

## EX-10.1 2 d271369dex101.htm LICENSE AGREEMENT

[\*\*\*] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

## Exhibit 10.1

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (“**Agreement**”) is entered into as of the 18<sup>th</sup> day of August, 2011 (the “**Execution Date**”), by and between Puma Biotechnology, Inc., a corporation organized and existing under the laws of Delaware with offices at 10940 Wilshire Blvd, Suite 600, Los Angeles, CA 90024 (“**LICENSEE**”) and Pfizer Inc., a corporation organized and existing under the laws of Delaware with offices at 235 East 42<sup>nd</sup> Street, New York, NY 10017 (“**PFIZER**”), on its own behalf and on behalf of its Affiliates. LICENSEE and PFIZER may, from time-to-time, be individually referred to as a “**Party**” and collectively referred to as the “**Parties**”.

**RECITALS**

WHEREAS, PFIZER controls, directly or through its affiliates, certain technology relating to a compound known as neratinib, and is conducting Phase III clinical trials of such compound for the treatment of cancer; and

WHEREAS, LICENSEE wishes to obtain, and PFIZER wishes to grant, at the Closing (as defined below) certain licenses under such technology for the development, manufacture and commercialization of neratinib worldwide, on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

**1. DEFINITIONS**

- 1.1. “**Affiliate**” means, with respect to a Party, any Person that controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “**control**” shall refer to: (a) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (b) the ownership, directly or indirectly, of fifty percent (50%) or more of the voting securities of such entity.
- 1.2. “**Applicable Laws**” means all applicable laws, statutes, rules, regulations and guidelines, including, without limitation, all good manufacturing practices and all applicable standards or guidelines promulgated by the appropriate Regulatory Authority.
- 1.3. “**Business Day**” means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York are authorized or required by law to remain closed.
- 1.4. “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

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- 1.5. **“Calendar Year”** means any twelve (12) month period commencing on January 1.
- 1.6. **“Clinical Trial”** means a clinical study of Product as described in 21 CFR §312.21(a) (**“Phase I Clinical Trial”**), 21 CFR §312.21(b) (**“Phase II Clinical Trial”**), or 21 CFR §312.21(c) (**“Phase III Clinical Trial”**) (in each case as hereafter modified or amended and including any foreign equivalents thereto).
- 1.7. **“Closing”** has the meaning provided in Section 2.7.1.
- 1.8. **“Closing Date”** has the meaning provided in Section 2.7.1.
- 1.9. **“Combination Product”** means a Product that includes a Compound and at least one (1) Other Active Ingredient.
- 1.10. **“Commence”** when used with respect to a Clinical Trial, means [\*\*\*].
- 1.11. **“Commercialize”** or **“Commercialization”** means to manufacture for sale, market, promote, distribute, and sell.
- 1.12. **“Commercially Reasonable Efforts”** means, with respect to the Development or Commercialization of a Product, that level of efforts and resources commonly dedicated in the research-based pharmaceutical industry by a company to the development or commercialization, as the case may be, of a product of similar commercial potential at a similar stage in its lifecycle, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then current competitive environment for such product and the likely timing of such product’s entry into the market, the regulatory environment and status of such product, and other relevant scientific, technical and commercial factors.
- 1.13. **“Compound”** means (a) the compound designated by PFIZER as PF-05208767, also known as “neratinib,” “WAY 179272” or “HKI-272” (the **“Neratinib Compound”**), (b) the compound designated by PFIZER as PF-05208766, also known as “WAY 178357” or “HKI-357” (the **“HKI-357 Compound”**), (c) [\*\*\*], (d) [\*\*\*], (e) [\*\*\*], and (f) [\*\*\*], as well as [\*\*\*].
- 1.14. **“Control”** or **“Controlled”** means, with respect to any Intellectual Property Rights, material or document, the legal authority or right (whether by ownership, license or otherwise) of a Party to grant a license or a sublicense of or under such Intellectual Property Rights, or to provide or provide access to such material or document, to the other Party without breaching the terms of any agreement with a Third Party.
- 1.15. **“Develop”** or **“Development”** means to conduct any and all research and development activities (including related manufacturing activities) necessary to obtain Regulatory Approval.

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- 1.16. **“DR Executives”** has the meaning provided in Section 16.2.
- 1.17. **“Excess Trial Expenses”** has the meaning provided in Section 3.6.4.
- 1.18. **“Existing Advanced Trials”** means [\*\*\*].
- 1.19. **“Existing Other Trials”** means the trials set forth under the headings [\*\*\*], excluding the Existing Advanced Trials.
- 1.20. **“Existing Product”** means any Product that is the subject of an Existing Trial as of the Execution Date.
- 1.21. **“Existing Trials”** means the Existing Advanced Trials and the Existing Other Trials.
- 1.22. **“FDA”** means the United States Food and Drug Administration, or a successor federal agency thereto.
- 1.23. **“Financing Condition”** means confirmation (1) that LICENSEE has issued and sold equity securities resulting in gross proceeds to LICENSEE of at least \$25 million, and (2) that the net worth of the LICENSEE immediately following such financing shall be at least \$22.5 million. To satisfy the Financing Condition, LICENSEE shall provide PFIZER with a Balance Sheet, certified by LICENSEE’s President or Chief Financial Officer, and such other evidence as PFIZER may reasonably request.
- 1.24. **“First Commercial Sale”** means with respect to a Product, the first sale for use or consumption by an end user of the Product following receipt of Regulatory Approval for such Product in a country in the Territory.
- 1.25. **“Future Patent Rights”** means all Patents other than Patent Rights that (a) are Controlled by PFIZER or its Affiliates during the term of the Agreement and (b) [\*\*\*]. For the avoidance of doubt, to the extent included in the foregoing, “Future Patent Rights” shall:
- 1.25.1. include [\*\*\*];
  - 1.25.2. exclude [\*\*\*]; and
  - 1.25.3. include [\*\*\*].
- 1.26. **“GAAP”** means the generally accepted accounting principles in the United States, consistently applied.
- 1.27. **“GHC License Agreement”** means the License Agreement between The General Hospital Corporation d/b/a Massachusetts General Hospital (“MGH”) and Wyeth, an Affiliate of PFIZER, acting through its Wyeth Pharmaceuticals Division dated as of December 21, 2006.

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- 1.28. **“Governance Committee”** has the meaning set forth in Section 4.6.
- 1.29. **“IND”** means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of a Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.
- 1.30. **“Intellectual Property Rights”** means all trade secrets, copyrights, patents and other patent rights, Trademarks, moral rights, know-how and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.
- 1.31. **“Know-How”** means all confidential and proprietary information and data Controlled by PFIZER (i) [\*\*\*], and (ii) any other confidential and proprietary information and data Controlled by PFIZER [\*\*\*].
- 1.32. **“Knowledge”** means first hand and actual knowledge of [\*\*\*] and is not meant to require or imply [\*\*\*].
- 1.33. **“Licensed Technology”** means collectively, the Patent Rights and Know-How.
- 1.34. **“Licensee Trial Cost Cap”** means the [\*\*\*] the [\*\*\*] that LICENSEE may incur beginning on January 1, 2012 in conducting the Existing Trials under Section 3.6. The parties acknowledge and agree that any expenses that LICENSEE incurs as a result of [\*\*\*] will not be counted towards the Licensee Trial Cost Cap. In addition, Section 4.4.2 sets forth certain [\*\*\*], and Section 4.4.3 sets forth [\*\*\*].
- 1.35. **“Major Market Country”** means each of the United States, Canada, the United Kingdom, France, Germany, Italy, Spain, the Nordic countries, China, and Japan.
- 1.36. **“Milestone”** means each milestone as set forth in Section 5.1.1.
- 1.37. **“NDA/BLA”** means: (a) a new drug application or a biologic license application filed with the FDA for authorization for marketing a Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.
- 1.38. **“Net Sales”** means the gross amount invoiced by or on behalf of LICENSEE, its Affiliates and their respective sublicensees for sales of any Product in the Territory (other than sales among LICENSEE, its Affiliates or sublicensees for subsequent resale in which case the first sale to a Third Party that is not a sublicensee shall be used for calculation of Net Sales), less the following deductions if and to the extent they are (i) included in the gross invoiced sales price of the Product or otherwise directly incurred by LICENSEE, its Affiliates and their respective sublicensees with respect to the sale of the Product, (ii) normal and customary, and (iii) not otherwise deducted in computing other amounts hereunder: (a) rebates, quantity and cash discounts, and other discounts

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to customers, (b) taxes (except income taxes) and tariffs or duties paid, absorbed or allowed which are directly related to the sale of the Product, (c) credits, allowances, discounts and rebates to, and chargebacks for, spoiled, damaged, out-dated, rejected or returned Product (including in connection with Product withdrawals, expired Product and Product recalls), (d) actual freight and insurance costs, including without limitation the costs of export licenses, shipping, postage and handling charges, incurred in transporting the Product to customers, (e) discounts or rebates or other payments required by Applicable Law, including any governmental special medical assistance programs, (f) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of the Product, and (g) bad debts actually written off in connection with such Products.

Subsections (a) through (g) shall be collectively referred to as “**Deductions**”. The following principles shall apply in the calculation of Net Sales:

1.38.1. In the case of any sale of Product which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Product is paid for, if paid for before shipment or invoice.

1.38.2. In the case of any sale or other disposal of Product for non-cash consideration, Net Sales shall be calculated as the fair market price of the Product in the country of sale or disposal. Notwithstanding the foregoing, provision of the Product for the purpose of conducting pre-clinical or clinical research shall not be deemed to be a sale. For clarity, any Product provided as free samples or as charitable donations shall not give rise to any Net Sales.

1.38.3. Net Sales shall be determined in accordance with GAAP.

Notwithstanding the foregoing, in the event a Product is sold in a country in the Territory as a Combination Product, Net Sales of the Combination Product will be calculated as follows:

(i) If the Compound contained in the Combination Product and Other Active Ingredient(s) contained in the Combination Product each are sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction  $A/(A+B)$ , where A is the average gross selling price in such country of the Compound sold separately in the same formulation and dosage, and B is the sum of the average gross selling prices in such country of such Other Active Ingredient(s) sold separately in the same formulation and dosage, during the applicable Calendar Year.

