stability testing, bulk packaging and finished product packaging (if agreed between the parties in the relevant Product Agreement), and related services, as set forth in this Agreement, required to manufacture Product or Products using the Active Materials, Components, and Bill Back Items;

"Manufacturing Site" means the facility owned and operated by Patheon where the Manufacturing Services will be performed as identified in a Product Agreement;

"Materials" means all Components and Bill Back Items required to manufacture the Products in accordance with the Specifications, other than the Active Materials;

"Maximum Credit Value" means the maximum value of Active Materials that may be credited by Patheon under this Agreement, as set forth in a Product Agreement on Schedule D;
“Minimum Order Quantity” means the minimum number of batches of a Product to be produced during the same cycle of manufacturing as set forth in a Product Agreement on Schedule B;

“Patheon Competitor” means an entity that generates greater than [...***...]% of its gross revenues from performing contract pharmaceutical commercial manufacturing services pursuant to arrangements with unrelated third party companies;

“Patheon Intellectual Property” means Intellectual Property generated or derived by Patheon before performing any Manufacturing Services, or generated or derived by Patheon in its business which Intellectual Property is not specific to, integral to, or dependent upon, Client’s Active Material or Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products, drug product dosage forms or drug delivery systems unrelated to the specific requirements of the Product(s);

“Price” means the price measured in US Dollars to be charged by Patheon for performing the Manufacturing Services, and includes the cost of Components (other than Client-Supplied Components), certain cost items as set forth in a Product Agreement on Schedule B, and annual stability testing costs as set forth in Schedule C;

“Product(s)” means the product(s) listed in a Product Agreement on Schedule A;

“Product Agreement” means the agreement between Patheon and Client issued under this Agreement in the form set forth in Appendix 1 (including Schedules A to D) under which Patheon will perform Manufacturing Services at a particular Manufacturing Site;

“Quality Agreement” means the agreement (the general form of which is set forth in Exhibit B) between the parties entering a Product Agreement that sets out the quality assurance standards for the Manufacturing Services to be performed by Patheon for Client;

“Recall” has the meaning specified in Section 6.2(a);

“Regulatory Authority” means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products including the Products in the Territory;

“RFID” means Radio Frequency Identification Devices which (at present or in the future) may be affixed to Products or Materials to assist in inventory control, tracking, and identification;

“Remediation Period” has the meaning specified in Section 8.2(a);

“Set Exchange Rate” means the exchange rate to convert one unit of the billing currency into the Patheon Manufacturing Site local currency for each Year, calculated as the average daily interbank exchange rate for conversion of one unit of the billing currency into the Patheon Manufacturing Site local currency during the full year period (October 1st [preceding year] to September 30th) as published by OANDA.com “The Currency Site” under the heading “FxHistory: historical currency exchange rates” at www.OANDA.com/convert/fxhistory;

“Shortfall” has the meaning specified in Section 2.2(b);
“Specifications” means the file, for each Product, which is given by Client to Patheon in accordance with the procedures listed in a Product Agreement on Schedule A and which contains documents relating to each Product, including, without limitation:
(a) specifications for Active Materials and Components;
(b) manufacturing and testing specifications, directions, and processes;
(c) storage requirements;
(d) all environmental, health and safety information for each Product including material safety data sheets; and
(e) the finished Product specifications, packaging specifications and shipping requirements for each Product;
all as updated, amended and revised from time to time by Client in accordance with the terms of this Agreement;

“Target Yield” has the meaning specified in Section 2.2(a);

“Target Yield Determination Batches” has the meaning specified in Section 2.2(a);

“Technical Dispute” has the meaning specified in Section 12.2;

“Territory” means the geographic area described in a Product Agreement where Products manufactured by Patheon will be distributed by Client;

“Third Party Rights” means the Intellectual Property of any third party; and

“Year” means in the first year of this Agreement or in the first year of a Product Agreement, the period from the Effective Date up to and including December 31 of the same calendar year, and thereafter will mean a calendar year.

1.4 Currency

Unless otherwise agreed in a Product Agreement, all monetary amounts expressed in this Agreement are in United States Dollars (USD).

1.5 Sections and Headings

The division of this Agreement into Articles, Sections, Subsections, an Appendix, and Exhibits and the insertion of headings are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Exhibit refers to the specified Section, Appendix, or Exhibit to this Agreement. In this Agreement, the terms “this Agreement”, “hereof”, “herein”, “hereunder” and similar expressions refer to this Agreement and not to any particular part, Section, Appendix or Exhibit of this Agreement.
1.6 **Singular Terms.**

Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

1.7 **Appendix 1 and Exhibits.**

Appendix 1 and the following Exhibits are attached to, incorporated in, and form part of this Agreement:

- **Appendix 1** — Form of Product Agreement (Including Schedules A to D)
- **Exhibit A** — Technical Dispute Resolution
- **Exhibit B** — Commercial Quality Agreement
- **Exhibit C** — Quarterly Active Materials Inventory Report
- **Exhibit D** — Report of Annual Active Materials Inventory Reconciliation and Calculation of Actual Annual Yield
- **Exhibit E** — Example of Price Adjustment Due to Currency Fluctuation
ARTICLE 2

PATHEON’S MANUFACTURING SERVICES

2.1 Manufacturing Services

Patheon will perform the Manufacturing Services for the Territory for the fees specified in a Product Agreement in Schedules B and C to manufacture Products for Client. Schedule B to a Product Agreement sets forth a list of cost items that are included in the Price for Products; all cost items that are not included in this list are excluded from the Price and are subject to additional fees to be paid by the Client. Patheon may amend the fees set out in Schedules B and C to a Product Agreement as set forth in Article 4. Patheon may change the Manufacturing Site for the Products only with the prior written consent of Client, this consent not to be unreasonably withheld. Unless otherwise agreed in a Product Agreement, Patheon will manufacture at least [...]% of the Products offered for sale by Client in the Territory if Patheon remains in material compliance with its obligations under this Agreement and the Product Agreement. In performing the Manufacturing Services, Patheon and Client agree that:

(a) Conversion of Active Materials and Components. Patheon will convert Active Materials and Components into Products.

(b) Quality Control and Quality Assurance. Patheon will perform the quality control and quality assurance testing specified in the Quality Agreement. Batch review and release to Client will be the responsibility of Patheon’s quality assurance group. Patheon will perform its batch review and release responsibilities in accordance with Patheon’s standard operating procedures. Each time Patheon ships Products to Client, it will give Client a certificate of analysis and certificate of compliance, including deviations as specified by the Quality Agreement, including a statement that the batch has been manufactured and tested in accordance with Specifications and cGMPs. Client will have sole responsibility for the release of Products to the market. The form and style of batch documents, including, but not limited to, batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of Patheon. Specific Product related information contained in those batch documents is Client property.

(c) Components. Patheon will purchase and test all Components (with the exception of Client-Supplied Components) at Patheon’s expense and as required by the Specifications.

(d) Stability Testing. Patheon will conduct stability testing on the Products in accordance with the protocols set out in the Specifications for the separate fees and during the time periods set out in Schedule C to a Product Agreement. Patheon will not make any changes to these testing protocols without prior written approval from Client. If a confirmed stability test failure occurs, Patheon will notify Client within [...] after which Patheon and Client will jointly determine the proceedings and methods to be undertaken to investigate the cause of the failure, including which party will bear the cost of the investigation. Patheon will not be liable for these costs unless it has failed to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws. Patheon will give Client all stability test data and results at Client’s request.

(e) Packaging. Patheon will package the Products as set out in the Specifications. Client will be responsible for the cost of artwork development. Patheon will determine and imprint the batch numbers and expiration dates for each Product shipped. The batch numbers...
and expiration dates will be affixed on the Products and on the shipping carton of each Product as outlined in the Specifications and as required by cGMPs. Client may, in its sole discretion, make changes to labels, product inserts, and other packaging for the Products. Those changes will be submitted by Client to all applicable governmental agencies and other third parties responsible for the approval of the Products. Client will be responsible for the cost of labelling obsolescence when changes occur, as contemplated in Section 4.4. Patheon’s name will not appear on the label or anywhere else on the Products unless: (i) required by any Laws; or (ii) Patheon consents in writing to the use of its name.

(f) **Active Materials and Client-Supplied Components.** At least [... *** ...] days before the scheduled production date, Client will deliver the Active Materials and any Client-Supplied Components to the Manufacturing Site [... *** ...] [Incoterms 2010], at no cost to Patheon, in sufficient quantity to enable Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If the Active Materials and/or Client-Supplied Components are not received [... *** ...] days before the scheduled production date, Patheon may delay the shipment of Product by the same number of days as the delay in receipt of the Active Materials and/or Client-Supplied Components. But if Patheon is unable to manufacture Product to meet this new shipment date due to prior third party production commitments, Patheon may delay the shipment until a later date as agreed to by the parties. All shipments of Active Material will be accompanied by certificate(s) of analysis from the Active Material manufacturer and the Client, confirming the identity and purity of the Active Materials and its compliance with the Active Material specifications. At a minimum, Patheon will perform identity testing on each incoming lot of API and a full testing will be performed at least for one batch per year. Additional incoming tests to be performed on the API will be defined in the respective Product Agreement.

(g) **Bill Back Items.** Bill Back Items will be charged to Client at Patheon’s cost plus a [... *** ...]% handling fee for an item costing $ [... *** ...] or less or, for an item costing in excess of $ [... *** ...], a handling fee of [... *** ...]%.

(h) **Validation Activities.** Patheon may assist in the development and approval of the validation protocols for analytical methods and manufacturing procedures (including packaging procedures) for the Products. The fees associated with Patheon’s assistance in providing validation development assistance are set out in Schedule C to a Product Agreement.

(i) **Product Rejection for Finished Product Specification Failure.** Internal process specifications will be defined and agreed upon. If it is determined by a quality investigation that Patheon manufactured Product in accordance with the agreed upon process specifications, the batch production record, and Patheon’s standard operating procedures for manufacturing, but a batch or portion of batch of Product does not meet a Finished Product Specification, Client will pay Patheon the applicable fee per unit for the non-conforming Product. The API in the non-conforming Product will be included in the “Quantity Converted” for purposes of calculating the “Actual Annual Yield” under Section 2.2(a).
2.2 Active Material Yield.

(a) Reporting. Patheon will give Client a quarterly inventory report of the Active Materials held by Patheon using the inventory report form set out in Exhibit C, which will contain the following information for the quarter:

Quantity Received: The total quantity of Active Materials that complies with the Specifications and is received at the Manufacturing Site during the applicable period.

Quantity Dispensed: The total quantity of Active Materials dispensed at the Manufacturing Site during the applicable period. The Quantity Dispensed is calculated by [...***...]. The Quantity Dispensed will only include Active Materials received and dispensed in commercial manufacturing of Products and, for certainty, will not include any (i) Active Materials that must be retained by Patheon as samples, (ii) Active Materials contained in Product that must be retained as samples, (iii) Active Materials used in testing (if applicable), and (iv) Active Materials received or dispensed in technical transfer activities or development activities during the applicable period, including without limitation, any regulatory, stability, validation or test batches manufactured during the applicable period.

Quantity Converted: The total amount of Active Materials contained in the Products manufactured with the Quantity Dispensed (including any additional Products produced in accordance with Section 6.3(a) or 6.3(b)), delivered by Patheon, and not rejected, recalled or returned in accordance with Section 6.1 or 6.2 because of Patheon’s failure to perform the Manufacturing Services in accordance with Specifications, cGMPs, and Applicable Laws.

Within [...***...] days after the end of each Year, Patheon will prepare an annual reconciliation of Active Materials on the reconciliation report form set forth in Exhibit D including the calculation of the “Actual Annual Yield” or “AAY” for the Product at the Manufacturing Site during the Year. AAY is the percentage of the Quantity Dispensed that was converted to Products and is calculated as follows:

\[
\text{Quantity Converted during the Year} \times 100\%
\]

Quantity Dispensed during the Year

Unless otherwise agreed in a Product Agreement, after Patheon has produced a minimum of [...***...] successful commercial production batches of Product and has produced commercial production batches for at least [...***...] months at the Manufacturing Site (collectively, the “Target Yield Determination Batches”), the parties will agree on the target yield for the Product at the Manufacturing Site (each, a “Target Yield”). The Target Yield will be revised annually to reflect the actual manufacturing experience as agreed to by the parties.

(b) Shortfall Calculation. If the Actual Annual Yield falls more than [...***...]% below the respective Target Yield in a Year, then the shortfall for the Year (the “Shortfall”) will be calculated as follows:
(c) **Credit for Shortfall.** If there is a Shortfall for a Product in a Year, then Patheon will credit Client’s account for the amount of the Shortfall not later than [...***... days after the end of the Year.

Each credit under this Section 2.2(c) will be summarized on the reconciliation report form set forth in Exhibit D. Upon expiration or termination of a Product Agreement, any remaining credit owing under this Section 2.2 will be paid to Client. The Annual Shortfall, if any, will be disclosed by Patheon on the reconciliation report form.

(d) **Maximum Credit.** Patheon’s liability for Active Materials calculated in accordance with this Section 2.2 for any Product in a Year will not exceed, in the aggregate, the Maximum Credit Value set forth in Schedule D to a Product Agreement.

(e) **No Material Breach.** It will not be a material breach of this Agreement by Patheon under Section 8.2(a) if the Actual Annual Yield is less than the Target Yield.

ARTICLE 3

**CLIENT’S OBLIGATIONS**

3.1 **Payment.**

Client will pay Patheon for performing the Manufacturing Services according to the Prices specified in Schedules B and C in a Product Agreement. These Prices may be subject to adjustment under other parts of this Agreement. Client will also pay Patheon for any Bill Back Items.

3.2 **Active Materials and Qualification of Additional Sources of Supply.**

Client will at its sole cost and expense, deliver the Active Materials to Patheon (in accordance with Section 2.1(f)) sufficient for Patheon to manufacture the desired quantities of Product and to ship Product on the Delivery Date. If applicable, Patheon and the Client will reasonably cooperate to permit the import of the Active Materials to the Manufacturing Site. Client’s obligation will include obtaining the proper release of the Active Materials from the applicable Customs Agency and Regulatory Authority. Client or Client’s designated broker will be the “Importer of Record” for Active Materials imported to the Manufacturing Site. The Active Materials will be held by Patheon on behalf of Client as set forth in this Agreement. Title to the Active Materials will at all times remain the property of Client. Any Active Materials received by Patheon will only be used by Patheon to perform the Manufacturing Services. If the Parties mutually determine a need to change the supplier of any Active Material or Component (other than a supplier that is specifically described in an applicable Product Agreement), they will work together to develop a plan to qualify such additional supplier.
ARTICLE 4

CONVERSION FEES AND COMPONENT COSTS

4.1 First Year Pricing

The tiered Price and annual stability Price for the Products for the first Year are listed in Schedules B and C in a Product Agreement and are subject to the adjustments set forth in Sections 4.2 and 4.3. Upon Client’s request, Patheon will provide a breakdown of the manufacturing conversion costs, packaging conversion costs, and the Component costs for a Product.

4.2 Price Adjustments – Subsequent Years’ Pricing

After the first Year of the Product Agreement, but in no case before [...***...], Patheon may adjust the Price effective January 1st of each Year as follows:

(a) Manufacturing and Stability Testing Costs. For Products manufactured in the United States or Puerto Rico, Patheon may adjust the Price for inflation, based upon the preliminary number for any increase in the Producer Price Index peu325412325412 for Pharmaceutical Preparation Manufacturing (“PPI”) published by the United States Department of Labor, Bureau of Labor Statistics in August of the preceding Year compared to the final number for the same month of the Year prior to that, unless the parties otherwise agree in writing. On or about November 1st of each Year, Patheon will give Client a statement setting forth the calculation for the inflation adjustment to be applied in calculating the Price for the next Year. For Products manufactured outside the United States or Puerto Rico, Patheon may similarly adjust the Price for inflation using an inflation index to be agreed by the parties in a Product Agreement.

(b) Component Costs. If Patheon incurs an increase in Component costs during the Year, it may increase the Price for the next Year to pass through the additional Component costs. On or about November 1st of each Year, Patheon will give Client information about the increase in Component costs which will be applied to the calculation of the Price for the next Year to reasonably demonstrate that the Price increase is justified.

(c) Pricing Basis. Client acknowledges that the Price in any Year is quoted based upon the Minimum Order Quantity and the Annual Volume specified in Schedule B to a Product Agreement. The Price is subject to change if [...***...].

(d) Adjustments Due to Currency Fluctuations. If the parties agree in a Product Agreement to invoice in a currency other than the local currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated after all ***Confidential Treatment Requested
other annual Price adjustments under this Section 4.2 have been made. The adjustment will proportionately reflect the increase or decrease, if any, in the Set Exchange Rate compared to the Set Exchange Rate established for the prior Year or the Initial Set Exchange Rate, as the case may be. An example of the calculation of the price adjustment (for a Canadian Manufacturing Site invoiced in USD) is set forth in Exhibit E.

(e) Tier Pricing (if applicable). The pricing in Schedule B of a Product Agreement is set forth in Annual Volume tiers based upon the Client’s volume forecasts under Section 5.1. The Client will be invoiced during the Year for the unit price set forth in the Annual Volume tier based on the [...] forecast provided in September of the previous Year. Within [...] days of the end of each Year or of the termination of the Agreement, Patheon will send Client a reconciliation of the actual volume of Product ordered by the Client during the Year with the pricing tiers. If Client has overpaid during the Year, Patheon will issue a credit to the Client for the amount of the overpayment within [...] days of the end of the Year or will issue payment to the Client for the underpayment within [...] days of the termination of the Agreement. If Client has underpaid during the Year, Patheon will issue an invoice to the Client under Section 5.6 for the amount of the underpayment within [...] days of the end of the Year or termination of the Agreement. If Client disagrees with the reconciliation, the parties will work in good faith to resolve the disagreement amicably. If the parties are unable to resolve the disagreement within [...] days, the matter will be handled under Section 12.1.

(f) Process Improvement Efforts. Patheon continually works to improve its processes to eliminate waste, improve cost efficiencies, deliver product as promised and adhere to strict quality standards. Patheon believes in the continuous improvement of its performance, which led Patheon to create the Patheon Advantage program. Patheon Advantage incorporates Lean6Sigma to identify opportunities and implement changes to maximize the efficiency of Patheon’s processes. If these improvement efforts result in quantifiable reductions in costs in providing the Services contemplated under this Agreement Patheon will promptly notify Client of the reductions, and the Price hereunder will be reduced by [...] % of the cost reduction from and after the date of the notice.

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on or about November 1st of each Year a revised Schedule B to the Product Agreement to be effective for Product delivered on or after the first day of the next Year.

4.2.1 Price Adjustment due to Volume Changes from Yearly Forecast Volumes for Sterile Products

On the execution of a Product Agreement, Client will give to Patheon a forecast of the volume of Product required for the first [...] Years of the Product Agreement (the “Yearly Forecast Volume” or “YFV”) that will become part of the Product Agreement. If at the end of the first Year the aggregate actual volume of Product ordered by Client and invoiced by Patheon under Section 5.6 (“Actual Yearly Volume” or “AYV”) during the Year is less than the YFV as set out in the Product Agreement, then Client will pay Patheon for its non-absorbed fixed manufacturing costs incurred during the Year in an amount to be determined as follows:

Amount due to Patheon = [...]
On or before June 10 of each Year, the parties will agree on the YFV for the next [...] of the Product Agreement on a rolling forward basis. The forecast of the volume of Product for the second Year may not vary by more than [...] from the original YFV for the second Year. Once agreed, the YFV for the next Year will become binding on the parties and any amount due to Patheon will be determined as set forth above.

4.3 Price Adjustments – Current Year Pricing

During any Year, the Prices set out in Schedule B of a Product Agreement will be adjusted as follows:

Extraordinary Increases in Component Costs. If, at any time, market conditions result in Patheon’s cost of Components being materially greater than normal forecasted increases, then Patheon will be entitled to an adjustment to the Price for any affected Product to compensate it for the increased Component costs. Changes materially greater than normal forecasted increases will have occurred if: (i) the cost of a Component increases by [...] of the cost for that Component upon which the most recent fee quote was based; or (ii) the aggregate cost for all Components required to manufacture a Product increases by [...] of the total Component costs for the Product upon which the most recent fee quote was based. If Component costs have been previously adjusted to reflect an increase in the cost of one or more Components, the adjustments set out in (i) and (ii) above will operate based on the last cost adjustment for the Components.

For a Price adjustment under this Section 4.3, Patheon will deliver to Client a revised Schedule B to the Product Agreement and budgetary pricing information, adjusted Component costs or other documents reasonably sufficient to demonstrate that a Price adjustment is justified. Patheon will have no obligation to deliver any supporting documents that are subject to obligations of confidentiality between Patheon and its suppliers. The revised Price will be effective for any Product delivered on or after the first day of the month following Client’s receipt of the revised Schedule B to the Product Agreement.

4.4 Adjustments Due to Technical Changes

Amendments to the Specifications or the Quality Agreement requested by Client will only be implemented following a technical and cost review that Patheon will perform at Client’s cost, and are subject to Client and Patheon reaching agreement on Price changes required because of the amendment. Amendments to the Specifications, the Quality Agreement, or the Manufacturing Site requested by Patheon will only be implemented following the written approval of Client, the approval not to be unreasonably withheld. If Client accepts a proposed Price change, the proposed change in the Specifications will be implemented at Client’s cost, and the Price change will become effective, only for those orders of Products that are manufactured under the revised Specifications. In addition, Client agrees to purchase, at Patheon’s cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), all Inventory used under the “old” Specifications and purchased or maintained by Patheon in order to fill Firm Orders or under Section 5.2, if the Inventory can no longer be used under the revised Specifications. Open purchase orders for Components no longer required under any revised Specifications that were placed by Patheon with suppliers in order to fill Firm Orders or under Section 5.2 will be cancelled where possible, and if the orders may not be cancelled without penalty, will be assigned to and satisfied by Client. If an amendment to the Specifications or the Quality Agreement becomes necessary as the result of changes to a compendia, the Parties will discuss the necessary changes and Client will be solely responsible for the costs associated with these changes.

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4.5 Multi-Country Packaging Requirements.

If Client decides to have Patheon perform Manufacturing Services for the Product for countries outside the Territory, then Client will inform Patheon of the packaging requirements for each new country and Patheon will prepare a quotation for consideration by Client of any additional costs for Components (other than Client-Supplied Components) and the change over fees for the Product destined for each new country. The agreed additional packaging requirements and related packaging costs and change over fees will be set out in a written amendment to this Agreement.

ARTICLE 5
ORDERS, SHIPMENT, INVOICING, PAYMENT

5.1 Orders and Forecasts

(a) Rolling [***…] Month Forecast. When each Product Agreement is executed, Client will give Patheon a non-binding [***…] month forecast of the volume of Product that Client expects to order in the first [***…] months of commercial manufacture of the Product. This forecast will then be updated by Client on or before the [***…] day of each month on a rolling forward basis. Client will update the forecast forthwith if it determines that the volumes estimated in the most recent forecast have changed by more than [***…]%.

(b) Firm Orders. On a rolling basis during the term of the Product Agreement, Client will issue an updated [***…] month forecast on or before the [***…] day of each month. This forecast will start on the first day of the next month. The first [***…] months of this updated forecast will be considered binding firm orders. Concurrent with the [***…] month forecast, Client will issue a new firm written order in the form of a purchase order or otherwise ("Firm Order") by Client to purchase and, when accepted by Patheon, for Patheon to manufacture and deliver the agreed quantity of the Products. The Delivery Date will not be less than [***…] days following the date that the Firm Order is submitted. Firm Orders submitted to Patheon will specify Client’s purchase order number, quantities by Product type, monthly delivery schedule, and any other elements necessary to ensure the timely manufacture and shipment of the Products. The quantities of Products ordered in those written orders will be firm and binding on Client and may not be reduced by Client.

(c) [***…] Year Forecast. On or before the [***…] of each Year, Client will give Patheon a written non-binding [***…]-year forecast, broken down by quarters for the [***…] and [***…] years of the forecast, of the volume of each Product Client then anticipates will be required to be manufactured and delivered to Client during the [***…]-year period.

(d) Acceptance of Firm Order. Patheon will accept Firm Orders by sending an acknowledgement to Client within [***…] Business Days of its receipt of the Firm Order. The acknowledgement will include, subject to confirmation from the Client, the Delivery Date for the Product ordered. The Delivery Date may be amended by agreement of the parties or as set forth in Section 2.1(f).
5.2 **Reliance by Patheon.**

(a) Client understands and acknowledges that Patheon will rely on the Firm Orders and rolling forecasts submitted under Sections 5.1(a), and (b) in ordering the Components (other than Client-Supplied Components) required to meet the Firm Orders. In addition, Client understands that to ensure an orderly supply of the Components, Patheon may want to purchase the Components in sufficient volumes to meet the production requirements for Products during part or all of the forecasted periods referred to in Section 5.1(a) or to meet the production requirements of any longer period agreed to by Patheon and Client. Accordingly, Client authorizes Patheon to purchase Components to satisfy the Manufacturing Services requirements for Products for the first [...***...] months contemplated in the most recent forecast given by Client under Section 5.1(a). Patheon may make other purchases of Components to meet Manufacturing Services requirements for longer periods if agreed to in writing by the parties. The Client will give Patheon written authorization to order Components for any launch quantities of Product requested by Client which will be considered a Firm Order when accepted by Patheon. If Components ordered by Patheon under Firm Orders or this Section 5.2 are not included in finished Products manufactured for Client within [...***...] months after the forecasted month for which the purchases have been made (or for a longer period as the parties may agree) or if the Components have expired during the period, then Client will pay to Patheon its costs therefor (including all costs incurred by Patheon for the purchase and handling of the Components). But if these Components are used in Products subsequently manufactured for Client or in third party products manufactured by Patheon, Client will receive credit for any costs of those Components previously paid to Patheon by Client.