(ii) If the Compound contained in the Combination Product is sold independently of the Other Active Ingredient(s) contained in the Combination Product in such country, but the average gross selling price of such Other Active Ingredient(s) in such country cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination

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Product by the fraction  $A/C$  where A is the average gross selling price in such country of such Compound sold independently and C is the average gross selling price in such country of the entire Combination Product, during the applicable Calendar Year.

(iii) If the Other Active Ingredient(s) contained in the Combination Product are sold independently of the Compound contained in the Combination Product in such country, but the average gross selling price of such Compound in such country cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction  $(1-(B/C))$ , where B is the average gross selling price in such country of such Other Active Ingredient(s) and C is the average gross selling price in such country of the entire Combination Product, during the applicable Calendar Year.

(iv) If the Compound contained in the Combination Product and Other Active Ingredient(s) contained in the Combination Product are not sold separately in such country, or if they are sold separately but the average gross selling price of neither such Compound nor such Other Active Ingredient(s) can be determined in such country, Net Sales of the Combination Product in such country will be calculated by mutual agreement of the Parties.

**1.39. “Other Active Ingredient”** means any therapeutically active pharmaceutical ingredient other than a Compound.

**1.40. “Patents”** means (a) unexpired letters patent (including without limitation inventor’s certificates), including without limitation any substitution, extension, registration, confirmation, reissue, re-examination, addition, renewal, supplemental protection certificate or inventor’s certificate, and (b) pending applications for letters patent, including without limitation any continuation, divisional, or continuation-in-part thereof, and any provisional or nonprovisional applications, and (c) all foreign or international equivalents of any of the foregoing in any country.

**1.41. “Patent Rights”** means all Patents that (i) (a) are Controlled by PFIZER or its Affiliates as of the Execution Date or the Closing Date and (b) [\*\*\*] or (ii) (A) are Controlled by PFIZER or its Affiliates during the term of this Agreement, (B) [\*\*\*] and (C) [\*\*\*]. The Patent Rights existing as of the Execution Date are set forth on Schedule A, which shall be updated from time to time, at least annually, to identify any new Patents or any changes in the status of Patents. “Patent Rights” shall also include any [\*\*\*]. For the avoidance of doubt, to the extent included in the foregoing, “Patent Rights” shall:

1.41.1. include [\*\*\*];

1.41.2. exclude [\*\*\*]; and

1.41.3. include [\*\*\*].

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- 1.42. **“Person”** means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.
- 1.43. **“[\*\*\*]”** has the meaning set forth in Section 3.5.
- 1.44. **“PFIZER Retained Rights”** means PFIZER’s rights under Sections 2.3 and 2.4 of this Agreement.
- 1.45. **“Product”** means a Compound or any product that contains a Compound.
- 1.46. **“Regulatory Approval”** means, with respect to a Product in any country or jurisdiction, any approval (including where required, pricing and reimbursement approvals), registration, license or authorization that is required by the applicable Regulatory Authority to market and sell the Product in such country or jurisdiction.
- 1.47. **“Regulatory Authority”** means any governmental agency or authority responsible for granting Regulatory Approvals for a Product in the Territory.
- 1.48. **“Regulatory Filings”** means, with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, NDA/BLA, any submission to a regulatory advisory board, any marketing authorization application, and any supplement or amendment thereto.
- 1.49. **“Royalty Term”** means, on a Product-by-Product and country-by-country basis, the period commencing on the First Commercial Sale of the Product in such country and expiring upon the later of: (a) expiration or abandonment of the last Valid Claim of the Patent Rights which covers Use of the Product in such country, or (b) the earlier of (x) the time when Generic Competitors to the Product have achieved [\*\*\*], or (y) [\*\*\*] following the date of First Commercial Sale of the Product in such country. **“Generic Competitors”** means, with respect to any Product being sold in any country, [\*\*\*].
- 1.50. **“Territory”** means worldwide.
- 1.51. **“Third Party”** means any Person other than a Party or an Affiliate of a Party.
- 1.52. **“Trademarks”** has the meaning as set forth in Section 13.6.5(d).
- 1.53. **“Transition Committee”** has the meaning set forth in Section 3.2.1.
- 1.54. **“Transition Committee Identification Date”** has the meaning set forth in Section 3.1.6.
- 1.55. **“Transition Plan”** has the meaning set forth in Section 3.2.1.
- 1.56. **“Trial Completion Activities”** has the meaning set forth in Section 3.6.
- 1.57. **“Trial Completion Plan”** has the meaning set forth in Section 3.6.
- 1.58. **“Use”** means to make, have made, Develop, Commercialize, use, sell, offer for sale, import, and export.

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**1.59. “Valid Claim”** means either: (a) a claim of an issued and unexpired patent included within the Patent Rights, which has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable or unreversed and unappealed decision of a court or other appropriate body of competent jurisdiction, or (b) a claim of a pending patent application included within the Patent Rights, which claim was filed in good faith, has not been pending for more than [\*\*\*], and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

## **2. LICENSE GRANT; CLOSING.**

### **2.1. License Grant.**

**2.1.1. Patent Rights.** Subject to the terms and conditions of this Agreement, including the PFIZER Retained Rights, PFIZER hereby grants to LICENSEE as of the Closing Date an exclusive, sublicensable (subject to Section 2.2), royalty-bearing right and license under the Patent Rights to Use the Products within the Territory. For clarity, the license rights include an exclusive sub-license of rights under the GHC License Agreement, subject to Section 2.6.

**2.1.2. Know How.** Subject to the terms and conditions of this Agreement, including the PFIZER Retained Rights, PFIZER hereby grants to LICENSEE as of the Closing Date an exclusive, sublicensable (subject to Section 2.2), royalty-bearing right and license to use the Know-How in connection with the Use of Products within the Territory.

#### **2.1.3. Future Patent Rights.**

(a) [\*\*\*].

(b) [\*\*\*]. Pfizer may by written notice to LICENSEE at any time (but subject to LICENSEE’s consent thereto) elect to [\*\*\*]. Additionally, as set forth in Section 8.7, LICENSEE has the right to request (which request is subject to PFIZER’s consent) [\*\*\*] subject to the [\*\*\*]. If a Party so proposes [\*\*\*], and the other Party consents to such proposal, as provided in this Section 2.1.3 [\*\*\*], then thereafter such [\*\*\*].

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- 2.2. Sublicense Rights.** After the Closing Date, LICENSEE may sublicense the rights granted to it by PFIZER under this Agreement to any of its Affiliates or to any Third Party, provided that LICENSEE provides to PFIZER prompt written notice after it grants any such sublicense, and further provided that any Third Party sublicensee shall have the necessary financial and technical capacity to carry out the portion of LICENSEE's obligations under this Agreement sublicensed to such Third Party. Any and all sublicenses shall be subject to the following requirements:
- 2.2.1. All sublicenses shall be subject to and consistent with the terms and conditions of this Agreement. In no event shall any sublicense relieve LICENSEE of any of its obligations under this Agreement.
- 2.2.2. LICENSEE shall furnish to PFIZER a true and complete copy of each sublicense agreement and each amendment thereto, which sublicense agreement may be redacted to omit information not directly relevant to the performance of LICENSEE's obligations under this Agreement, within thirty (30) days after the sublicense or amendment has been executed.
- 2.2.3. Any sublicense of the rights granted to LICENSEE under Section 2.1.3(a) shall be granted only in connection with a sublicense of the rights granted to LICENSEE under Section 2.1.1.
- 2.3. Retained Rights.** LICENSEE acknowledges and agrees that PFIZER retains the right for itself and its Affiliates to make, have made, use, have used, import and export Products [\*\*\*].
- 2.4. Residuals.** PFIZER may use for any purpose (other than the development, manufacture or Commercialization of Compounds or Products during the term of this Agreement) the Residuals resulting from PFIZER's access to or work with Products and Know-How. As used herein, "**Residuals**" means information in non-tangible form which may be retained by persons who have had access to Products or Know-How, including information relating to ideas, concepts, know-how or techniques.
- 2.5. No Additional Rights.** Nothing in this Agreement shall be construed to confer any rights upon LICENSEE by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of PFIZER or its Affiliates other than the Licensed Technology, regardless of whether such technology or Intellectual Property Rights shall be dominant or subordinate to any Licensed Technology.
- 2.6. The GHC License Agreement.** LICENSEE acknowledges that its rights herein under Patent Rights that are subject to the GHC License Agreement are, in addition to being limited by the terms and conditions of this Agreement, further limited by the terms and conditions of the GHC License Agreement. To the extent requested by PFIZER from time-to-time, LICENSEE will assume Wyeth's (or PFIZER's) obligations under the GHC License Agreement and/or take reasonable steps to support Wyeth's (or PFIZER's) compliance with obligations therein. At any time, LICENSEE may, upon [\*\*\*] advanced written notice to PFIZER, elect to terminate its license (and sublicense) under the Patent Rights that are subject to the GHC License Agreement. Upon and after the effective date of such termination, LICENSEE shall have no further obligations under this Section 2.6, and no further rights or obligations under this Agreement, with

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respect to such Patent Rights, which shall no longer be considered “Patent Rights” herein. Additionally, no breach by LICENSEE of its obligations under the second sentence of this Section 2.6 (the “GHC Obligations”) shall be a material breach of this Agreement by LICENSEE permitting termination of the entire Agreement by PFIZER. Instead, PFIZER’s right to terminate for any material breach by LICENSEE of the GHC Obligations shall be limited to terminating LICENSEE’s license and sublicense under the Patent Rights that are subject to the GHC License Agreement.

## 2.7. Closing.

2.7.1. Generally. The licenses granted pursuant to Section 2.1 shall become effective (the “**Closing**”) as of the date (the “**Closing Date**”) on which the satisfaction or waiver of each of the conditions set forth in Sections 2.7.2 and 2.7.3 has occurred. If the Closing does not occur within [\*\*\*] days of the Execution Date, this Agreement shall terminate effective as of the end of such period.

2.7.2. Pfizer Closing Condition. The obligations of PFIZER to consummate the transactions contemplated by this Agreement, including the licenses granted pursuant to Section 2.1, are conditioned upon satisfaction of the Financing Condition and PFIZER’s receipt of written notice thereof from LICENSEE; provided that PFIZER may waive such condition. Following such satisfaction and receipt of written notice (or PFIZER’s waiver of such condition), PFIZER will provide to LICENSEE written confirmation (the “**Pfizer Confirmation**”) that the representations and warranties of PFIZER contained in Sections 10.1 and 10.2 are true and correct in all material respects as of the date of such confirmation as if made on the date of such confirmation; provided that such written confirmation may include exceptions (“**Exceptions**”) to such representations and warranties if applicable (which Exceptions, for clarity, if deemed accepted by LICENSEE pursuant to Section 2.7.3, will then apply to such representations and warranties of PFIZER herein made both as of the Execution Date and the Closing Date).

2.7.3. Licensee Closing Condition. The obligations of LICENSEE to consummate the transactions contemplated by this Agreement, including the licenses granted pursuant to Section 2.1, are conditioned upon PFIZER providing the Pfizer Confirmation (as defined in Section 2.7.2) without Exceptions to LICENSEE; provided that if PFIZER provides the Pfizer Confirmation with Exceptions to LICENSEE, LICENSEE may waive such condition by written notice to PFIZER. If LICENSEE so waives the above condition, LICENSEE shall be deemed to have accepted the Exceptions, and PFIZER’s representations and warranties under Sections 10.1 and 10.2 shall be deemed modified by the Exceptions both as of the Execution Date and as of the Closing Date.

2.7.4. Financing Condition. LICENSEE will use commercially reasonable efforts to satisfy the Financing Condition in as short a time as practicable, and

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will provide PFIZER prompt written notice thereof. LICENSEE will provide PFIZER with weekly updates regarding its progress towards satisfying the Financing Condition.

### 3. TRANSITION, [\*\*\*], AND EXISTING TRIALS

**3.1. Overview.** This Section provides for the transition of legal, operational and financial responsibility for Existing Trials and certain related Product development efforts from PFIZER to LICENSEE. The Parties shall use commercially reasonable efforts to complete such transition as expeditiously as practicable.

3.1.1. During the period from the Execution Date until the Closing Date, PFIZER shall have sole responsibility for conducting all Product Development, including the Existing Trials, as PFIZER may determine, in PFIZER's sole discretion, and [\*\*\*].

3.1.2. As of the Closing Date, LICENSEE shall have sole responsibility for Product Development and Commercialization, subject to the terms and conditions of this Agreement, including the transition provisions of this Section 3 and the provisions of Section 4, at LICENSEE's sole expense, except as otherwise expressly provided in this Agreement.

3.1.3. During the period from the Closing Date through December 31, 2011 (the "**Transition Period**"), as more fully provided below, [\*\*\*], subject to the direction and control of the Transition Committee (once formed, as provided for below), [\*\*\*].

3.1.4. During the Transition Period, PFIZER will provide necessary documentation and other materials to LICENSEE and PFIZER and LICENSEE will satisfy their respective obligations under an agreed Transition Plan, as more fully provided below.

3.1.5. During the period from January 1, 2012 through [\*\*\*] in accordance with Section 3.5 below.

3.1.6. As soon as reasonably practicable, but no later than [\*\*\*], the Parties will identify in writing to each other their initial members of the Transition Committee (it being understood that it is important to have the Transition Committee available as soon as reasonably practicable). As used herein, the "**Transition Committee Identification Date**" means the earlier of [\*\*\*].

#### 3.2. Transition Committee.

3.2.1. The Parties will establish, as of the Transition Committee Identification Date, a joint committee to provide advice and input, and make decisions, with respect to (a) the implementation of the Transition Plan set forth in Schedule B

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(the “**Transition Plan**”), (b) the Parties’ Trial Completion Activities and Trial Completion Plan set forth in Schedule C and (c) [\*\*\*], if any, and to review the progress of such activities (the “**Transition Committee**”). The Transition Committee will have an equal number of representatives from each Party and decisions of the Transition Committee shall be made unanimously by the representatives. In the event that the Transition Committee cannot or does not, after good faith efforts, reach agreement on any issue within [\*\*\*] after first considering such issue, such issue shall be referred directly to dispute resolution by the DR Executives as set forth in the second and third sentences of Section 16.2, and Sections 16.4 and 16.5.

3.2.2. Unless otherwise agreed upon in writing by the Parties, the Transition Committee shall meet, in person or by telephone, not less than [\*\*\*] after the Transition Committee Identification Date and not less than [\*\*\*] thereafter until [\*\*\*]. In such meetings, the Transition Committee shall (i) review the progress being made under the Transition Plan and Trial Completion Plan, and the [\*\*\*], (ii) discuss future activities to be conducted under the Transition Plan and Trial Completion Plan, and the [\*\*\*], and the extent to which additional resources need to be applied by either Party or both to complete the transition and achieve trial completion, (iii) review and monitor the budget for Trial Completion Activities for Existing Trials, and (iv) review and agree upon any necessary or desired revisions to the Transition Plan or Trial Completion Plan, or the [\*\*\*]. Upon the request of a Party’s representative on the Transition Committee, subject to the other Party’s prior consent (not to be unreasonably withheld or delayed), other personnel from such Party may attend and participate in such meetings. It is the objective of the Parties, working through the Transition Committee, and in accordance with the terms and conditions of this Agreement including the Schedules hereto, to insure (A) as smooth and efficient a transition from PFIZER to LICENSEE as reasonably practical of all relevant documentation, materials, contractual obligations and regulatory responsibilities related to Products and the Existing Trials and (B) as smooth and efficient a completion of the Existing Trials as reasonably practicable, in both cases in accordance with accepted pharmaceutical industry norms, ethical practices and Applicable Law.

3.2.3. PFIZER’s participation in the Transition Committee is a right and not an obligation; provided that in the event that PFIZER elects not to participate in such committee, LICENSEE shall have the right to proceed with decision-making with respect to such committee at its sole discretion.

- 3.3. Transfer of Documentation.** PFIZER will make available and transfer to LICENSEE, at no cost to LICENSEE, originals or copies of currently available records, data and documentation described in Schedule B as being provided by PFIZER to LICENSEE, as set forth in Section 1.1.1 of Schedule B which exist and are Controlled by PFIZER or its Affiliates as of the Execution Date and are necessary for LICENSEE to continue Developing Products (collectively, “**Documentation**”); provided that LICENSEE agrees that any failure by PFIZER to provide [\*\*\*] to LICENSEE shall [\*\*\*].

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- 3.4. Transition Plan.** During the Transition Period, PFIZER and LICENSEE shall each use commercially reasonable efforts to perform the transition activities specified for each Party in the Transition Plan.
- 3.5. [\*\*\*].** After December 31, 2011, [\*\*\*]. PFIZER will [\*\*\*] and LICENSEE shall [\*\*\*].
- 3.6. Trial Completion Activities With Respect to Existing Trials.** Starting on the Closing Date, each Party will conduct the Existing Trials to the extent it is obligated to do so in this Section 3.6, in accordance with the Trial Completion Plan attached as Schedule C (the “**Trial Completion Plan**” and such activities, the “**Trial Completion Activities**”). The Parties’ Trial Completion Activities will be subject to the Transition Committee’s oversight and any modification of a Party’s obligations with respect to Trial Completion Activities will [\*\*\*].
- 3.6.1. During the Transition Period, PFIZER will continue to conduct or have conducted the Existing Trials on behalf of LICENSEE, subject to the direction and control of the Transition Committee, [\*\*\*].
- 3.6.2. PFIZER and LICENSEE will use commercially reasonable efforts to effect the assignment or other transfer by PFIZER or its Affiliate to LICENSEE, [\*\*\*], of all existing INDs filed by PFIZER or its Affiliates for Compounds prior to the end of the Transition Period, as more fully provided in the Transition Plan.
- 3.6.3. No later than [\*\*\*], LICENSEE shall assume direct operational management and sole financial responsibility (subject to the Licensee Trial Cost Cap provisions as provided below) for all Existing Trials.
- 3.6.4. Solely with respect to LICENSEE’s conduct of Trial Completion Activities with respect to Existing Trials on and after [\*\*\*], PFIZER will reimburse LICENSEE for Excess Trial Expenses, if any. “**Excess Trial Expenses**” means those [\*\*\*] in excess of the Licensee Trial Cost Cap to conduct such Trial Completion Activities, excluding any expenses that are [\*\*\*]. LICENSEE will deliver to PFIZER a written report within [\*\*\*] after the end of each Calendar Quarter setting forth in reasonable detail [\*\*\*]. PFIZER will reimburse LICENSEE for applicable Excess Trial Expenses within [\*\*\*] after its receipt of such report stating such expenses, with such back-up information documenting such expenses as PFIZER may reasonably request, and an invoice for the relevant amount.
- 3.6.5. Notwithstanding anything herein to the contrary, PFIZER shall not be obligated to [\*\*\*] in conducting any Trial Completion Activities or in connection with the Trial Completion Plan, or in regard to any other Development or Commercialization activities, except as expressly set forth in this Section 3.