(b) If Client fails to take possession or arrange for the destruction of Components within [...***...] months of purchase or, in the case of finished Product, within [...***...] of manufacture, Client will pay Patheon $[...***...] per pallet, per month thereafter for storing the Components or finished Product. Storage fees for Components or Product which contain controlled substances or require refrigeration will be charged at $[...***...] per pallet per month. Storage fees are subject to a one pallet minimum charge per month. Patheon may ship finished Product held by it longer than [...***...] to the Client at Client’s expense on [...***...] days written notice to the Client.

5.3 **Minimum Orders.**

Client may only order Manufacturing Services for batches of Products in multiples of the Minimum Order Quantities as set out in Schedule B to a Product Agreement.

5.4 **Shipments.**

Shipments of Products will be made [...***...] (Incoterms 2010) Patheon’s shipping point unless otherwise agreed in a Product Agreement. Risk of loss or of damage to Products will remain with Patheon until Patheon loads the Products onto the carrier’s vehicle for shipment at which time risk of loss or damage will transfer to Client. Patheon will, in accordance with Client’s instructions and as agent for Client, (i) arrange for shipping to be paid by Client and (ii) obtain any export license or other official authorization necessary to export the Products. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Products and may monitor Patheon’s shipping and freight practices as they pertain to this Agreement. Products will be transported in accordance with the Specifications.
5.5 Late Delivery

If Patheon is unable to deliver the quantity of Product ordered under a Firm Order within [***] of the Delivery Date due to an act or omission by Patheon (a “Late Delivery”), Client will receive a credit from Patheon for the Late Delivery that will be applied against the purchase price under the next Firm Order. The credit will be [***]% of the Price of the quantities of Product not delivered by Patheon under the Firm Order within [***] of the Delivery Date [***]. An additional credit of [***]% of the Price of the quantities of Product not delivered by Patheon under a Firm Order will accrue for each additional [***] of the Late Delivery up to a maximum aggregate credit of [***]% of the Price of the quantities of Product not delivered by Patheon under a Firm Order. A Late Delivery will not be a material breach of this Agreement by Patheon for the purposes of Section 8.2(a). For clarity, a Late Delivery will not include any delay in shipment of Product caused by events outside of Patheon’s reasonable control, such as a Force Majeure Event, a delay in delivery of API or Materials, a delay in Product release approval from Client, inaccurate Client forecasts, receipt of non-conforming API or Client-Supplied Components, or any market driven delays in deliveries from approved vendors.

5.6 Invoices and Payment

Invoices will be sent by fax or email to the fax number or email address given by Client to Patheon in writing. Invoices will be sent when the Product is manufactured and released by Patheon to the Client. Patheon will also submit to Client, with each shipment of Products, a duplicate copy of the invoice covering the shipment. Patheon will also give Client an invoice covering any Inventory or Components which are to be purchased by Client under Section 5.2 of this Agreement. Each invoice will, to the extent applicable, identify Client’s Manufacturing Services purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [***] days of the date thereof. If any portion of an invoice is disputed, the Client will pay Patheon for the undisputed amount and the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. Beginning [***] days after the date of the invoice, interest on undisputed past due accounts will accrue at [***]% per month which is equal to an annual rate of [***]%. The Late Delivery credits set forth in Section 5.5 are only available to Client if all outstanding undisputed invoices have been paid in full or are within [***] days outstanding from the invoice date when the Late Delivery arose.

ARTICLE 6

PRODUCT CLAIMS AND RECALLS

6.1 Product Claims

(a) Product Claims. Client has the right to reject any portion of any shipment of Products that deviates from the Specifications, cGMPs, or Applicable Laws without invalidating any remainder of the shipment. Client will inspect the Products manufactured by Patheon upon receipt and will give Patheon written notice (a “Deficiency Notice”) of all claims for Products that deviate from the Specifications, cGMPs, or Applicable Laws within [***] days after Client’s receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt of the Product, within [***] days after discovery by Client, but not after the expiration date of the Product). Should Client fail to give Patheon the Deficiency Notice within the applicable [***] day period, then the delivery will be deemed to have been accepted by Client on the [***] day after delivery or discovery, as applicable. Except as set out in Section 6.3, Patheon will have no liability for any deviations for which it has not received notice within the applicable [***] day period.
6.2 Product Recalls and Returns

(a) Records and Notice. Patheon and Client will each maintain records necessary to permit a Recall of any Products delivered to Client or customers of Client. Each party will promptly notify the other by telephone (to be confirmed in writing) of any information which might affect the marketability, safety or effectiveness of the Products or which might result in the Recall or seizure of the Products. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Products in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client. “Recall” will mean any action (i) by Client to recover title to or possession of quantities of the Products sold or shipped to third parties (including, without limitation, the voluntary withdrawal of Products from the market); or (ii) by any regulatory authorities to detain or destroy any of the Products. Recall will also include any action by either party to refrain from selling or shipping quantities of the Products to third parties which would have been subject to a Recall if sold or shipped.

(b) Recalls. If (i) any governmental or regulatory authority issues a directive, order or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled, (ii) a court of competent jurisdiction orders a Recall, or (iii) Client determines that any Product should be Recalled or that a “Dear Doctor” letter is required relating the restrictions on the use of any Product, Patheon will cooperate as reasonably required by Client, having regard to all applicable laws and regulations.

(c) Product Returns. Client will have the responsibility for handling customer returns of the Products. Patheon will give Client any assistance that Client may reasonably require to handle the returns.

6.3 Patheon’s Responsibility for Defective and Recalled Products

(a) Defective Product. If Client rejects Products under Section 6.1 and the deviation is determined to have arisen from Patheon’s failure to provide the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will credit Client’s account for Patheon’s invoice price for the defective Products. If Client previously paid for the defective Products, Patheon will promptly, at Client’s election, either: (i) refund the invoice price for the defective Products; (ii) offset the
amount paid against other amounts due to Patheon hereunder; or (iii) replace the Products with conforming Products without Client being liable for payment therefor under Section 3.1, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon’s responsibility for any loss of Active Materials in defective Product will be captured and calculated in the Active Materials Yield under Section 2.2.

(b) Recalled Product. If a Recall or return results from, or arises out of, a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, or Applicable Laws, Patheon will be responsible for the documented out-of-pocket expenses of the Recall or return and will use its commercially reasonable efforts to replace the Recalled or returned Products with new Products, contingent upon the receipt from Client of all Active Materials and Client-Supplied Components required for the manufacture of the replacement Products. For greater certainty, Patheon’s responsibility for any loss of Active Materials in Recalled Product will be captured and calculated in the Active Materials Yield under Section 2.2. If Patheon is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the required Active Materials and Client-Supplied Components), then Client may request Patheon to reimburse Client for the price that Client paid to Patheon for Manufacturing Services for the affected Products. In all other circumstances, Recalls, returns, or other corrective actions will be made at Client’s cost and expense.

(c) Except as set forth in Sections 6.3(a) and (b) above, Patheon will not be liable to Client nor have any responsibility to Client for any deficiencies in, or other liabilities associated with, any Product manufactured by it, (collectively, “Product Claims”). For greater certainty, Patheon will have no obligation for any Product Claims to the extent the Product Claim (i) is caused by deficiencies in the Specifications, the safety, efficacy, or marketability of the Products or any distribution thereof, (ii) results from a defect in a Component that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iii) results from a defect in the Active Materials or Client-Supplied Components that is not reasonably discoverable by Patheon using the test methods set forth in the Specifications, (iv) is caused by actions of third parties occurring after the Product is shipped by Patheon under Section 5.4, (v) is due to packaging design or labelling defects or omissions for which Patheon has no responsibility, (vi) is due to any unascertainable reason despite Patheon having performed the Manufacturing Services in accordance with the Specifications, cGMP’s, and Applicable Laws, or (vii) is due to any other breach by Client of its obligations under this Agreement.

6.4 Disposition of Defective or Recalled Products.

Client will not dispose of any damaged, defective, returned, or Recalled Products for which it intends to assert a claim against Patheon without Patheon’s prior written authorization to do so. Alternatively, Patheon may instruct Client to return the Products to Patheon. Patheon will bear the cost of disposition for any damaged, defective, returned or Recalled Products for which it bears responsibility under Section 6.3. In all other circumstances, Client will bear the cost of disposition, including all applicable fees for Manufacturing Services, for any damaged, defective, returned, or Recalled Products.

6.5 Healthcare Provider or Patient Questions and Complaints.

Client will have the sole responsibility for responding to questions and complaints from its customers. Questions or complaints received by Patheon from Client’s customers, healthcare providers or patients will be promptly referred to Client. Patheon will co-operate as reasonably required to allow Client to determine the cause of and resolve any questions and complaints. This assistance will include follow-up investigations, including testing. In addition, Patheon will give Client all agreed upon information that will enable Client to respond properly to questions or complaints about the Products as
6.6 Sole Remedy.

Except for the indemnity set forth in Section 10.3 and subject to the limitations set forth in Sections 10.1 and 10.2, the remedies described in this Article 6 will be Client’s sole remedy for any failure by Patheon to provide the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws.

ARTICLE 7
CO-OPERATION

7.1 Quarterly Review.

Each party will forthwith upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet not less than quarterly to review the current status of the business relationship and manage any issues that have arisen.

7.2 Governmental Agencies.

Subject to Section 7.8, each party may communicate with any governmental agency, including but not limited to governmental agencies responsible for granting regulatory approval for the Products, regarding the Products if, in the opinion of that party’s counsel, the communication is necessary to comply with the terms of this Agreement or the requirements of any law, governmental order or regulation. Unless, in the reasonable opinion of its counsel, there is a legal prohibition against doing so, a party will permit the other party to accompany and take part in any communications with the agency, and to receive copies of all communications from the agency.

7.3 Records and Accounting by Patheon.

Patheon will keep records of the manufacture, testing, and shipping of the Products, and retain samples of the Products as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, as well as to assist with resolving Product complaints and other similar investigations. Copies of the records and samples will be retained for [...***...] following the date of Product expiry, or longer if required by law, at which time Client will be contacted concerning the delivery and destruction of the documents and/or samples of Products. Client is responsible for retaining samples of the Products necessary to comply with the legal/regulatory requirements applicable to Client.

7.4 Inspection.

Client may inspect Patheon reports and records relating to this Agreement during normal business hours and with reasonable advance notice, but a Patheon representative must be present during the inspection.
7.5 Access

Patheon will give Client reasonable access at agreed times to the areas of the Manufacturing Site in which the Products are manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, and Applicable Laws. But, with the exception of “for-cause” audits, Client will be limited each Year to one cGMP-type audit, lasting no more than [...***...] days, and involving no more than [...***...] auditors. Client may request additional cGMP-type audits, additional audit days, or the participation of additional auditors subject to payment to Patheon of a fee of $[...***...] for each additional audit day and $[...***...] per audit day for each additional auditor. The right of access set forth in this Section 7.5 will not include a right to access or inspect Patheon’s financial records. In addition to any other rights to audit, otherwise described in this Agreement, Client will have the right to have up to [...***...] representatives present for [...***...] days during the manufacturing campaigns of any Product during normal business hours and upon reasonable advance notice to Patheon. If Client’s representatives are present for more than [...***...] days during the manufacturing campaigns of any Products, Client will pay Patheon a fee of $[...***...] per day for each additional day.

7.6 Notification of Regulatory Inspections

Patheon will notify Client within [...***...] of any inspections by any governmental agency specifically involving the Products. Patheon will also notify Client of receipt of any form 483’s or warning letters or any other significant regulatory action which Patheon’s quality assurance group determines could impact the regulatory status of the Products.

7.7 Reports

Patheon will supply on an annual basis all Product data in its control, including release test results, complaint test results, and all investigations (in manufacturing, testing, and storage), that Client reasonably requires in order to complete any filing under any applicable regulatory regime, including any Annual Report that Client is required to file with the FDA. At the Client’s request, Patheon will provide a copy of the Annual Product Review Report to the Client at no additional cost. Any additional report requested by Client beyond the scope of cGMPs and customary FDA requirements will be subject to an additional fee to be agreed upon between Patheon and the Client.

7.8 Regulatory Filings

(a) Regulatory Authority. Client will have the sole responsibility for filing all documents with all Regulatory Authorities and taking any other actions that may be required for the receipt and/or maintenance of Regulatory Authority approval for the commercial manufacture of the Products. Patheon will assist Client, to the extent consistent with Patheon’s obligations under this Agreement, to obtain Regulatory Authority approval for the commercial manufacture of all Products as quickly as reasonably possible.