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#### **4. DEVELOPMENT, COMMERCIALIZATION, REGULATORY, MANUFACTURING, COMPARATOR DRUGS, TRIAL COMPLETION, GOVERNANCE COMMITTEE AND REPORTS.**

##### **4.1. Development.**

4.1.1. General Diligence. LICENSEE shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop Products in each Major Market Country and each other country in which LICENSEE determines that Development of Products would fall within Commercially Reasonable Efforts to Develop Products. Such Development activities shall include without limitation, and without limiting the generality of the foregoing, those set forth in the Development plan attached to this Agreement as Schedule D (as the same may be modified from time to time by LICENSEE, as delivered in writing to PFIZER, the “**Development Plan**”). The Parties acknowledge that under appropriate circumstances it may fall within Commercially Reasonable Efforts in Developing Products for LICENSEE to decide not to advance to the next stage of Development depending on the outcomes of prior stages of Development. Subject to Section 4.1.2 below, the Parties further acknowledge that under appropriate circumstances it may fall within Commercially Reasonable Efforts in Developing Products for LICENSEE to decide to terminate or wind down a clinical trial.

4.1.2. Existing Trials. The Parties acknowledge and agree on the importance of conducting the Existing Trials in accordance with the Transition Plan and Trial Completion Plan. Notwithstanding any other provision of this Agreement, no Existing Advanced Trial will be terminated or wound down (other than as set forth in the relevant Trial Completion Plan) other than in the following circumstances:

- (a) if at any time LICENSEE becomes aware of safety concerns with respect to the relevant Product in a given indication, LICENSEE may terminate or wind down the Existing Advanced Trial in the same indication (or if in the reasonable judgment of LICENSEE, such safety concerns affect the Product regardless of indication, both Existing Advanced Trials) without any need for PFIZER’s consent thereto, provided that LICENSEE shall discuss such concerns with PFIZER;
- (b) if, on a trial-by-trial basis, after the date which is [\*\*\*], any of the following events occurs, LICENSEE may terminate or wind down such Existing Advanced Trial without any need for PFIZER’s consent thereto, provided that LICENSEE shall discuss such events with PFIZER: (i) the occurrence of material changes in the market for, or the commercial potential of, the relevant Product, (ii) material adverse changes in the

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intellectual property protection available for the relevant Product (other than by reason of any actions taken by LICENSEE), or (iii) LICENSEE becomes aware of any material change in data that indicates that the relevant Product will not be efficacious for the indication being studied in such Existing Advanced Trial; or

- (c) except as set forth in clause (a) or (b) above, only with PFIZER's prior written consent (not to be unreasonably withheld).

4.1.3. New Clinical Trial. Without limiting the generality of the foregoing, LICENSEE shall itself, or through its Affiliates or sublicensees, (a) Commence a new Clinical Trial for a Product no later than [\*\*\*] (subject to extension for a period mutually agreed upon by the Parties in the event that LICENSEE is unable to Commence such Clinical Trial by such date because of events or circumstances beyond its reasonable control), (b) use Commercially Reasonable Efforts to complete such Clinical Trial in accordance with the Development Plan, and (c) use Commercially Reasonable Efforts to achieve the clinical and regulatory milestones set forth in the Development Plan.

4.1.4. LICENSEE will undertake the activities described in this Section 4.1 at its sole expense, subject to Section 3.6 with respect to the Existing Trials. Subject to its obligations under this Section 4.1 and Sections 3 and 4.3, LICENSEE shall have sole decision making authority with respect to such activities.

- 4.2. **Commercialization**. LICENSEE shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize the Product in each Major Market Country after obtaining Regulatory Approval of Products in such country, and each other country in which LICENSEE determines that Commercialization of Products would fall within Commercially Reasonable Efforts to Commercialize Products, after obtaining Regulatory Approval of Products in such country. LICENSEE will undertake such activities at the sole expense of LICENSEE, its Affiliates or sublicensees, and subject to the foregoing diligence obligations, LICENSEE will have sole decision making authority with respect to such activities. The Parties acknowledge that under appropriate circumstances it may fall within Commercially Reasonable Efforts in Commercializing Products for LICENSEE to decide not to advance to the next stage of Commercialization depending on the outcomes of prior stages of Commercialization.

4.3. **Regulatory and Pharmacovigilance.**

4.3.1. In connection with its efforts to Develop Products, as between the Parties, LICENSEE shall bear all responsibility (subject to Sections 3 and 4.3.2) and expense for filing Regulatory Filings in LICENSEE's name and obtaining Regulatory Approval for Products.

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4.3.2. PFIZER shall use commercially reasonable efforts to transfer sponsorship of the Existing Trials (other than the IIRs) and all regulatory reporting requirements relating to the safety of the Product effective as of December 31, 2011. After sponsorship for all such trials has been transferred to LICENSEE pursuant to the Transition Plan, LICENSEE shall have all regulatory and pharmacovigilance responsibilities for the Compounds and Products as of such transfer date. During the period after the Closing Date and prior to such transfer date, the Parties shall keep each other informed as to the status of this transfer via the Transition Committee and shall discuss whether or not it may be necessary to put in place a written agreement for exchanging adverse event and other safety information relating to the Products prior to PFIZER's or its Affiliate's transfer of any existing IND to LICENSEE. If they agree that such an agreement is necessary, they shall promptly meet and agree upon such an agreement (the "**Pharmacovigilance Agreement**"). The Pharmacovigilance Agreement shall ensure that adverse events and other safety information is exchanged upon terms that will permit each Party to comply with Applicable Laws and requirements of Regulatory Authorities.

#### **4.4. Product Manufacturing and Use; Comparator Drugs.**

4.4.1. As of the Closing Date, LICENSEE will be responsible, at its own cost, for all aspects of manufacturing Products for its Use; provided that during the period from the Closing Date through December 31, 2011, if LICENSEE has been negotiating in good faith with Third Party contract manufacturers but has not yet entered into agreements for the manufacture of Products with such Third Parties, then at LICENSEE's request, PFIZER will use reasonable efforts upon reasonable notice to order the quantities of Product requested by LICENSEE in writing, at LICENSEE's cost; provided further that via the Transition Committee, the Parties will discuss necessary lead times and how to handle release testing and any other activities related to any such request. LICENSEE agrees that it shall comply with the applicable requirements of 35 U.S.C. § 204 to the extent required in connection with manufacturing Products; provided, however, that PFIZER will, upon LICENSEE's request and at LICENSEE's expense, request pursuant to the GHC License Agreement that MGH assist LICENSEE in obtaining a waiver of the foregoing requirement, in the event such a waiver should be required.

4.4.2. With respect to the Pfizer Neratinib Inventory and Comparator Inventory (as both defined in Section 6.2 of the Transition Plan) transferred to LICENSEE pursuant to the Transition Plan, to the extent that either (a) LICENSEE uses any such Pfizer Neratinib Inventory or Comparator Inventory [\*\*\*] and LICENSEE subsequently [\*\*\*] for use in conducting the Existing Trials under Section 3.6 or (b) LICENSEE [\*\*\*] and instead LICENSEE [\*\*\*], then [\*\*\*].

4.4.3. To the extent any comparator drugs are required for the Trial Completion Activities beyond the Comparator Inventory transferred to LICENSEE pursuant to the Transition Plan, LICENSEE shall be responsible for acquiring such

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additional comparator drugs at its own expense; provided that during the period from the Closing Date through December 31, 2011, if LICENSEE has been negotiating in good faith with Third Party suppliers of comparator drugs but has not yet entered into agreements for the supply of comparator drugs with such Third Parties, then at LICENSEE's request, PFIZER will use reasonable efforts upon reasonable notice to order the quantities of comparator drugs for use in the Existing Advanced Trials requested by LICENSEE in writing, at LICENSEE's expense [\*\*\*]; provided further that via the Transition Committee, the Parties will discuss necessary lead times and any other activities related to any such request.

**4.5. Trial Completion.** With respect to the Existing Trials, each Party will perform the Trial Completion Activities in accordance with Section 3.6.

**4.6. Governance Committee and Reports.**

4.6.1. The Parties will establish a joint governance committee to provide advice and input with respect to Development and Commercialization plans and activities relating to Products and to review the progress of such activities (the "**Governance Committee**"). The Governance Committee will have an equal number of representatives from each Party, provided that LICENSEE will have final decision making authority with respect to matters before the committee (subject to LICENSEE's commitments and obligations under the Agreement). The Governance Committee will meet at least once per year or more frequently as agreed-upon by the Parties. Upon the request of a Party's representative on the Governance Committee, subject to the other Party's prior consent (not to be unreasonably withheld or delayed), other personnel from such Party may attend and participate in such meetings. PFIZER's participation in the Governance Committee is a right and not an obligation; provided that in the event that PFIZER elects not to participate in such committee, LICENSEE shall have the right to proceed with decision-making with respect to such committee at its sole discretion.

4.6.2. LICENSEE shall provide PFIZER a written report in reasonable detail regarding LICENSEE's progress in Development and Commercialization of each Product, including a summary of activities conducted, significant events or milestones achieved, and data obtained since the last report, and other activities under this Section 4. With respect to each Product, LICENSEE will deliver such report (a) within [\*\*\*] after each June 30 and December 31 prior to the [\*\*\*] for such Product, and (b) within [\*\*\*] after the end of each Calendar Quarter thereafter.

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## 5. PAYMENT TERMS

### 5.1. Payment Terms.

5.1.1. **Milestone Payments.** LICENSEE shall notify PFIZER as soon as practicable upon achievement of each Milestone. In partial consideration of the licenses and rights granted to LICENSEE, within [\*\*\*] after achievement of each Milestone set forth below, LICENSEE shall pay to PFIZER the corresponding non-creditable and non-refundable milestone payment (each, a “Milestone Payment”).

<u>MILESTONE</u>	<u>MILESTONE PAYMENT</u>
(1) [***]	[***]
(2) [***]	[***]
(3) [***]	[***]
(4) [***]	[***]
(5) [***]	[***]
(6) [***]	[***]

- (a) For the avoidance of doubt: (i) each Milestone Payment shall be payable only once upon achievement of the applicable Milestone; and (ii) satisfaction of a Milestone by an Affiliate of LICENSEE or a sublicensee or assignee of, or Third Party retained by, LICENSEE or its Affiliates shall be deemed to have been satisfied by LICENSEE for purposes of this Section 5.1.1.

### 5.1.2. Royalty Payments.

- (a) In further consideration of the licenses and rights granted to LICENSEE hereunder, LICENSEE shall pay to PFIZER the royalties set forth below on Net Sales of Products in the Territory in each Calendar Year during the applicable Royalty Terms (collectively, “Royalties”).

<u>NET SALES</u>	<u>INCREMENTAL ROYALTY RATE</u>
The portion of aggregate worldwide Net Sales of all Products that is less than [***] per Calendar Year	[***] of Net Sales
The portion of aggregate worldwide Net Sales of all Products that is equal to or greater than [***] per Calendar Year	[***] of Net Sales

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- (b) LICENSEE shall pay to PFIZER the applicable Royalties within [\*\*\*] following the end of each Calendar Quarter after the date of the First Commercial Sale of a Product.
- (c) In the event that LICENSEE [\*\*\*] (the “Third Party Patents”), and if LICENSEE pays [\*\*\*] under license agreements with such Third Parties [\*\*\*] (the “Third Party Payments”), then LICENSEE may credit [\*\*\*] of such Third Party Payments against the Royalties owed and payable on the Net Sales for such Product, as determined on a country-by-country basis. Notwithstanding the foregoing, in no event shall such credits reduce the Royalties payable to PFIZER [\*\*\*] and [\*\*\*].
- (d) All payments shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation, on a country-by-country basis, of Net Sales of each Product (including gross sales and all Deductions) and all Royalties payable to PFIZER for the applicable Calendar Quarter (including any foreign exchange rates employed and conversion calculations).

**5.1.3. Assumption of Responsibility.** The Parties acknowledge that LICENSEE’s assumption of all responsibility, at its sole cost (except as set forth in Section 3), for the Existing Trials with effect from the Closing Date in accordance with Section 3, including LICENSEE’s Trial Completion Activities, shall serve as further consideration for the licenses and rights being granted to LICENSEE hereunder.

**5.1.4. Other Payments.** Except as otherwise expressly set forth herein, LICENSEE shall pay to PFIZER any other amounts due under this Agreement within [\*\*\*] following receipt of invoice.

**5.1.5. Late Payments.** Any late payments shall bear interest, to the extent permitted by law, [\*\*\*] above the Prime Rate of interest as reported in the Wall Street Journal on the date payment is due.

## **5.2. Payment Method.**

5.2.1. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due for Royalties hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, such Net Sales will be converted to U.S. dollars using the average of the applicable daily foreign exchange rates published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the last day of each month of the Calendar Quarter in which such Net Sales occurred, and the amounts due for Royalties hereunder will be expressed in U.S. dollars. For purposes of calculating the Net Sales thresholds set forth in [\*\*\*], the aggregate Net Sales with respect to each Calendar Quarter within a Calendar Year will be calculated based on the currency exchange rates for the Calendar Quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in the immediately preceding sentence.

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5.2.2. All payments from LICENSEE to PFIZER shall be made by wire transfer in US Dollars to the credit of such bank account as may be designated by PFIZER in writing to LICENSEE. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

### 5.3. Taxes.

5.3.1. **VAT.** It is understood and agreed between the Parties that any amounts payable by LICENSEE to PFIZER hereunder are [\*\*\*] applicable sales, use, VAT, GST, excise, property, and other taxes, levies, duties or fees (collectively, “**Taxes**”), [\*\*\*].

5.3.2. **Withholding Taxes.** If LICENSEE is required to make a payment to PFIZER subject to a deduction of tax or withholding tax, the sum payable by LICENSEE (in respect of which such deduction or withholding is required to be made) shall be made to PFIZER after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with applicable law, *provided, however*, that if such withholding or deduction obligation arises solely as a result of [\*\*\*], then the sum payable by LICENSEE (in respect of which such deduction or withholding is required to be made) shall be [\*\*\*]. Any amounts deducted, withheld and remitted in accordance with the provisions of this Section 5.3.2 shall be treated as having been paid by the LICENSEE to PFIZER for all purposes of this Agreement.

5.3.3. **Tax Cooperation.** To the extent LICENSEE is required to deduct and withhold taxes on any payments to PFIZER, LICENSEE shall pay the amounts of such taxes to the proper governmental authority in a timely manner and, upon PFIZER’s request, shall promptly transmit to PFIZER an official tax certificate or other evidence of such withholding sufficient to enable PFIZER to claim such payments of taxes. PFIZER shall provide to LICENSEE any tax forms that may be reasonably necessary in order for LICENSEE not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax or VAT.

5.3.4. **Tax Forms.** The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Form W-8BEN, reasonably requested by the other Party in connection with any payment made by LICENSEE to PFIZER under this Agreement.

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## 6. RECORDS; AUDIT RIGHTS

### 6.1. Relevant Records.

6.1.1. **Relevant Records.** LICENSEE shall keep, and shall cause its Affiliates and sublicensee to keep accurate financial books and records pertaining to: LICENSEE's and its Affiliates' and sublicensees' sale of Products, including any and all calculations of payments due to PFIZER hereunder; LICENSEE's prosecution, maintenance and enforcement of Patent Rights; and LICENSEE's Trial Completion Activities (collectively, "**Relevant Records**"). LICENSEE, its Affiliates and sublicensees shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) three (3) years following expiration or termination of this Agreement. LICENSEE shall require its sublicensees to provide to LICENSEE copies of all Relevant Records relating to such sublicensees' sale of Products as necessary to allow PFIZER to review such Relevant Records when conducting an audit of LICENSEE pursuant to Section 6.1.2.

6.1.2. **Audit Request.** PFIZER shall have the right during the term and for three (3) years thereafter to engage, at its own expense, an independent auditor reasonably acceptable to LICENSEE to examine the Relevant Records in LICENSEE's or its Affiliates' possession from time-to-time, but no more frequently than once every twelve (12) months, as may be necessary to verify compliance with the terms of this Agreement. Such audit shall be requested in writing at least fifteen (15) Business Days in advance, and shall be conducted during LICENSEE's (or its Affiliate's, as applicable) normal business hours and otherwise in manner that minimizes any interference to LICENSEE's (or its Affiliate's, as applicable) business operations.

6.1.3. **Audit Fees and Expenses.** PFIZER shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; provided, however, in the event an audit reveals an underpayment by LICENSEE of more than [\*\*\*] as to the period subject to the audit, LICENSEE shall reimburse PFIZER for any reasonable and documented out-of-pocket costs and expenses of the audit within [\*\*\*] after receiving invoices thereof.

6.1.4. **Payment of Deficiency.** If any audit establishes that LICENSEE underpaid any amounts due to PFIZER under this Agreement, then LICENSEE shall pay PFIZER any such deficiency within [\*\*\*] after receipt of written notice thereof. For the avoidance of doubt, such payment will be considered a late payment, subject to Section 5.1.5. If any audit establishes that LICENSEE overpaid any amounts due to PFIZER under this Agreement, then LICENSEE shall be entitled to take a credit against future amounts becoming due to PFIZER equal to the overpaid amount.

## 7. INTELLECTUAL PROPERTY RIGHTS

7.1. **Pre-existing IP.** Subject only to the rights expressly granted to the other Party under this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned by, or licensed or sublicensed to, such Party prior to or independent of this Agreement.

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## 7.2. Ownership of Inventions and Intellectual Property Rights.

7.2.1. “**Inventions**” means any and all inventions (whether or not patentable), that are conceived during the term of and in the course of activities conducted pursuant to this Agreement by one or more employees, Affiliates, sublicensees or independent contractors of PFIZER and/or LICENSEE.

7.2.2. Inventorship of Inventions shall be determined in accordance with the rules and regulations of the U.S. Patent and Trademark Office. All Inventions made solely by employees, agents and independent contractors of PFIZER or its Affiliates and all Intellectual Property Rights therein, shall be owned solely by PFIZER (“**Pfizer Inventions**”). All Inventions made solely by employees, agents and independent contractors of LICENSEE or its Affiliates or sublicensees, and all Intellectual Property Rights therein, shall be owned, as between the Parties, solely by LICENSEE (“**Licensee Inventions**”). All Inventions made jointly by employees, agents and independent contractors of each Party or its Affiliates or sublicensees (as applicable), and all Intellectual Property Rights therein, shall be owned jointly by the Parties such that each Party shall have an undivided interest therein (“**Joint Inventions**”). All Patents claiming patentable, jointly owned Joint Inventions shall be referred to herein as “**Joint Patent Rights**.” Except to the extent either Party is restricted by the licenses granted to the other Party and covenants set forth herein, each Party shall be entitled to practice and exploit the Joint Inventions without any duty of accounting or obligation to seek consent from the other Party with respect thereto.

7.3. **Further Actions; Developed IP.** Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees and agents of such Party, to cooperate with the other Party and take all reasonable actions and execute such agreements, declarations, assignments, legal instruments and documents as may be reasonably required to perfect the other Party’s right, title and interest in and to Inventions, and Patents thereon, and other Intellectual Property Rights as set forth in Section 7.2.2. Each Party shall also include provisions in its relevant agreements with Third Parties that affect the intent of this Section 7.3. Licensee Inventions and LICENSEE’s interest in Joint Inventions, and all Intellectual Property Rights therein, that are related to any Compound or Product shall be “**Developed IP**.”

## 7.4. Patent Prosecution and Maintenance.

7.4.1. LICENSEE shall be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions and the like) and maintaining the Patent Rights in the Territory. LICENSEE shall file, prosecute and maintain the Patent Rights using qualified outside patent counsel and foreign patent

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associates selected by LICENSEE; provided that LICENSEE identifies such counsel for PFIZER in advance and PFIZER consents to such counsel (such consent not to be unreasonably withheld or delayed). LICENSEE shall be responsible for all costs and expenses in connection with such filing, prosecution and maintenance; provided that if LICENSEE intends to abandon, or not file a patent application included in, any of the Patent Rights in any given country for any purposes, LICENSEE shall provide PFIZER with a written notice of such intent at least [\*\*\*] in advance of the relevant deadline. In such case: (a) PFIZER will provide a written response to LICENSEE at least [\*\*\*] in advance of the relevant deadline if PFIZER wishes, or wishes to allow a Third Party to, file, prosecute and maintain (in its sole discretion) such Patent Right in such country; (b) if PFIZER provides the affirmative notice under clause (a) above, the LICENSEE shall promptly provide all files related to filing, prosecuting and maintaining such Patent Right to counsel designated by PFIZER; (c) upon completion of the transfer of such files under clause (b), LICENSEE shall no longer be responsible for the costs and expenses relating to filing, prosecuting and maintaining (as applicable) such Patent Right in such country; and (d) the terms "Patent Rights" and "Future Patent Rights," as applicable, automatically shall be [\*\*\*].