(b) Verification of Data. Prior to filing any documents with any Regulatory Authority that incorporate data generated by Patheon, Client will give Patheon a copy of the documents incorporating this data to give Patheon the opportunity to verify the accuracy and regulatory validity of those documents as they relate to Patheon generated data. Patheon requires [...***...] days to perform this review but the parties may agree to a shorter time for the review as needed.

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(c) **Verification of CMC.** Prior to filing with any Regulatory Authority any documentation which is or is equivalent to the FDA’s Chemistry and Manufacturing Controls (all such documentation herein referred to as “CMC”) related to any Marketing Authorization, such as a New Drug Application or Abbreviated New Drug Application, Client will give Patheon a copy of the CMC as well as all supporting documents which have been relied upon to prepare the CMC. This disclosure will permit Patheon to verify that the CMC accurately describes the work that Patheon has performed and the manufacturing processes that Patheon will perform under this Agreement. Patheon requires […***…] days to perform this review but the parties may agree to a shorter time for the review as needed. Client will give Patheon copies of all FDA filings which contain CMC information regarding the Product within […***…] days of the approval submission.

(d) **Deficiencies.** If, in Patheon’s sole discretion, acting reasonably, Patheon determines that any of the information given by Client under clauses (b) and (c) above is inaccurate or deficient in any manner whatsoever (the “Deficiencies”), Patheon will notify Client in writing of the Deficiencies. The parties will work together to have the Deficiencies resolved prior to any pre-approval inspection.

(e) **Client Responsibility.** For clarity, the parties agree that in reviewing the documents referred to in clause (b) above, Patheon’s role will be limited to verifying the accuracy of the description of the work undertaken or to be undertaken by Patheon. Subject to the foregoing, Patheon will not assume any responsibility for the accuracy of any application for receipt of an approval by a Regulatory Authority. The Client is solely responsible for the preparation and filing of the application for approval by the Regulatory Authority and any relevant costs will be borne by the Client.

(f) **Inspection by Regulatory Authorities.** If Client does not give Patheon the documents requested under clause (b) above within the time specified and if Patheon reasonably believes that Patheon’s standing with a Regulatory Authority may be jeopardized, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

**ARTICLE 8**

**TERM AND TERMINATION**

8.1 **Initial Term.**

This Agreement will become effective as of the Effective Date and will continue until December 31, 2019 (the “Initial Term”), unless terminated earlier by one of the parties in accordance herewith. This Agreement will automatically renew after the Initial Term for successive terms of three Years each if there is a Product Agreement in effect, unless either party gives written notice to the other party of its intention to terminate this Agreement at least 24 months prior to the end of the then current term. In any event, the legal terms and conditions of this Agreement will continue to govern any Product Agreement in effect as provided in Section 1.2. Each Product Agreement will have an initial term of five Years from the start of commercial manufacture at the Manufacturing Site for the Product unless the parties agree to a different number of Years in the applicable Product Agreement (each, an “Initial Product Term”). Product Agreements will automatically renew after the Initial Product Term for successive terms of three Years each unless either party gives written notice to the other party of its intention to terminate the Product Agreement at least 24 months prior to the end of the then current term.

8.2 **Termination for Cause.**

(a) Either party at its sole option may terminate this Agreement or a Product Agreement upon written notice where the other party has failed to remedy a material breach of any of its representations,
warranties, or other obligations under this Agreement or the Product Agreement within 60 days following receipt of a written notice (the “Remediation Period”) of the breach that expressly states that it is a notice under this Section 8.2(a) (a “Breach Notice”). The aggrieved party’s right to terminate this Agreement or a Product Agreement under this Section 8.2(a) may only be exercised for a period of 60 days following the expiry of the Remediation Period (where the breach has not been remedied) and if the termination right is not exercised during this period then the aggrieved party will be deemed to have waived the breach of the representation, warranty, or obligation described in the Breach Notice.

(b) Either party at its sole option may immediately terminate this Agreement or a Product Agreement upon written notice, but without prior advance notice, to the other party if: (i) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by the other party; or (iii) this Agreement or a Product Agreement is assigned by the other party for the benefit of creditors.

(c) Client may terminate a Product Agreement upon 30 days’ prior written notice if any Authority takes any action, or raises any objection, that prevents Client from importing, exporting, purchasing, or selling the Product. But if this occurs, Client must still fulfill all of its obligations under Section 8.4 below and under any Capital Equipment Agreement regarding the Product.

(d) Patheon may terminate this Agreement or a Product Agreement upon six months’ prior written notice if Client assigns under Section 13.6 any of its rights under this Agreement or a Product Agreement to an assignee that, in the reasonable opinion of Patheon, is: (i) not a credit worthy substitute for Client or (ii) a Patheon Competitor.

8.3 Product Discontinuation.

Client will give at least six months’ advance notice if it intends to no longer order Manufacturing Services for a Product due to this Product’s discontinuance in the market.

8.4 Obligations on Termination.

If a Product Agreement is completed, expires, or is terminated in whole or in part for any reason, then:

(a) Client will take delivery of and pay for all undelivered Products that are manufactured and/or packaged under a Firm Order, at the price in effect at the time the Firm Order was placed, subject to Client’s right to reject any such Product as described in Article 6 of this Agreement;

(b) Client will purchase, at Patheon’s cost (including all costs incurred by Patheon for the purchase and handling of the Inventory), the Inventory applicable to the Products which was purchased, produced or maintained by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, but not including Components which Patheon can use in its other Manufacturing operations and not including any Inventory that has been stored or otherwise maintained in an environment that a Regulatory Authority has determined, or would reasonably determine, is not cGMP compliant;

(c) Client will satisfy the purchase price payable under Patheon’s orders with suppliers of Components, if the orders were made by Patheon in reliance on Firm Orders or in accordance with Section 5.2;
(d) Client acknowledges that no Patheon Competitor will be permitted access to the Manufacturing Site; and

(e) Client will make commercially reasonable efforts, at its own expense, to remove from Patheon site(s), within 30 days, all unused Active Material and Client-Supplied Components, all applicable Inventory and Materials (whether current or obsolete), supplies, undelivered Product, chattels, equipment or other moveable property owned by Client, related to the Agreement and located at a Patheon site or that is otherwise under Patheon’s care and control (“Client Property”). If Client fails to remove the Client Property within 30 days following the completion, termination, or expiration of the Product Agreement, Client will pay Patheon $100.00 per pallet, per month, one pallet minimum (except that Client will pay $200 per pallet, per month, one pallet minimum, for any of the Client Property that contains controlled substances, requires refrigeration or other special storage requirements) thereafter for storing the Client Property and will assume any third party storage charges invoiced to Patheon regarding the Client Property. Patheon will invoice Client for the storage charges as set forth in Section 5.6 of this Agreement.

(f) The parties will reasonably cooperate to support the transfer of the manufacture of the Products to a third party manufacturer.

Any termination or expiration of this Agreement or a Product Agreement will not affect any outstanding obligations or payments due prior to the termination or expiration, nor will it prejudice any other remedies that the parties may have under this Agreement or a Product Agreement or any related Capital Equipment Agreement. For greater certainty, termination of this Agreement or of a Product Agreement for any reason will not affect the obligations and responsibilities of the parties under Articles 6, 10 and 11 and Sections 5.4, 5.6, 8.4, 13.1, 13.2, 13.3, and 13.16, all of which survive any termination.

ARTICLE 9

REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Authority

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.

9.2 Client Warranties

Client covenants, represents, and warrants that:

(a) Non-Infringement

(i) the Specifications for each of the Products are its or its Affiliate’s property and that Client may lawfully disclose the Specifications to Patheon;

(ii) any Client Intellectual Property, used by Patheon in performing the Manufacturing Services according to the Specifications (A) is Client’s or its Affiliate’s unencumbered property, (B) may be lawfully used as directed by Client, and (C) does not infringe and will not infringe any Third Party Rights;
(iii) the performance of the Manufacturing Services by Patheon for any Product under this Agreement or any Product Agreement or the use or other disposition of any Product by Patheon as may be required to perform its obligations under this Agreement or under any Product Agreement does not and will not infringe any Third Party Rights;

(iv) there are no actions or other legal proceedings, concerning the infringement of Third Party Rights related to any of the Specifications, or any of the Active Materials and the Components, or the sale, use, or other disposition of any Product made in accordance with the Specifications;

(b) Quality and Compliance.

(i) the Specifications for all Products conform to all applicable cGMPs and Applicable Laws;

(ii) the Products, if labelled and manufactured in accordance with the Specifications and in compliance with applicable cGMPs and Applicable Laws (i) may be lawfully sold and distributed in every jurisdiction in which Client markets the Products, (ii) will be fit for the purpose intended, and (iii) will be safe for human consumption;

(iii) on the date of shipment, the API will conform to the specifications for the API that Client has given to Patheon and that the API will be adequately contained, packaged, and labelled and will conform to the affirmations of fact on the container.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) it will perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws; and

(b) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon’s or its Affiliate’s unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights.

9.4 Debarred Persons.

Patheon covenants that it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b). Patheon represents that it does not currently have, and covenants that it will not hire, as an officer or an employee any person who has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the Federal Food, Drug, and Cosmetic Act (United States).
9.5 Permits.

Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will maintain at all relevant times all governmental permits, licenses, approval, and authorities required to enable it to lawfully and properly perform the Manufacturing Services.

9.6 No Warranty.

PATHEON MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT. PATHEON MAKES NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OF MERCHANTABILITY FOR THE PRODUCTS.

ARTICLE 10

REMEDIES AND INDEMNITIES

10.1 Consequential Damages.

Under no circumstances whatsoever will either party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Active Materials. Except as expressly set forth in Section 2.2, under no circumstances will Patheon be responsible for any loss or damage to the Active Materials. Patheon’s maximum responsibility for loss or damage to the Active Materials will not exceed the Maximum Credit Value set forth in Schedule D of a Product Agreement.

(b) Maximum Liability. Patheon’s maximum liability to Client under this Agreement or any Product Agreement for any reason whatsoever, including, without limitation, any liability arising under Article 6 hereof or resulting from any and all breaches of its representations, warranties, or any other obligations under this Agreement or any Product Agreement, but excluding […***…], will not exceed on a per Product basis […***…]% of revenues per Year to Patheon under the applicable Product Agreement, up to a maximum of $[…***…] in the aggregate per Year for all Products.

10.3 Patheon.

Patheon agrees to defend and indemnify Client, its officers, employees, and agents against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of personal injury or property damage to the extent that the injury or damage is the result of a failure by Patheon to perform the Manufacturing Services in accordance with the Specifications, cGMPs, and Applicable Laws except to the extent that

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the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Client, its officers, employees, agents, or Affiliates.

If a claim occurs, Client will: (a) promptly notify Patheon of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Patheon in the defense of the claim; and (d) permit Patheon to control the defense and settlement of the claim, all at Patheon’s cost and expense.

10.4 Client

Client agrees to defend and indemnify Patheon, its officers, employees, and agents against all losses, damages, costs, claims, demands, judgments and liability to, from and in favour of third parties (other than Affiliates) resulting from, or relating to any claim of infringement or alleged infringement of any Third Party Rights in the Products, or any portion thereof, or any claim of personal injury or property damage to the extent that the injury or damage is the result of a breach of this Agreement by Client, including, without limitation, any representation or warranty contained herein, except to the extent that the losses, damages, costs, claims, demands, judgments, and liability are due to the negligence or wrongful act(s) of Patheon, its officers, employees, or agents.

If a claim occurs, Patheon will: (a) promptly notify Client of the claim; (b) use commercially reasonable efforts to mitigate the effects of the claim; (c) reasonably cooperate with Client in the defense of the claim; and (d) permit Client to control the defense and settlement of the claim, all at Client’s cost and expense.

10.5 Reasonable Allocation of Risk

This Agreement (including, without limitation, this Article 10) is reasonable and creates a reasonable allocation of risk for the relative profits the parties each expect to derive from the Products. Patheon assumes only a limited degree of risk arising from the manufacture, distribution, and use of the Products because Client has developed and holds the marketing approval for the Products, Client requires Patheon to manufacture and label the Products strictly in accordance with the Specifications, and Client, not Patheon, is best positioned to inform and advise potential users about the circumstances and manner of use of the Products.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidentiality

The Confidentiality Agreement will apply to all confidential information disclosed by the parties under this Agreement or any Product Agreement. If the Confidentiality Agreement expires or is terminated prior to the expiration or termination of this Agreement or any Product Agreement, the terms of the Confidentiality Agreement will continue to govern the parties’ obligations of confidentiality for any confidential or proprietary information disclosed by the parties hereunder, for the term of this Agreement or any Product Agreement, as though the Confidentiality Agreement remained in full force and effect.
ARTICLE 12
DISPUTE RESOLUTION

12.1 Commercial Disputes

If any dispute arises out of this Agreement or any Product Agreement (other than a dispute under Section 6.1(b) or a Technical Dispute, as defined herein), the parties will first try to resolve it amicably. In that regard, any party may send a notice of dispute to the other, and each party will appoint, within [...] Business Days from receipt of the notice of dispute, a single representative having full power and authority to resolve the dispute. The representatives will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within [...] from their appointment, or if a party fails to appoint a representative within the [...] Business Day period set forth above, the dispute will immediately be referred to the Chief Operating Officer (or another officer as he/she may designate) of each party who will meet and discuss as necessary to try to resolve the dispute amicably. Should the parties fail to reach a resolution under this Section 12.1, the dispute will be referred to a court of competent jurisdiction in accordance with Section 13.16.