7.4.2. LICENSEE shall provide PFIZER with material correspondence with each of the patent offices pertaining to LICENSEE's prosecution of the Patent Rights. Upon the written request of PFIZER, LICENSEE shall provide PFIZER with draft copies of all filings and relevant documentation (to the extent not previously submitted to and reviewed by PFIZER) relating to a Patent Rights at least [\*\*\*] prior to the required submission date and shall not file or submit any such filing or documentation until LICENSEE has received comments on such filing and documentation from PFIZER and considered any proposed comments to such filings and documentation in good faith, provided that LICENSEE may file or submit such filings or documentation without considering PFIZER'S comments if LICENSEE has not received any comments from PFIZER at least [\*\*\*] prior to the required submission date. LICENSEE is not required to [\*\*\*].

7.4.3. LICENSEE shall have the first right, but not the obligation, to prepare, file, prosecute and maintain any Joint Patent Right that is not a Patent Right, in each case throughout the world, using patent counsel that is reasonably acceptable to PFIZER. If LICENSEE declines to exercise its first right, PFIZER shall have the right (but not the obligation) to prepare, file, prosecute and maintain such Joint Patent Right, in each case throughout the world. The Party that at the time exercises the right to prepare, file, prosecute and maintain such a Joint Patent Right may be referenced as the "Controlling Party" below with respect thereto, and the other Party may be referenced as the "Other Party" below with respect thereto. The Controlling Party shall give the Other Party an opportunity to review the text of any patent application with respect to such Joint Patent Right at least [\*\*\*] before filing and shall consider the Other Party's

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comments in good faith. The Controlling Party shall supply the Other Party with a copy of the patent application as filed, together with notice of its filing date and serial number. To the extent it is Controlling Party for such Joint Patent Rights, LICENSEE shall follow the patent prosecution practice described in Sections 7.4.1 and 7.4.2. The Other Party shall reimburse the Controlling Party for fifty percent (50%) of the costs incurred by the Controlling Party in preparing, filing, prosecuting and maintaining any such Joint Patent Right, which reimbursement will be made pursuant to invoices submitted by the Controlling Party to the Other Party no more often than once per Calendar Quarter; provided that, for clarity, LICENSEE shall be responsible for all such costs for any Joint Patent Right that is also a Patent Right. If either Party (the “Declining Party”) at any time declines to share in the costs of filing, prosecuting and maintaining any such Joint Patent Right, on a country by country basis, the Declining Party shall provide the other Party (the “Continuing Party”) with [\*\*\*] prior written notice to such effect, in which event, (i) the Declining Party shall have no responsibility for any expenses incurred in connection with such Joint Patent Right after the end of such [\*\*\*] period, (ii) if the Continuing Party elects to continue prosecution or maintenance, the Declining Party, upon the Continuing Party’s request, shall execute such documents and perform such acts, at the Continuing Party’s expense, as may be reasonably necessary to assign to the Continuing Party all of the Declining Party’s right, title and interest in and to such Joint Patent Right, with such Joint Patent Right automatically ceasing to be a Joint Patent Right and becoming the patent right solely of the Continuing Party as of the date of such written notice from the Declining Party, and (iii) for clarity, if the Declining Party is LICENSEE and such Joint Patent Right would otherwise thereafter be a Patent Right or Future Patent Right, then [\*\*\*].

## **8. ACTUAL OR THREATENED INFRINGEMENT, DISCLOSURE OR MISAPPROPRIATION; DEFENSE ACTIONS; ORANGE BOOK LISTINGS; AND PATENT TERM EXTENSION**

- 8.1. Notice.** Each Party will promptly notify the other Party in writing of (a) any actual or threatened infringement, misappropriation, other violation, or challenge to the validity, scope or enforceability by a Third Party of any Licensed Technology in the Territory of which it becomes aware (“**Third Party Infringement**”) and (b) any allegation by a Third Party that any Intellectual Property Right owned by it is infringed, misappropriated, or otherwise violated by the Development, Commercialization, and/or Use of any Product of which it becomes aware (“**Defense Action**”).
- 8.2. Licensee Control.** LICENSEE shall have the first right (but not the obligation), at its own expense, to control enforcement of the Licensed Technology against any Third Party Infringement. Prior to commencing involvement in any such suit, action or proceeding, LICENSEE shall consult with PFIZER and shall consider PFIZER’s timely recommendations regarding the proposed suit, action or

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proceeding, except to the extent delay may reasonably result in the loss of rights by or otherwise adversely impact LICENSEE or PFIZER. LICENSEE shall give PFIZER timely notice of any proposed settlement of any such suit, action or proceeding that LICENSEE controls and LICENSEE shall not settle, stipulate to any facts or make any admission with respect to any Third Party Infringement without PFIZER's prior written consent (not to be unreasonably withheld) if such settlement, stipulation or admission would: (a) adversely affect the validity, enforceability or scope, or admit non-infringement, of any of the Licensed Technology; (b) give rise to liability of PFIZER or its Affiliates; (c) grant to a Third Party a license or covenant not to sue under, or with respect to, any Intellectual Property Rights Controlled by PFIZER or its Affiliates (other than as expressly provided for in this Agreement with respect to LICENSEE's rights to sublicense the Licensed Technology); or (d) otherwise impair PFIZER's or any of its Affiliates' rights in any Licensed Technology or PFIZER's or any of its Affiliates' rights in this Agreement.

- 8.3. Pfizer Control.** PFIZER shall have the right (but not the obligation) to control enforcement of the Licensed Technology against any Third Party Infringement if LICENSEE provides PFIZER with written notice that it is not exercising its right to control such enforcement, or if LICENSEE fails to initiate or file the relevant response to (as applicable), a suit, action or proceeding with respect to such Third Party Infringement prior to or upon the earlier of: (a) expiration of the [\*\*\*] period following first receipt by either Party of notice from the other Party of such Third Party Infringement or (b) [\*\*\*] prior to the deadline for filing, or filing the applicable response to (as applicable), such suit, action or proceeding (including suits, actions or proceedings based on a Third Party's filing of a Paragraph IV Certification under 21 CFR §314.94(a)(12)(i)(A)(4))).
- 8.4. Rights of Non-Controlling Party.** Notwithstanding anything to the contrary herein, the Party that is not controlling the suit, action or proceeding pertaining to enforcement of the Licensed Technology against Third Party Infringement as described in this Section 8 shall join as a party to such suit, action or proceeding upon the reasonable request and expense of the Party controlling such action if necessary for standing purposes. The Party that is not controlling such a suit, action or proceeding shall have the right to be represented by counsel (which shall act in an advisory capacity only, except for matters solely directed to such Party) of its own choice and at its own expense (subject to Section 8.5) in any such suit, action or proceeding.
- 8.5. Recoveries.** Any and all recoveries resulting from a suit, action or proceeding relating to a claim of Third Party Infringement shall first be applied to reimburse each Party's costs and expenses in connection with such suit, action or proceeding, with any remaining recoveries (the "Remaining Recoveries") allocated (i) if the controlling Party is LICENSEE, [\*\*\*], with [\*\*\*], and (ii) if the controlling Party is PFIZER [\*\*\*].
- 8.6. Defense.** Upon LICENSEE's request, PFIZER will reasonably cooperate with

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LICENSEE, at LICENSEE's expense, to the extent necessary to defend LICENSEE or any Affiliate or sublicensee of LICENSEE in a Defense Action in which the claim of infringement, misappropriation or other violation is directed at LICENSEE's or its sublicensee's Use of a Compound (as such Compound exists as of the Execution Date) or the Know-How (in accordance with Section 2). LICENSEE shall have all authority with respect to any Defense Action, including the right to exclusive control of the defense of any such suit, action or proceeding and the exclusive right to compromise, litigate, settle or otherwise dispose of any such suit, action, or proceeding; provided that LICENSEE shall keep PFIZER timely informed of the proceedings and filings, and provide PFIZER with copies of all communications pertaining to each Defense Action and LICENSEE shall not settle, stipulate to any facts or make any admission with respect to any Defense Action without PFIZER's prior written consent if such settlement, stipulation or admission would: (a) adversely affect the validity, enforceability or scope, or admit non-infringement, of any of the Licensed Technology; (b) give rise to liability of PFIZER or its Affiliates; (c) grant to a Third Party a license or covenant not to sue under, or with respect to, any Intellectual Property Rights Controlled by PFIZER or its Affiliates, other than as expressly provided for in this Agreement with respect to LICENSEE's rights to sublicense the Licensed Technology; or (d) otherwise impair PFIZER's or any of its Affiliates' rights in any Licensed Technology or PFIZER's or any of its Affiliates' rights in this Agreement.

**8.7. Orange Book Listings.** To the extent required by or permitted by Applicable Law, LICENSEE will have the right to decide whether to list with the applicable Regulatory Authorities during the term of this Agreement any applicable Patent Rights for a Compound or Product that has become the subject of an application for Regulatory Approval submitted to FDA. Such listings may include without limitation all so-called "Orange Book" listings required under the Hatch-Waxman Act and all so-called "Patent Register" listings as required in Canada. PFIZER will reasonably cooperate, at LICENSEE's request and expense, in preparing and/or filing such listings within the time frames available or required for such listings to be submitted in connection with such Compound and/or Product. LICENSEE may request in writing that [\*\*\*], in order for it to be listed with the applicable Regulatory Authorities under this paragraph. In such case, PFIZER shall not unreasonably withhold its consent to such [\*\*\*]; provided that if PFIZER reasonably believes it might want to list such [\*\*\*] with the Regulatory Authorities for products other than Products, then it may withhold its consent without further explanation.