12.2 Technical Dispute Resolution

If a dispute arises (other than disputes under Sections 6.1(b) or 12.1) between the parties that is exclusively related to technical aspects of the manufacturing, packaging, labelling, quality control testing, handling, storage, or other activities under this Agreement (a “Technical Dispute”), the parties will make all reasonable efforts to resolve the dispute by amicable negotiations. In that regard, senior representatives of each party will, as soon as possible and in any event no later than [...] Business Days after a written request from either party to the other, meet in good faith to resolve any Technical Dispute. If, despite this meeting, the parties are unable to resolve a Technical Dispute within a reasonable time, and in any event within [...] Business Days of the written request, the Technical Dispute will, at the request of either party, be referred for determination to an expert in accordance with Exhibit A. If the parties cannot agree that a dispute is a Technical Dispute, Section 12.1 will prevail. For greater certainty, the parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.

ARTICLE 13
MISCELLANEOUS

13.1 Corporate Responsibility. Patheon, while performing the Manufacturing Services under this Agreement, will comply, in all material respects, with all applicable laws, rules, regulations, and standards that relate to the Agreement including, but not limited to, those relating to environmental matters, public health, wages, hours and conditions of employment, subcontractor selection, discrimination and occupational health/safety. Without limiting the foregoing, Patheon covenants that neither Patheon nor any of its subcontractors will utilize child or any form of forced or involuntary labor in while performing the Manufacturing Services under this Agreement. Upon Client’s reasonable written request, Patheon will certify in writing its compliance with this Section 13.1 and will provide copies of all applicable permits, certificates and licenses that may be required for its performance under this Agreement. Upon Client’s reasonable written request, Patheon will allow Client or its authorized representatives to audit the Manufacturing Site to verify Patheon’s performance against the requirements.

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in this Section 13.1. This audit right does not include the right to interview any Patheon employee or subcontractor or to review any personnel or medical
files of Patheon’s employees, any Environmental, Health or Safety files of Patheon, any internal audit files of Patheon, or any financial records, including
payroll records, of Patheon. Client will have the right to terminate this Agreement in whole or in part, as set forth in Section 8.2(a), if Patheon fails to
materially comply with the requirements of this Section 13.1.

13.2 Inventions.

(a) For the term of this Agreement, Client hereby grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client’s
Intellectual Property which Patheon must use in order to perform the Manufacturing Services.

(b) All Intellectual Property generated or derived by Patheon while performing the Manufacturing Services, to the extent it is specific to the
development, manufacture, use, and sale of Client’s Product that is the subject of the Manufacturing Services, will be the exclusive property of Client.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Patheon hereby grants to Client a perpetual, irrevocable, non-exclusive,
paid-up, royalty-free, transferable license to use the Patheon Intellectual Property used by Patheon to perform the Manufacturing Services to enable Client to
manufacture the Product(s).

(d) Each party will be solely responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions.

(e) Either party will give the other party written notice, as promptly as practicable, of all Inventions which can reasonably be deemed to constitute
improvements or other modifications of the Products or processes or technology owned or otherwise controlled by the party.

13.3 Intellectual Property.

Subject to Section 13.1, all Client Intellectual Property will be owned by Client and all Patheon Intellectual Property will be owned by Patheon.
Neither party has, nor will it acquire, any interest in any of the other party’s Intellectual Property unless otherwise expressly agreed to in writing. Neither
party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its
obligations under this Agreement.

13.4 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of
that party under this Agreement through the term of this Agreement and for a period of three years thereafter. This insurance will have policy limits of not less
than (i) $[...***...]

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13.5 **Independent Contractors.**

The parties are independent contractors and this Agreement and any Product Agreement will not be construed to create between Patheon and Client any other relationship such as, by way of example only, that of employer-employee, principal agent, joint-venturer, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.6 **No Waiver.**

Either party’s failure to require the other party to comply with any provision of this Agreement or any Product Agreement will not be deemed a waiver of the provision or any other provision of this Agreement or any Product Agreement, with the exception of Sections 6.1 and 8.2 of this Agreement.

13.7 **Assignment.**

(a) Patheon may not assign this Agreement or any Product Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld. But Patheon may arrange for subcontractors to perform specific testing services arising under any Product Agreement without the consent of Client. Further it is specifically agreed that Patheon may subcontract any part of the Manufacturing Services under a Product Agreement to any of its Affiliates with Client’s written consent, this consent not to be unreasonably withheld.

(b) Subject to Section 8.2(d), Client may assign this Agreement or any Product Agreement or any of its associated rights or obligations without approval from Patheon. But Client will give Patheon prior written notice of any assignment, any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement or the Product Agreement, and Client will remain liable hereunder. Any partial assignment will be subject to Patheon’s cost review of the assigned Products and Patheon may terminate this Agreement or any Product Agreement or any assigned part thereof, on [...] months’ prior written notice to Client and the assignee if good faith discussions do not lead to agreement on amended Manufacturing Service fees within a reasonable time.

(c) Despite the foregoing provisions of this Section 13.6, either party may assign this Agreement or any Product Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business, but the assignee must execute an agreement with the non-assigning party whereby it agrees to be bound hereunder.

13.8 **Force Majeure.**

Neither party will be liable for the failure to perform its obligations under this Agreement or any Product Agreement if the failure is caused by an event beyond that party’s reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, quarantines, communicable disease outbreaks, wars, acts of terrorism, fires, floods, storms, interruption of or delay in transportation, defective equipment, lack of or inability to obtain fuel, power or components, or compliance with any order or regulation of any government entity acting within colour of right (a "**Force Majeure Event**"). A party claiming a right to excused performance under this Section 13.7 will immediately notify the other party in writing of the extent of its inability to perform, which notice will specify the event beyond its reasonable control that prevents the performance. Neither party will be entitled to rely on a Force Majeure Event to relieve it from an obligation to pay money (including any interest for

***Confidential Treatment Requested***
13.9 **Additional Product.**

Additional Products may be added to, or existing Products deleted from, any Product Agreement by amendments to the Product Agreement including Schedules A, B, C, and D as applicable.

13.10 **Notices.**

Unless otherwise agreed in a Product Agreement, any notice, approval, instruction or other written communication required or permitted hereunder will be sufficient if made or given to the other party by personal delivery, by telecopy, facsimile communication, or confirmed receipt email or by sending the same by first class mail, postage prepaid to the respective addresses, telecopy or facsimile numbers or electronic mail addresses set forth below:

If to Client:
Horizon Pharm Inc.
520 Lake Cook Road Suite 520
Deerfield, IL 60015
Attention: Jeff Sherman
Telecopier No.: (224) 383-3001
Email address: JSherman@horizonpharma.com

With a copy to:
Horizon Pharm Inc.
520 Lake Cook Road Suite 520
Deerfield, IL 60015
Attention: Brian Beeler
Telecopier No.: (224) 383-3001
Email address: BBeeler@horizonpharma.com

If to Patheon:
Patheon Pharmaceuticals Inc
2110 East Galbraith Road
Cincinnati, OH 45237-1625
Attention: [***...]
Telecopier No.: [***...]
Email address: [***...]

With a copy to:
Patheon Inc.
4721 Emperor Boulevard
Research Triangle Park,
NC 27703

***Confidential Treatment Requested"
given by personal delivery, telecopy, facsimile, or electronic mail will be deemed to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the United States, Canada, or European Union mail, postage prepaid or upon receipt, whichever is sooner.

13.11 Severability

If any provision of this Agreement or any Product Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.12 Entire Agreement

This Agreement, together with the applicable Product Agreement, Quality Agreement and the Confidentiality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings concerning the subject matter hereof. Any modification, amendment, or supplement to this Agreement or any Product Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement, the Product Agreement, the Quality Agreement, and the Confidentiality Agreement.

13.13 Other Terms

No terms, provisions or conditions of any purchase order or other business form or written authorization used by Client or Patheon will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement or any Product Agreement, regardless of any failure of Client or Patheon to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement or the applicable Product Agreement and is signed by both parties.

13.14 No Third Party Benefit or Right

For greater certainty, nothing in this Agreement or any Product Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement or any Product Agreement.

13.15 Execution in Counterparts

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

13.16 Use of Client Name

Patheon will not make any use of Client’s name, trademarks or logo or any variations thereof, alone or with any other word or words, without the prior written consent of Client, which consent will not be unreasonably withheld. Despite this, Client agrees that Patheon may include Client’s name and logo in customer lists or related marketing and promotional material for the purpose of identifying users of Patheon’s Manufacturing Services.
13.17 **Governing Law**

This Agreement and, unless otherwise agreed by the parties, any Product Agreement, will be construed and enforced in accordance with the laws of the State of New York and the laws of the United States of America applicable therein and subject to the exclusive jurisdiction of the courts thereof. The UN Convention on Contracts for the International Sale of Goods will not apply to this Agreement.

[Signature page to follow]

- 33 -
IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Agreement as of the Effective Date.

PATHEON PHARMACEUTICALS INC.

By: /s/ Dean Wilson
Name: Dean Wilson
Title: Corporate Controller

HORIZON PHARMA INC.

By: /s/ Jeffrey W. Sherman
Name: Jeffrey W. Sherman, M.D., FACP
Title: Chief Medical Officer, EVP

HORIZON PHARMA INC.

By: /s/ Todd N. Smith
Name: Todd N. Smith
Title: CCO, EVP
APPENDIX 1

FORM OF PRODUCT AGREEMENT
(Includes Schedules A to D)

PRODUCT AGREEMENT

This Product Agreement (this "Product Agreement") is issued under the Master Manufacturing Services Agreement dated October 31, 2013 between Patheon Pharmaceuticals Inc., and Horizon Pharma Inc., (the "Master Agreement"), and is entered into [insert effective date] (the "Effective Date"), between Patheon Pharmaceuticals Inc., [or applicable Patheon Affiliate], a corporation existing under the laws of the State of Delaware [or applicable founding jurisdiction for Patheon Affiliate], having a principal place of business at 2110 East Galbraith Road, Cincinnati, OH 45237-1625 [or Patheon Affiliate address] ("Patheon") and [insert Client name, legal entity, founding jurisdiction and address] ("Client").

The terms and conditions of the Master Agreement are incorporated herein except to the extent this Product Agreement expressly references the specific provision in the Master Agreement to be modified by this Product Agreement. All capitalized terms that are used but not defined in this Product Agreement will have the respective meanings given to them in the Master Agreement.

The Schedules to this Product Agreement are incorporated into and will be construed in accordance with the terms of this Product Agreement.

1. Product List and Specifications (See Schedule A attached hereto)
2. Minimum Order Quantity, Annual Volume, and Price (See Schedule B attached hereto)
3. Annual Stability Testing and Validation Activities (if applicable) (See Schedule C attached hereto)
4. Active Materials, Active Materials Credit Value, and Maximum Credit Value (See Schedule D attached hereto)
5. Yearly Forecasted Volume: (insert for sterile products in Italy if applicable under section 4.2.1)
6. Territory: (insert the description of the Territory here)
7. Manufacturing Site: (insert address of Patheon Manufacturing Site where the Manufacturing Services will be performed)
8. Governing Law: (if applicable under Section 13.16 of the Master Agreement)
9. Inflation Index: (if applicable under Section 4.2(a) of the Master Agreement for Products manufactured outside of the United States or Puerto Rico)
10. Currency: (if applicable under Section 1.4 of the Master Agreement)
11. **Initial Set Exchange Rate**: (if applicable under Section 4.2(d) of the Master Agreement)

12. **Initial Product Term**: (if applicable under Section 8.1 of the Master Agreement)

13. **Notices**: (if applicable under Section 13.9 of the Master Agreement)

14. **Other Modifications to the Master Agreement**: (if applicable under Section 1.2 of the Master Agreement)

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed this Product Agreement as of the Effective Date set forth above.

**PATHEON PHARMACEUTICALS INC. [or applicable Patheon Affiliate]**

By: 
Name: __________________________
Title: __________________________

**HORIZON PHARMA INC. [or applicable Horizon Affiliate]**

By: 
Name: __________________________
Title: __________________________
SCHEDULE A

PRODUCT LIST AND SPECIFICATIONS

[...***...]

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- 3 -
SCHEDULE B

MINIMUM ORDER QUANTITY, ANNUAL VOLUME, AND PRICE

[...***...]

***Confidential Treatment Requested

- 1 -
SCHEDULE C

ANNUAL STABILITY TESTING [and VALIDATION ACTIVITIES (if applicable)]

[...***...]

***Confidential Treatment Requested

- 1 -
### SCHEDULE D

**ACTIVE MATERIALS**

<table>
<thead>
<tr>
<th>Active Materials</th>
<th>Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**ACTIVE MATERIALS CREDIT VALUE**

The Active Materials Credit Value will be as follows:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>ACTIVE MATERIALS CREDIT VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[...***...</td>
</tr>
</tbody>
</table>

**MAXIMUM CREDIT VALUE**

Patheon’s liability for Active Materials calculated in accordance with Section 2.2 of the Master Agreement [for any Product] in a Year will not exceed, in the aggregate, the maximum credit value set forth below:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MAXIMUM CREDIT VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[% of revenues per Year to Patheon under this Product Agreement, up to a maximum of $[ ] in the aggregate per Year.</td>
</tr>
</tbody>
</table>

[End of Product Agreement]

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**EXHIBIT A**

**TECHNICAL DISPUTE RESOLUTION**

Technical Disputes which cannot be resolved by negotiation as provided in Section 12.2 will be resolved in the following manner:

1. **Appointment of Expert.** Within [...] Business Days after a party requests under Section 12.2 that an expert be appointed to resolve a Technical Dispute, the parties will jointly appoint a mutually acceptable expert with experience and expertise in the subject matter of the dispute. If the parties are unable to so agree within the [...] Business Day period, or in the event of disclosure of a conflict by an expert under Paragraph 2 hereof which results in the parties not confirming the appointment of the expert, then an expert (willing to act in that capacity hereunder) will be appointed by an experienced arbitrator on the roster of the American Arbitration Association.

2. **Conflicts of Interest.** Any person appointed as an expert will be entitled to act and continue to act as an expert even if at the time of his appointment or at any time before he gives his determination, he has or may have some interest or duty which conflicts or may conflict with his appointment if before accepting the appointment (or as soon as practicable after he becomes aware of the conflict or potential conflict) he fully discloses the interest or duty and the parties will, after the disclosure, have confirmed his appointment.

3. **Not Arbitrator.** No expert will be deemed to be an arbitrator and the provisions of the American Arbitration Act or of any other applicable statute (foreign or domestic) and the law relating to arbitration will not apply to the expert or the expert’s determination or the procedure by which the expert reaches his determination under this Exhibit A.

4. **Procedure.** Where an expert is appointed:
   
   (a) **Timing.** The expert will be so appointed on condition that (i) he promptly fixes a reasonable time and place for receiving representations, submissions or information from the parties and that he issues the authorizations to the parties and any relevant third party for the proper conduct of his determination and any hearing and (ii) he renders his decision (with full reasons) within [...] Business Days (or another other date as the parties and the expert may agree) after receipt of all information requested by him under Paragraph 4(b) hereof.

   (b) **Disclosure of Evidence.** The parties undertake one to the other to give to any expert all the evidence and information within their respective possession or control as the expert may reasonably consider necessary for determining the matter before him which they will disclose promptly and in any event within [...] Business Days of a written request from the relevant expert to do so.

   (c) **Advisors.** Each party may appoint any counsel, consultants and advisors as it feels appropriate to assist the expert in his determination and so as to present their respective cases so that at all times the parties will co-operate and seek to narrow and limit the issues to be determined.

   (d) **Appointment of New Expert.** If within the time specified in Paragraph 4(a) above the expert will not have rendered a decision in accordance with his appointment, a new expert may (at the request of either party) be appointed and the appointment of the
existing expert will thereupon cease for the purposes of determining the matter at issue between the parties save this if the existing expert renders his decision with full reasons prior to the appointment of the new expert, then this decision will have effect and the proposed appointment of the new expert will be withdrawn.

(c) Final and Binding. The determination of the expert will, except for fraud or manifest error, be final and binding upon the parties.

(f) Costs. Each party will bear its own costs for any matter referred to an expert hereunder and, in the absence of express provision in the Agreement to the contrary, the costs and expenses of the expert will be shared equally by the parties.

For greater certainty, the release of the Products for sale or distribution under the applicable marketing approval for the Products will not by itself indicate compliance by Patheon with its obligations for the Manufacturing Services and further that nothing in this Agreement (including this Exhibit A) will remove or limit the authority of the relevant qualified person (as specified by the Quality Agreement) to determine whether the Products are to be released for sale or distribution.
EXHIBIT B

COMMERCIAL QUALITY AGREEMENT

- 2 -
QUALITY AGREEMENT
Commercial Product

Between

Horizon Pharma Inc.,
a corporation existing under the laws of the State of Delaware
(“Client”)

-and-

PATHEON PHARMACEUTICALS INC.,
a corporation existing under the laws of the State of Delaware.

Specific sites covered by this Agreement:
2110 E. Galbraith Rd. Cincinnati OH 45237-1625
(“Patheon”)

Effective Date: December 9, 2013

Version: QG01-05-T001-01
SECTION 1: BACKGROUND AND AGREEMENT

BACKGROUND. Under a Master Manufacturing Services Agreement dated October 31, 2013 (the “Master Agreement”) and a Product Agreement issued under the Master Agreement dated October 31, 2013 between Patheon and the Client (collectively, the “MSA”), Patheon agreed to perform pharmaceutical manufacturing services (the “Manufacturing Services”) for certain Products (as described in Appendix A hereto) and the Client is required to give certain information to Patheon in order for Patheon to perform the Manufacturing Services (the “Specifications”). Under the MSA, Patheon is required to operate within the Specifications. The parties desire to allocate the responsibility for procedures and Specifications impacting on the identity, strength, quality, and purity of the Products.

AGREEMENT. NOW THEREFORE in consideration of rights conferred and the obligations assumed under the MSA and herein, and for other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each party), and intending to be legally bound, the parties agree as follows:
## SECTION 2: RESPONSIBILITIES TABLE

Patheon will be responsible for all the operations that are marked with “X” in the column titled “Patheon” and the Client will be responsible for all the operations that are marked with “X” in the column titled “Client”. If marked with “(X)”, cooperation is required from the designated party.

<table>
<thead>
<tr>
<th>Section No.</th>
<th>Subject / Terms</th>
<th>Client</th>
<th>Patheon</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1.1</td>
<td>GMP, Health and Safety Compliance</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>4.1.2</td>
<td>Client Audit Rights; rights to have a man in plant during mfg campaigns</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>4.1.3</td>
<td>Subcontracting</td>
<td>(X)</td>
<td>X</td>
</tr>
<tr>
<td>4.1.4</td>
<td>Self-Inspection</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.2.1</td>
<td>Permits</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.2.2</td>
<td>Regulatory Filing / Registration Change Control</td>
<td>X</td>
<td>(X)</td>
</tr>
<tr>
<td>4.2.3</td>
<td>Regulatory Compliance</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.2.4</td>
<td>Government Agency Inspections, Communications and Requisitions</td>
<td>(X)</td>
<td>X</td>
</tr>
<tr>
<td>4.3.1</td>
<td>Test Methods and Specifications</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.3.2</td>
<td>Material Destruction</td>
<td>(X)</td>
<td>X</td>
</tr>
<tr>
<td>4.3.3</td>
<td>Vendor Audit Responsibility</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.3.4</td>
<td>Client Furnished Materials</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.3.5</td>
<td>Incoming Material Release</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.4.1</td>
<td>General</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.4.2</td>
<td>Equipment, Calibration and Preventative Maintenance</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.4.3</td>
<td>Environmental Monitoring Program</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.5.1</td>
<td>Master Batch Record</td>
<td>(X)</td>
<td>X</td>
</tr>
<tr>
<td>4.5.2</td>
<td>Reprocessing and Rework</td>
<td>(X)</td>
<td>X</td>
</tr>
<tr>
<td>4.5.3</td>
<td>Personnel Training</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.6.1</td>
<td>Master Batch Packaging Records</td>
<td>(X)</td>
<td>X</td>
</tr>
<tr>
<td>4.6.2</td>
<td>Printed Material and Artwork</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.6.3</td>
<td>Test Methods and Method Validation</td>
<td></td>
<td>(X)</td>
</tr>
<tr>
<td>4.7.1</td>
<td>Manufacturing Instruction Deviations</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.7.2</td>
<td>Packaging Instructions Deviations</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4.7.3</td>
<td>Notification of Deviations</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
### 4.8 Release of Product

<table>
<thead>
<tr>
<th>4.8.1 Test Methods and Specifications</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide executed batch records at least for all bulk batches to Client</td>
<td>X</td>
</tr>
<tr>
<td>Provide detailed deviation reports to Client</td>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4.8.2 Batch Release for Shipment</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.8.3 Certificate of Compliance</td>
<td>X</td>
</tr>
<tr>
<td>4.8.4 Product Release</td>
<td>X</td>
</tr>
</tbody>
</table>

### 4.9 Validation

<table>
<thead>
<tr>
<th>4.9.1 Master Validation Plan</th>
<th>(X) X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.9.2 Cleaning Validation Program</td>
<td>(X) X</td>
</tr>
<tr>
<td>4.9.3 Analytical Method and Procedure Validation</td>
<td>(X) X</td>
</tr>
</tbody>
</table>

### 4.10 Change Control

<table>
<thead>
<tr>
<th>4.10.1 General</th>
<th>X X</th>
</tr>
</thead>
</table>

### 4.11 Documentation

<table>
<thead>
<tr>
<th>4.11.1 Record Retention</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.11.2 Batch Document Requisition</td>
<td>X</td>
</tr>
</tbody>
</table>

### 4.12 Laboratory Controls

<table>
<thead>
<tr>
<th>4.12.1 Specifications and Test Methods</th>
<th>X X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.12.2 Out of Specifications (OOS) / Out of Trend (OOT)</td>
<td>X</td>
</tr>
</tbody>
</table>

### 4.13 Stability

<table>
<thead>
<tr>
<th>4.13.1 Sample Storage</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.13.2 Stability Studies and Protocol</td>
<td>X X</td>
</tr>
<tr>
<td>4.13.3 Stability Failures</td>
<td>X</td>
</tr>
<tr>
<td>4.13.4 Continue Stability on Termination of MSA</td>
<td>X</td>
</tr>
</tbody>
</table>

### 4.14 Annual Product Review

<table>
<thead>
<tr>
<th>4.14.1 General</th>
<th>X X</th>
</tr>
</thead>
</table>

### 4.15 Storage and Distribution

<table>
<thead>
<tr>
<th>4.15.1 General</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.15.2 Product Storage and Shipment Changes</td>
<td>(X) X</td>
</tr>
<tr>
<td>4.15.3 Product Quarantine</td>
<td>X</td>
</tr>
</tbody>
</table>

### 4.16 Product Complaints

<table>
<thead>
<tr>
<th>4.16.1 Complaint Investigation</th>
<th>X (X)</th>
</tr>
</thead>
</table>

### 4.17 Product Recall

<table>
<thead>
<tr>
<th>4.17.1 Product Recall Notification</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.17.2 Government Agency Notification</td>
<td>X</td>
</tr>
</tbody>
</table>

### 4.18 Reference and Retention Samples

<table>
<thead>
<tr>
<th>4.18.1 Excipient and Active Ingredient Reference Sample</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.18.2 Finished Product Retention Sample</td>
<td>X</td>
</tr>
</tbody>
</table>
SECTION 3: GENERAL

3.1 Any communications about the subject matter of this Agreement will be directed, in the first instance, to the person(s) identified in Appendix B.

3.2 Capitalized terms not otherwise defined herein will have the meaning specified in the MSA.

3.3 If any provision of this Agreement should be or found invalid, or unenforceable by law, the rest of the Agreement will remain valid and binding and the parties will negotiate a valid provision which meets as close as possible the objective of the invalid provision.

3.4 If this Agreement requires modification so that the party affected cannot be reasonably expected to continue to perform under this Agreement, then the parties will negotiate and revise the Agreement accordingly.

3.5 Any amendment of this Agreement will be made in writing and signed by both parties.

3.6 This Agreement will start on the Effective Date that is set forth on the cover page of this Agreement and will remain valid until all Quality obligations under all applicable MSA’s have been fulfilled.

3.7 If there is any conflict between the terms of this Agreement and the MSA, the MSA will control except for any specific quality issue.

3.8 The “Background” provisions of Section 1 are incorporated into this Agreement.
SECTION 4: DESCRIPTION OF RESPONSIBILITIES

4.1 QUALITY MANAGEMENT

4.1.1 GMP, Health and Safety Compliance

Patheon will conduct operations in compliance with applicable environmental, occupational health and safety laws, and cGMP regulations.

4.1.2 Client Audit Rights

Patheon will permit audits by the Client, on reasonable prior written notice, of all relevant premises, procedures, and documentation that relate to Client’s Product. Client audits are limited to one audit per calendar year unless for cause.