**8.8. Patent Term Extension.** LICENSEE shall notify PFIZER of the date of Regulatory Approval of a Product by the relevant Regulatory Authority. LICENSEE shall have the right to prepare and file, or to cause PFIZER to prepare and file (at LICENSEE's request and expense), a patent term extension or supplementary protection certificate application upon Regulatory Approval of such Product. At LICENSEE's request and expense, PFIZER shall provide to

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LICENSEE for inclusion in such filing any information not in LICENSEE's possession relating to the regulatory timeline, diligence and regulatory period calculations required as part of the application to complete such application(s), and otherwise reasonably cooperate in any other matters related to preparation or filing of the application(s) therefor to make such filing within the applicable time period.

## 9. CONFIDENTIALITY

- 9.1. Definition.** "Confidential Information" means the terms and provisions of this Agreement and other proprietary information and data of a financial, commercial or technical nature (including such information or data of or relating to a Third Party) that the disclosing Party or any of its Affiliates has supplied or otherwise made available to the other Party or its Affiliates, which are disclosed, whether orally, visually or in writing. All Know-How shall be considered PFIZER's Confidential Information.
- 9.2. Obligations.** During the term of this Agreement and for five (5) years thereafter, the receiving Party will (a) protect all Confidential Information of the disclosing Party against unauthorized disclosure to Third Parties, and (b) not use the Confidential Information of the disclosing Party except as permitted by or in furtherance of exercising rights or carrying out obligations hereunder. Each receiving Party will treat Confidential Information provided by the other Party with the same degree of care as if it were the receiving Party's own confidential information (but under no circumstances less than reasonable care). The receiving Party may disclose the Confidential Information of the disclosing Party to its Affiliates, and their respective directors, officers, employees, subcontractors, sublicensees, consultants, attorneys, accountants, banks, acquirers and investors (collectively, "**Recipients**") who have a need-to-know such information for purposes related to this Agreement, provided that the receiving Party shall hold such Recipients to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement.
- 9.3. Exceptions.**
- 9.3.1. The obligations under this Section 9 shall not apply to any information to the extent the receiving Party can demonstrate by competent evidence that such information:
- (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the receiving Party or any Recipients to whom it disclosed such information;
  - (b) was known to, or was otherwise in the possession of, the receiving Party prior to the time of disclosure by the disclosing Party other than under obligations of confidentiality;

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- (c) is disclosed to the receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the disclosing Party; or
- (d) is independently developed by or on behalf of the receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

9.3.2. The restrictions set forth in this Section 9 shall not prohibit the receiving Party from disclosing or using (as specified below) any Confidential Information of the disclosing Party (i) that the receiving Party is required to disclose under Applicable Laws, a court order or other governmental order, or the rules and regulations of the Securities and Exchange Commission ("SEC") or any national securities exchange, (ii) that the receiving Party needs to disclose or use to file, prosecute or enforce any Patent Rights under Sections 7 and 8, or (iii) that LICENSEE, as receiving Party, needs to disclose or use for purposes of obtaining or maintaining Regulatory Approval of Products; provided that the receiving Party (a) as to subsection (i), provides the disclosing Party at least [\*\*\*] prior written notice of such disclosure (and the right to review and comment on the proposed disclosure), to the extent practicable, (b) as to subsection (i), affords the disclosing Party an opportunity to oppose or limit, or secure confidential treatment for such required disclosure or, for submissions or disclosures required by the SEC or national securities exchange, itself uses reasonable efforts to secure confidential treatment for such required disclosure, (c) as to subsection (i) discloses only that portion of the Confidential Information that the receiving Party is legally required to disclose as advised by the receiving Party's legal counsel and (d) as to subsections (ii) and (iii), the receiving Party provides reasonable advance notice to the other Party where reasonably practicable and discloses only that portion of the Confidential Information that it is reasonably necessary to disclose for such purpose.

9.3.3. In the event that PFIZER wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, PFIZER may disclose to a Third Party Confidential Information of LICENSEE in connection with any such proposed assignment, pledge or transfer, provided that PFIZER shall hold such Third Parties to written obligations of confidentiality with terms and conditions at least as restrictive as those set forth in this Agreement. To the extent that any such assignment would affect LICENSEE's performance of its obligations hereunder, PFIZER shall notify LICENSEE promptly if it enters into any agreement under which it has assigned its rights to receive some or all of the Milestone Payments and Royalties payable hereunder.

**9.4. Right to Injunctive Relief.** Each Party agrees that breaches of this Section 9 may cause irreparable harm to the disclosing Party and may entitle the disclosing Party, in addition to any other remedies available to it (subject to the terms of this Agreement), the right to seek injunctive relief enjoining such action.

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**9.5. Ongoing Obligation for Confidentiality.** Upon expiration or termination of this Agreement, the receiving Party shall, and shall cause its Recipients to, destroy, delete, or return (as requested by the disclosing Party) any Confidential Information of the disclosing Party, except for one copy which may be retained in its confidential files for archive purposes.

**9.6. Specific Procedures in Regard to Financing.** Any disclosure made by LICENSEE to prospective investors or others in connection with the financing LICENSEE expects to complete in order to satisfy the Financing Condition shall be made only pursuant to Confidentiality and Non-Disclosure Agreements or other arrangements in form and substance satisfactory to PFIZER.

## **10. REPRESENTATIONS, WARRANTIES AND COVENANTS**

**10.1. Representations and Warranties by Each Party.** Each Party represents and warrants to the other Party as of the Execution Date (and from and after the Closing, as of the Closing Date, subject to Sections 2.7.2 and 2.7.3) that:

10.1.1. it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;

10.1.2. it has full corporate power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

10.1.3. this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;

10.1.4. all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and

10.1.5. the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

**10.2. Representations and Warranties by PFIZER.** PFIZER represents and warrants to LICENSEE as of the Execution Date (and from and after the Closing, as of the Closing Date, subject to Sections 2.7.2 and 2.7.3) that:

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- 10.2.1. to its Knowledge, the Use of an Existing Product in the form existing as of the Execution Date within the Territory will not infringe, misappropriate or otherwise violate the Intellectual Property Rights of a Third Party;
- 10.2.2. to its Knowledge, the Use of an Existing Product on or prior to the Execution Date did not infringe, misappropriate or otherwise violate the Intellectual Property Rights of any Third Party;
- 10.2.3. to its Knowledge, no Third Party is or was infringing, misappropriating or otherwise violating the Licensed Technology within the Territory;
- 10.2.4. neither PFIZER nor its Affiliates [\*\*\*] has received [\*\*\*], and no such entity has [\*\*\*] of an Existing Product;
- 10.2.5. to its Knowledge, no Third Parties have any right, title or interest in or to any Patent Right existing as of the Execution Date that claims an Existing Product, or the use or manufacture thereof, other than MGH;
- 10.2.6. The HKI-357 Compound is the only Back-up Compound for the Neratinib Compound. As used herein, the terms “HKI-357 Compound” and “Neratinib Compound” have the meaning set forth in the definition of “Compound” in Section 1, and “**Back-up Compound**” means, [\*\*\*];
- 10.2.7. PFIZER has not [\*\*\*] in connection with an Existing Product any [\*\*\*] that have been or are [\*\*\*];
- 10.2.8. PFIZER has not received any notices of [\*\*\*] with respect to the [\*\*\*] of a Compound or Existing Product that could reasonably be deemed to adversely affect the [\*\*\*];
- 10.2.9. All [\*\*\*] PFIZER or its Affiliates conducting activities prior to the Execution Date with respect to any Compound or Existing Product have [\*\*\*] PFIZER or its Affiliate, as applicable, of [\*\*\*] in connection with the activities [\*\*\*] conducted with respect to any Compound or Existing Product, [\*\*\*], if any, to PFIZER or its Affiliate, as applicable, [\*\*\*];
- 10.2.10. PFIZER is not a party to any litigation in which any Third Party has alleged that the Use of an Existing Product within the Territory (a) [\*\*\*] or (b) infringes, misappropriates or otherwise violates the Intellectual Property Rights of such Third Party; and
- 10.2.11. To the extent material to Development of the Compounds or Existing Product, all [\*\*\*] by or on behalf of PFIZER or its Affiliates prior to the Execution Date in the course of developing the Compounds or Existing Product have been [\*\*\*].

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**10.3. Representations, Warranties and Covenants by LICENSEE and Covenants of PFIZER.**

10.3.1. LICENSEE represents, warrants and covenants to PFIZER that, to the extent material to Use of the Compounds and the Products, it shall, and shall ensure all Third Parties that it engages with respect to activities directed to the Compounds and the Products shall, comply in all material respects with all Applicable Laws with respect to its activities and the performance of its obligations hereunder.

10.3.2. Without limiting the generality of Section 10.3.1, LICENSEE shall comply with the U.S. Foreign Corrupt Practices Act of 1977 (as modified or amended). LICENSEE represents, warrants and covenants that it has not and will not directly or indirectly offer or pay, or authorize such offer or payment of, any money, or transfer anything of value, to improperly seek to influence any Government Official.

10.3.3. LICENSEE covenants that it will not utilize, in conducting Development or Commercialization of Product, any person or entities that at such time are debarred by FDA, or that, at such time, are under investigation by FDA for debarment action pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335).

10.3.4. LICENSEE covenants that all employees, officers, contractors, and consultants of LICENSEE or its Affiliates working under this Agreement shall execute agreements requiring assignment to LICENSEE of all right, title and interest in and to their inventions and discoveries invented or otherwise discovered or generated during the course of and as a result of their association with LICENSEE, whether or not patentable, if any, to LICENSEE as the sole owner thereof.