4.1.3 Subcontracting

Patheon will not subcontract tasks to a third party without Client’s consent. Patheon may subcontract raw material testing to other Patheon facilities and to other qualified third party laboratories. If Patheon employs a third party to perform any or part of the manufacturing, packaging, labeling, inspection, testing, release and/or handling of Client Product, Patheon shall assure that the third party has been fully qualified via the Patheon’s third party qualification process prior to performing such activity(ies). A quality agreement shall exist between Patheon and any third party contractor performing any or part of the manufacturing, packaging, labeling, testing, handling, and/or release of Client Product.

4.1.4 Self-Inspection

Patheon will perform self-inspections of its premises, facilities, and processes used to manufacture, package, test, and store the Client’s starting, intermediate, and/or finished products in accordance with Patheon’s written standard operating procedures (“SOPs”) to ensure compliance with cGMP and this Agreement.

4.2 REGULATORY REQUIREMENTS

4.2.1 Permits

The Client will be solely responsible for obtaining or maintaining, on a timely basis, any permits or other regulatory approvals for the Products or the Specifications, including, without limitation, all marketing and post-marketing approvals.

Patheon will obtain and maintain the appropriate manufacturing license(s) to allow for the Manufacturing Services.
4.2.2 Regulatory Filing / Registration Change Control

The Client will determine whether changes to the Product or related to the Product will impact a regulatory filing and will apply for and receive approval for any required manufacturing amendment, change or addition to their Product marketing authorization. Upon request, Patheon will assist in the preparation and review of pertinent sections of new or supplemental regulatory applications before filing. The Client will give Patheon copies of sections of product registration/regulatory submissions that are relevant to the manufacture of the Product. The Client is responsible for all communications with Regulatory Authorities as well as for the approval, maintenance, and updating of marketing approval in a timely manner.

4.2.3 Regulatory Compliance

Patheon will ensure that Product(s) are manufactured and tested in strict compliance with current US Federal regulatory and statutory requirements relating to Good Manufacturing Practices (GMP) (US 21 CFR parts 210 and 211 for the manufacture of finished medicinal product) as applicable, regulatory approvals and local laws and regulations applicable at the site(s) of manufacture and/or testing.

Patheon warrants that is not debarred under the U.S. Generic Drug Enforcement Act of 1992 and does not employ or use the services of any individual who is debarred or who has engaged in activities that could lead to being debarred.

Patheon further warrants that they shall not use in any capacity the services of any person or company debarred or convicted of a crime for which a person could be debarred.

4.2.4 Government Agency Inspections, Communication and Requisitions

Patheon will permit all relevant inspections by regulatory authorities of premises, procedures, and documentation.

Patheon will notify the Client within three Business Days of receipt of any notice of inspection from a regulatory authority and within one Business Day of any regulatory authority request for Product samples, batch documentation, or other information related to the Product.

Patheon will notify the Client within one Business Day of receipt of any Form 483’s warning letter or the like from any regulatory agency that relates to the Product; or if the supply of Product will be affected, or if the facilities used to produce, test or package the Product will be affected.

The responses from Patheon related to the Product will be reviewed and approved by the Client before submission to the regulatory agency. But...
Patheon reserves the right to respond to the regulatory agency without approval, if, in the reasonable opinion of Patheon’s Legal counsel, it is required to do so.

4.3 MATERIAL CONTROL

4.3.1 Test Methods and Specifications
The Client will give Patheon a copy of the Specifications and test methods used if the Client issues raw material Specifications.

4.3.2 Material Destruction
Patheon has the right to either return to the Client or dispose of any outdated or rejected material. If the material is disposed of, disposal will be consistent with the nature of the material and sent to a permitted waste disposal facility. Before disposal:

(i) Patheon will send notice to the Client of Patheon’s intent to dispose of the material. If no direction is received from the Client, Patheon will dispose of the material no sooner than 90 days after the date of the notice.

(ii) The materials will be disposed and destroyed in compliance with local environmental regulations and performed in a secure and legal manner that prevents unauthorized use or diversion.

Patheon will maintain destruction records in accordance with Patheon SOPs.

4.3.3 Vendor Audit Responsibility

4.3.3.1 Excipient and API Vendors:

(i) If the Client stipulates an excipient or API vendor, the Client will audit and approve the vendor and ensure cGMP compliance in accordance with Section 4.3.4 of this Agreement. The Client stipulated vendor(s) will be included on the Client’s approved vendor list (Appendix D).

(ii) If Patheon stipulates the excipient vendor, Patheon will audit and approve the vendor and ensure cGMP compliance in accordance with Patheon’s SOPs. The Patheon stipulated vendor(s) will be included on Patheon’s approved vendor list (Appendix C).

4.3.3.2 Packaging Component Vendors:

(i) If the Client stipulates a packaging component vendor, the Client will audit and approve the manufacturer and ensure cGMP compliance. The
Client stipulated vendor(s) will be included on the approved vendor list (Appendix D).

(ii) If Patheon stipulates the packaging component vendor, Patheon will audit and approve the vendor and ensure cGMP compliance in accordance with Patheon’s SOP. The Patheon stipulated vendor(s) will be included on the approved supplier list (Appendix C).

4.3.4 Client Furnished Materials

The Client is responsible for vendor qualification of Client furnished materials and for providing a certificate of compliance confirming the following:

(i) That the materials are compliant with the provisions outlined in the “Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products” (EMEA/410/01, Rev.2 or update); and

(ii) A residual solvent certificate confirming that there is no potential for specific toxic solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III to be present and the material, if tested, will comply with established EP / USP / ICH requirements. If any of the solvents listed in the EP / USP / ICH residual solvents Class I, Class II or Class III are used in the manufacture or are generated in the manufacturing process, solvents of concern will be indicated.

4.3.5 In-Coming Material Release

Before its use in the manufacture of any Product, all material(s) will be inspected, tested, and released by Patheon against the Specification approved by the Client.

Patheon to certify that raw materials and components under their control are compliant with the provisions outlined in the “Note for Guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products” (EMEA/410/01, Rev.2 or update).

4.4 BUILDING, FACILITIES, UTILITIES, AND EQUIPMENT

4.4.1 General

All buildings and facilities used in the manufacturing, packaging, testing and storage of any materials and/or Product will be of suitable size, construction and location to facilitate cleaning, and will be maintained in a good state of repair. Maintenance and cleaning records will be kept in accordance with Patheon’s SOPs.
4.4.2 Equipment, Calibration and Preventative Maintenance
All equipment used in the manufacturing, packaging, testing, and storage of any materials and/or Product will be suitable for its intended use and appropriately located to allow for cleaning and maintenance. Calibration and maintenance records will be kept according to Patheon SOPs for all critical equipment. Patheon will calibrate instrumentation and qualify computer systems used in the manufacture and testing of the Product in accordance with Patheon’s SOPs.

4.4.3 Environmental Monitoring Program
Patheon will perform and maintain an environmental monitoring program. The collected data will be reviewed and interpreted by the responsible person within Patheon’s quality unit. Any out of limit results will be managed appropriately in accordance with Patheon SOPs.

4.5 PRODUCTION CONTROLS

4.5.1 Master Batch Record
The Client will give Patheon the Specifications and Patheon will manufacture Product in accordance with the Specifications. Patheon is responsible for preparing the master batch records for the Product. The Client is responsible to review and approve the master batch records before the manufacture of the Product. Patheon will not make changes to master batch records except through the established Patheon change control system, and all master document revisions will be approved by the Client’s quality unit. Any changes made to issued batch records (before master revisions) must be reviewed and approved by the Client’s quality unit before implementation unless otherwise agreed to in writing.

4.5.2 Reprocessing and Rework
Patheon will not reprocess or rework the Product without the prior written consent from the Client. Reprocessing is defined as the introduction of material back into the process and repeating a step, (e.g. redrying, remilling) using the same equipment and techniques of the established manufacturing process. Rework is defined as the introduction of material to one or more processing steps that are different from the established manufacturing process.
4.5.3 Personnel Training

Patheon will give appropriate training to its employees. Each person engaged in the manufacture, packaging, testing, storage, and shipping of the Product will have the education, training, and experience necessary, consistent with current GMP and safety training requirements.

4.6 PACKAGING, LABELING AND PRINTED MATERIALS

4.6.1 Master Batch Packaging Records

The Client will give Patheon the Specifications for all packaging components. Patheon will create, control, issue, and execute in accordance with the master batch packaging record and the Specifications. The Client is responsible to review and approve the master batch records before the packaging of the Product.

Patheon will not make changes to master batch packaging records except through the established Patheon change control system, and all master document revisions will be approved by the Client’s quality unit. Any changes made to issued batch records (before Master revisions) must be reviewed and approved by the Client’s quality unit before implementation unless otherwise agreed to in writing.
4.6.2 **Printed Material and Artwork**

The Client will give Patheon the Specifications for artwork and labelling text (blister, carton, leaflet, label etc.). The labelling proofs must be reviewed and approved by the Client.

4.6.3 **Test Methods and Method Validation**

The Client will give Patheon the test methods and method validation for packaging components. Where applicable, Patheon will provide test methods and validation for packaging components purchased from vendors on the Patheon approved vendor list only (Appendix C).

4.7 **EXCEPTION REPORTS (DEVIATIONS / INVESTIGATIONS)**

4.7.1 **Manufacturing Instruction Deviations**

Patheon will document, investigate, and resolve deviations from approved manufacturing instructions or Specifications in accordance with Patheon’s SOPs. Patheon will report and obtain approval from the Client’s responsible person for deviation report (“DR”) type deviations where there is a potential to affect Product quality. This Client approval will not be unreasonably withheld. Patheon will give the Client copies of all DR’s as part of the executed batch record. Any additional studies that may be needed as part of the investigation are to be reviewed and approved by Client prior to the initiation of the study.

4.7.2 **Packaging Instructions Deviations**

Patheon will document, investigate, and resolve any deviation from approved packaging instructions or Specifications according to Patheon SOPs. Patheon will report and obtain approval from the Client’s responsible person for DR type deviations where there is a potential to affect Product quality. This Client approval will not be unreasonably withheld. Patheon will give the Client copies of all DR’s as part of the executed batch packaging record.

4.7.3 **Notification of Deviations**

Patheon will notify the Client within one Business Day if any significant deviation occurs during manufacture or packaging of the Product, where the deviation has the potential to affect the quality, efficacy or availability of the Product.

4.8 **RELEASE OF PRODUCT**

4.8.1 **Test Methods and Specifications**
4.8.2 Batch Release for Shipment
Batch review and release for shipment to the Client will be the responsibility of Patheon’s Quality Assurance department who will act in accordance with Patheon’s SOPs.

4.8.3 Certificate of Compliance
For each batch released by Patheon for shipment to the Client, Patheon will deliver to the Client a certificate of compliance that will include a statement that the batch has been manufactured in accordance with cGMPs and the Specifications.

4.8.4 Product Release
The Client will have sole responsibility for release of the Product to the market. When Patheon qualified person (“QP”) services are employed, Patheon QP may release the Product for distribution on behalf of the Client.

4.9 VALIDATION

4.9.1 Master Validation Plan
Patheon will establish applicable master validation plans and maintain a validation program for the Product. The Client will review and approve the master validation plan, performance qualification and process validation protocols and reports for the Product.

4.9.2 Cleaning Validation Program
The Client will give Patheon the toxicological information to be used in the development of a cleaning program. Patheon will maintain an appropriate cleaning and cleaning validation program.

4.9.3 Analytical Method and Procedure Validation
The Client must ensure that its analytical methods and manufacturing procedures (including packaging procedures) are validated. If the methods and procedures are not validated by the Client, then Patheon may assist in validation development at Client’s cost.

4.10 CHANGE CONTROL

4.10.1 General
Patheon will notify and obtain approval from the Client before implementing any proposed changes to the process, materials, testing, equipment or...
premises, where the changes may directly affect the Product. This Client approval will not to be unreasonably withheld.

The Client will be responsible for determining whether or not to initiate registration variation procedures and for maintaining adequate control over the quality commitments of the marketing authorization made to the regulatory authorities by the Client for the Products.

Following validation of a process change, Patheon will deliver a copy of the related validation report to the Client and the associated stability data, if applicable, as it becomes available.

4.11 DOCUMENTATION

4.11.1 Record Retention

Patheon will maintain all batch records for a minimum of one year past Product expiry date and supply all these records to the Client upon request.

Patheon will maintain records and evidence on the testing of raw materials and packaging/labeling materials for five years after the materials were last used in the manufacture or packaging/labeling of the Product.

At the end of the above noted retention period, the Client will be contacted concerning the future storage or destruction of the documents.

4.11.2 Batch Document Requisition

At the request of the Client, Patheon will give the Client a copy of any of the executed batch documents relating to Products within five Business Days of the request.

4.12 LABORATORY CONTROLS

4.12.1 Specifications and Test Methods

Patheon will test and approve starting material, intermediate, and the finished Product in accordance with the approved Specifications, analytical methods, and Patheon’s SOPs.

Patheon will provide copies of the internal versions of the analytical test methods to Client.

The Client will give Patheon the Active Material Specifications including a certificate of analysis.
The Client will give Patheon the test methods for Active Material and excipient’s (if non-compendial). The Client is responsible for validating non-compendial testing methods. If these methods are not validated by the Client, then Patheon may assist in validation development at Client’s cost.

4.12.2 Out of Specifications (OOS) / Out of Trend (OOT)
Patheon will notify Client’s quality unit of confirmed out-of-Specification (“OOS”) or out-of-trend (“OOT”) results within one Business Day. Patheon will generate a DR type deviation as per Patheon SOPs and obtain approval of the DR from the Client’s responsible person within their quality unit. This Client approval will not be unreasonably withheld. Any additional studies that may be needed as part of the investigation are to be reviewed and approved by Client prior to the initiation of the study.

4.13 STABILITY
4.13.1 Sample Storage
Patheon will store stability samples as required.

4.13.2 Stability Studies and Protocol
The Client will develop and validate stability indicating assay(s) before process validation. If required, Patheon may assist at Client’s cost.
If applicable, Patheon will conduct stability studies in accordance with the agreed and validated stability testing analytical methods at the agreed upon testing points in accordance with the approved stability protocol.
Patheon will perform the stability testing described in a stability protocol agreed to by both Patheon and the Client. Patheon will give the Client the stability data on an ongoing basis as agreed to by both parties.

4.13.3 Stability Failures
Patheon will notify the Client of any stability failure for Product supplied to the Client. If a result indicates that a Product has failed to remain within stability Specifications, Patheon will notify the Client within one Business Day.
Any trend in stability results indicating a potential OOS at a future stability test point should be communicated to the other party in written form within 1 (one) month of identifying such trend.

4.13.4 Termination of MSA

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If the MSA is terminated, Patheon will continue to give the Client the stability data supporting the acceptability of the Product until all Product distributed by the Client has reached the end of its shelf-life.

4.14 **Annual Product Review**

4.14.1 **General**

The Client will complete the annual product review in accordance with regulatory requirements of the Product marketed authorization. Patheon to prepare annual product review for third party commercial products and will give the Client copies of all information and correspondence necessary to support the annual product reviews.

4.15 **Storage and Distribution**

4.15.1 **General**

Patheon will ship Product in accordance with the agreed qualified transportation requirements provided by the Client to Patheon.

4.15.2 **Product Storage and Shipment Changes**

Patheon will communicate any proposed changes in storage or shipping to the Client for review and approval. The Client approval will not be unreasonably withheld.

4.15.3 **Product Quarantine**

Patheon will have a system in place for assuring that unreleased Product is not shipped unless authorized by the Client’s quality unit.

4.16 **Product Complaints**

4.16.1 **Complaint Investigation**

The Client will investigate and resolve all medical and non-medical Product complaints. Patheon will investigate all Patheon manufacturing and packaging-type Product complaints related to the Manufacturing Services. The Client, using reasonable efforts, will retrieve complaint sample(s) and forward them to Patheon in a timely manner to aid a complete and comprehensive investigation. Patheon will respond to Client in writing within 20 business days, with exception of critical complaints in which Patheon will respond within 15 days. If a longer investigation is required Patheon will provide an investigation plan to Client. In this case both parties have to mutually agree upon the timeline.
If Patheon receives a complaint from a Client customer directly, Patheon must forward that complaint to Client within 2 (two) business days of receipt.

4.17 **PRODUCT RECALL**

4.17.1 **Product Recall Notification**

The Client will notify Patheon about a Product recall or other regulatory type product notification (e.g. field alert) as soon as possible, but, in any event, before informing the appropriate regulatory authorities. The Client will be responsible for all related recall activities.

4.17.2 **Government Agency Notification**

The Client will perform the Product recall and will inform the appropriate regulatory authorities. Where legislated, Patheon reserves the right to notify regulatory authorities of Product quality issues. Patheon will inform the Client before notifying the regulatory authorities.

4.18 **REFERENCE AND RETENTION SAMPLES**

4.18.1 **Excipient and Active Ingredient Reference Sample**

Patheon will keep a reference sample of each material received by Patheon and used to manufacture the Product. The reference sample will consist of at least two times the necessary quantity for all Quality Control tests required to determine whether the materials meet required Specifications.

The reference samples will be stored by Patheon under controlled conditions in accordance with GMP storage requirements for one year beyond the expiration date of the last batch of the product containing the materials. The reference samples will be made available by Patheon to the Client, if requested.

4.18.2 **Finished Product Retention Sample**

Retention samples of finished Product will be retained by Patheon for one year past Product expiry or for a longer period as required by law. Where applicable, the legal sample(s) of finished Product must be retained by the Client.

***

Quality Agreement
QG01-05-T001-01
IN WITNESS WHEREOF, the parties have caused their duly authorized officer to execute and deliver this Quality Agreement as of the Effective Date identified on the first page:

**Horizon Pharma Inc.**

By: /s/ Cara Weyker  
Cara Weyker  
Vice President, CMC Regulatory and Quality Systems  
Date: 10 Dec. 2013

By: /s/ Jeff Sherman  
Jeff Sherman, MD, FACP  
Chief Medical Officer & Executive Vice President, Development, Manufacturing, and Regulatory Affairs  
Date: 10 Dec. 2013

**Patheon Pharmaceuticals Inc.**

By: /s/ David J. Leuck  
David J. Leuck  
Associate Director Quality Compliance  
Date: 09 Dec. 2013

APPROVED BY LEGAL

FPM / 12-09-13
Initials  Date

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SECTION 5: APPENDICES

- Appendix A: Product(s)
- Appendix B: Quality Contacts
- Appendix C: Patheon Approved Supplier List
- Appendix D: Client Approved Supplier List
- Appendix E: Patheon Approved Contract Laboratories List
**APPENDIX A: PRODUCT(S)**

<table>
<thead>
<tr>
<th>Products(s)</th>
<th>Package</th>
<th>Dosage (Strength)</th>
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</thead>
<tbody>
<tr>
<td>Vimovo</td>
<td>60 Count Bottles</td>
<td>500mg</td>
</tr>
<tr>
<td></td>
<td>60 Count Bottles</td>
<td>375mg</td>
</tr>
<tr>
<td></td>
<td>6 Count Bottles</td>
<td>500mg</td>
</tr>
</tbody>
</table>

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# APPENDIX B: QUALITY CONTACTS

## Patheon

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Name</th>
<th>Title</th>
<th>Phone</th>
<th>Fax</th>
<th>E-mail</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Assurance</td>
<td>Garry Hedgepeth</td>
<td>Quality Assurance Manager-GMP Services</td>
<td>513-948-</td>
<td>513-948-7393</td>
<td><a href="mailto:Patty.Mclean@Patheon.com">Patty.Mclean@Patheon.com</a></td>
<td>2110 E. Galbraith Rd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>224-383-3063</td>
<td></td>
<td></td>
<td>Cincinnati, OH 45237-1625</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Greg Hammer</td>
<td>QA Regulatory Leader</td>
<td>513-948-3135</td>
<td>513-948-7393</td>
<td><a href="mailto:Gregory.Hammer@Patheon.com">Gregory.Hammer@Patheon.com</a></td>
<td>2110 E. Galbraith Rd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cincinnati, OH 45237-1625</td>
</tr>
<tr>
<td>Product Complaints</td>
<td>Tina Cranmer</td>
<td>QA Complaints</td>
<td>513-948-7042</td>
<td>513-948-7393</td>
<td><a href="mailto:cpatheoncomplaints@patheon.com">cpatheoncomplaints@patheon.com</a></td>
<td>2110 E. Galbraith Rd</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cincinnati, OH 45237-1625</td>
</tr>
<tr>
<td>Product Release</td>
<td>Charles Venable</td>
<td>Quality Assurance Manager-Master Documents</td>
<td>513-948-7783</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### APPENDIX C: PATHEON APPROVED VENDOR LIST

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Vendor</th>
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</thead>
<tbody>
<tr>
<td>50004558</td>
<td>CROSCARMELLOSE SODIUM</td>
<td>FMC Biopolymer</td>
</tr>
<tr>
<td>50018602</td>
<td>MAGNESIUM STEARATE 5712</td>
<td>Mallinckrodt</td>
</tr>
<tr>
<td>70013874</td>
<td>SILICON DIOXIDE COLLOIDAL NF/EP/JP</td>
<td>Cabot Corp.</td>
</tr>
<tr>
<td>70014144</td>
<td>Povidone K90 NF/EP</td>
<td>ISP</td>
</tr>
<tr>
<td>50004341</td>
<td>CARNAUBA WAX</td>
<td>Strohmeyer &amp; Arpe</td>
</tr>
<tr>
<td>50004447</td>
<td>ISOPROPYL ALCOHOL</td>
<td>Dow Chemical</td>
</tr>
<tr>
<td>70012868</td>
<td>PLASACRYL</td>
<td>Emerson Resources</td>
</tr>
<tr>
<td>70012869</td>
<td>OPADRY II WHITE 40F18389</td>
<td>Colorcon</td>
</tr>
<tr>
<td>70012870</td>
<td>OPADRY CLEAR 00F19246</td>
<td>Colorcon</td>
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<tr>
<td>70013591</td>
<td>OPACODE WB BLACK NS-78-17821</td>
<td>Colorcon</td>
</tr>
<tr>
<td>70014142</td>
<td>EUDRAGIT L 30 D-55 NF/EP</td>
<td>Evonik Rohm GmbH</td>
</tr>
<tr>
<td>70014143</td>
<td>POLYSORBATE 80 NF/EP</td>
<td>Croda Inc.</td>
</tr>
<tr>
<td>70014146</td>
<td>TRIETHYL CITRATE NF/EP</td>
<td>Vertellus Specialties Inc.</td>
</tr>
<tr>
<td>70016831</td>
<td>OPADRY YELLOW 05F92577</td>
<td>Colorcon</td>
</tr>
<tr>
<td></td>
<td>Bottle—110cc</td>
<td>Rexam</td>
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<tr>
<td></td>
<td>HDPE bottles—45cc</td>
<td>Amcor -</td>
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<tr>
<td></td>
<td>PP Caps</td>
<td>Berry Plastics</td>
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<tr>
<td></td>
<td>Liners</td>
<td>Selig FS1-7</td>
</tr>
<tr>
<td></td>
<td>Silica Desiccants</td>
<td>Unipac SafeGuard 100</td>
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<td>Multisorb</td>
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</tbody>
</table>

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### APPENDIX D: CLIENT APPROVED VENDOR LIST

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>70014942</td>
<td>Esomeprazole</td>
<td>Minakem</td>
</tr>
<tr>
<td>70015517</td>
<td>Naproxen</td>
<td>Divis</td>
</tr>
</tbody>
</table>

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---

**Performance the World Over**
APPENDIX E: PATHEON APPROVED CONTRACT LABORATORIES LIST

Accugenix

223 Lake Dr.

Newark Delaware 19702

302-292-8888

Lancaster Labs

2425 New Holland Pike

Lancaster PA 17605

717-656-2300

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EXHIBIT C

QUARTERLY ACTIVE MATERIALS INVENTORY REPORT

TO: HORIZON PHARMA INC  
FROM: PATHEON PHARMA INC. [or applicable Patheon entity]  
RE: Active Materials quarterly inventory report under Section 2.2(a) of the Master Manufacturing Services Agreement dated October 31, 2013 (the “Agreement”)

[…***…]

- 2 -
EXHIBIT D

REPORT OF ANNUAL ACTIVE MATERIALS INVENTORY RECONCILIATION
AND CALCULATION OF ACTUAL ANNUAL YIELD

TO: HORIZON PHARMA INC.
FROM: PATHEON PHARMACEUTICALS INC. [or applicable Patheon entity]
RE: Active Materials annual inventory reconciliation report and calculation of Actual Annual Yield under Section 2.2(a) of the Master Manufacturing Services Agreement dated October 31, 2013 (the “Agreement”)

[...***…]

***Confidential Treatment Requested

- 2 -
Based on the foregoing reimbursement calculation Patheon will reimburse Client the amount of $ .

Capitalized terms used in this report have the meanings given to the terms in the Agreement.

DATE: ________________

PATHEON PHARMACEUTICALS INC.

[or applicable Patheon entity]

Per: ________________________________
Name: ________________________________
Title: ________________________________

***Confidential Treatment Requested

- 2 -
EXHIBIT E

EXAMPLE OF PRICE ADJUSTMENT DUE TO CURRENCY FLUCTUATION

Section 4.2(d)

SAMPLE EXCHANGE CALCULATION

| Initial Exchange Rate: | 1.000 | CAD/USD |
| Set Exchange Rate:     | 0.998 | CAD/USD |

Initial Price: 3.59
Revised Price (FX): 3.70 (Material price and PPI adjustments)

Calculation:

\[
\text{[Revised Price (After FX)] = [Revised Price (Before FX)] \times [Initial Exchange Rate] / [Set Exchange Rate]}\\
\]

\[
= 3.70 \times \frac{1.000}{0.998}\\
= 3.71
\]