10.3.5. PFIZER shall conduct all Trial Completion Activities or activities under the Transition Plan in material compliance with all Applicable Laws and shall not, to its Knowledge, utilize any person or entity to perform and such activities that has been or is debarred by FDA pursuant to the provisions of the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335).

**10.4. No Other Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 10, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. ANY INFORMATION PROVIDED BY PFIZER OR ITS AFFILIATES IS MADE AVAILABLE ON AN “AS IS” BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY STANDARDS, REGULATIONS OR APPLICABLE LAW OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

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## 11. INDEMNIFICATION

- 11.1. Indemnification by LICENSEE.** From and after the Closing, LICENSEE agrees to indemnify, hold harmless and defend PFIZER and its Affiliates, and their respective officers, directors, employees, contractors, agents and assigns (collectively, “**PFIZER Indemnitees**”), from and against any Claims to the extent arising or resulting from: (a) the Development, Commercialization and other Use of Products by LICENSEE, its Affiliates, subcontractors or sublicensees, (b) LICENSEE’s, its Affiliates’, subcontractors’ and sublicensees’ performance of Trial Completion Activities or activities under the Transition Plan, (c) the gross negligence or wrongful intentional acts or omissions of LICENSEE, its Affiliates, subcontractors or sublicensees, (d) breach by LICENSEE of any representation, warranty, obligation or covenant as set forth in this Agreement, (e) breach by LICENSEE of the scope of the license set forth in Section 2.1 or (f) PFIZER’s conduct after the Closing of the Trial Completion Activities, activities under the Transition Plan or the [\*\*\*], except (in the case of (f)) to the extent that PFIZER is obligated to indemnify LICENSEE with respect to any such activity or service under the provisions of Section 11.2. As used herein, “**Claims**” means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees).
- 11.2. Indemnification by PFIZER.** From and after the Closing, PFIZER agrees to indemnify, hold harmless and defend LICENSEE and its Affiliates and sublicensees, and their respective officers, directors, employees, contractors, agents and assigns (collectively, “**LICENSEE Indemnitees**”), from and against any Claims to the extent arising or resulting from (a) the Development and other Use of Compounds and Products by PFIZER, its Affiliates, subcontractors or sublicensees prior to the Closing Date, (b) the gross negligence or wrongful intentional acts or omissions of PFIZER, its Affiliates, or subcontractors, or (c) breach by PFIZER of any representation, warranty, obligation or covenant as set forth in this Agreement.
- 11.3. Indemnification Procedure.** In connection with any Claim for which a Party (the “Indemnified Party”) seeks indemnification from the other Party (the “Indemnifying Party”) pursuant to this Agreement, the Indemnified Party shall: (a) give the Indemnifying Party prompt written notice of the Claim; provided, however, that failure to provide such notice shall not relieve the Indemnifying Party from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with the Indemnifying Party, at the Indemnifying Party’s expense, in connection with the defense and settlement of the Claim; and (c) permit the Indemnifying Party to control the defense and settlement of the Claim only if the Indemnifying Party

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confirms in writing that it is liable to indemnify the PFIZER Indemnitees or the LICENSEE Indemnitees, as applicable, in connection with the relevant matter and provides reasonable substantiation that the Indemnifying Party has the financial resources to pay for the defense and settlement of the Claim (including any settlement thereof or judgment thereon); provided, however, that the Indemnifying Party may not settle the Claim without the Indemnified Party's prior written consent, which shall not be unreasonably withheld or delayed, in the event such settlement materially adversely impacts the Indemnified Party's rights or obligations. Further, the Indemnified Party shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

## **12. LIMITATION OF LIABILITY**

**12.1. No Consequential Damages.** EXCEPT FOR A BREACH OF SECTION 2.1 OR SECTION 9 OR OBLIGATIONS ARISING UNDER SECTION 11, NEITHER PARTY SHALL BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

## **13. TERM; TERMINATION**

**13.1. Term.** The term of this Agreement shall commence as of the Execution Date and unless earlier terminated as expressly provided herein, shall expire upon the last-to-expire Royalty Term.

### **13.2. Termination by LICENSEE.**

13.2.1. Termination At Will. LICENSEE may, provided that LICENSEE is not then in material breach of this Agreement, terminate this Agreement in its entirety at will, in its sole discretion, at any time on or after the date that is eighteen (18) months after the Closing Date on not less than one hundred eighty (180) days prior written notice to PFIZER.

13.2.2. Termination for Safety Concerns. LICENSEE may terminate this Agreement in its entirety on not less than sixty (60) days prior written notice to PFIZER if LICENSEE has evidence of safety issues on the basis of which a reasonable investigator would conclude that such issues will prevent the successful Development and Commercialization of Products hereunder. LICENSEE shall provide such evidence to PFIZER together with such notice and shall discuss such evidence as reasonably requested by PFIZER.

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13.2.3. Termination Generally. This Agreement may not be terminated by LICENSEE under this Section 13.2 on a Compound-by-Compound, or country-by-country or other partial basis.

**13.3. Termination for Cause.** Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party breaches any of its material obligations hereunder and fails to cure such breach within thirty (30) days of receiving notice thereof; provided, however, if such breach is capable of being cured, but cannot be cured within such thirty (30) day period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed sixty (60) days unless otherwise agreed in writing by the Parties. Any termination by a Party under this Section 13.3 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. For the avoidance of doubt, LICENSEE's failure to use Commercially Reasonable Efforts to Develop and Commercialize Products in each Major Market Country shall constitute a breach of a material obligation by LICENSEE under this Agreement.

**13.4. Termination for a Bankruptcy Event.** PFIZER shall have the right to terminate this Agreement by written notice to LICENSEE in the event of a Bankruptcy Event. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against LICENSEE under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within ninety (90) days after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by LICENSEE of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of LICENSEE not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of LICENSEE's assets, or (e) any corporate action taken by the board of directors of LICENSEE in furtherance of any of the foregoing actions.

**13.5. Termination for Closing Failure.** This Agreement shall terminate as set forth in Section 2.7.1.

**13.6. Effect of Termination or Expiration.**

13.6.1. Upon termination or expiration of this Agreement, LICENSEE shall pay to PFIZER all amounts due to PFIZER as of the effective date of termination or expiration within thirty (30) days following the effective date of termination or expiration.

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13.6.2. Upon expiration of this Agreement pursuant to Section 13.1, PFIZER hereby grants to LICENSEE a royalty-free right and license to use the Know-How for the purpose of the Development and Commercialization of Compounds and Products within the Territory.

13.6.3. Upon termination of this Agreement, LICENSEE shall have the right to sell its remaining inventory of Products following the termination of this Agreement so long as LICENSEE has fully paid, and continues to fully pay when due, any and all Royalties and Milestone Payments owed to PFIZER, and LICENSEE otherwise is not in material breach of this Agreement.

13.6.4. Subject to Section 13.6.3, upon termination of this Agreement all licenses granted by PFIZER to LICENSEE shall terminate. For clarity, termination of the licenses granted by PFIZER to LICENSEE shall [\*\*\*]. At LICENSEE's request, [\*\*\*]: (i) PFIZER shall [\*\*\*] and (ii) if it is [\*\*\*]; provided that PFIZER shall have [\*\*\*].

13.6.5. With the exception of termination of this Agreement by LICENSEE pursuant to Section 13.3, upon termination of this Agreement:

- (a) LICENSEE hereby grants to PFIZER a [\*\*\*], worldwide, transferable, perpetual and irrevocable license, with the right to sublicense, under any Intellectual Property Rights Controlled by LICENSEE claiming Inventions that are necessary or reasonably useful for the Development, Commercialization or other Use of Products as they exist at the time of such termination of this Agreement, including without limitation, any and all Developed IP (as defined in Section 7.3), to Develop, Commercialize and otherwise Use the Products.
- (b) To the extent permitted by applicable Regulatory Authorities and requested by PFIZER, LICENSEE shall: (i) transfer to PFIZER all Regulatory Filings and Regulatory Approvals held by LICENSEE with respect to Products, and (ii) to the extent subsection (i) is not permitted by the applicable Regulatory Authority, permit PFIZER to cross-reference and rely upon any Regulatory Approvals and Regulatory Filings filed by LICENSEE with respect to Products.
- (c) LICENSEE, if requested in writing by PFIZER, shall provide any and all (i) material correspondence with the relevant patent offices pertaining to the LICENSEE's prosecution of the Patent Rights to the extent not previously provided to PFIZER during the course of the Agreement, and (ii) a report detailing the status of all Patent Rights at the time of termination or expiration.
- (d) LICENSEE hereby grants to PFIZER a [\*\*\*], worldwide, transferable, sublicensable, perpetual and irrevocable license to use the Trademarks specifically identifying each Product, excluding for clarity all Trademarks

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also used in connection with LICENSEE's business other than with respect to Product, for the purpose of manufacturing, marketing, distributing, selling, and otherwise Developing and Commercializing, such Product. As used herein, "**Trademarks**" means all registered and unregistered trademarks, service marks, trade dress, trade names, logos, insignias, domain names, symbols, designs, and combinations thereof.

- (e) At PFIZER's option on a study-by-study basis for any study then on-going, and to the extent permitted under applicable agreements, LICENSEE will take such actions as PFIZER may reasonably request, at PFIZER's expense, to allow PFIZER or its CRO to complete the applicable study and to assign all related Regulatory Filings and Regulatory Approvals and investigator and other agreements relating to such study to PFIZER. LICENSEE shall, at PFIZER's request (to be made within thirty (30) days after the effective date of termination of this Agreement), (i) transfer to PFIZER or its Affiliate or designee all Inventory then owned and possessed by LICENSEE provided that PFIZER shall reimburse LICENSEE's direct costs thereof, and (ii) assign to PFIZER or its Affiliate or designee any agreements with Third Parties with respect to the Development or Commercialization of Products to the extent permitted under the terms of such agreements. As used herein, "**Inventory**" means all Products and components and works in process produced by or on behalf of LICENSEE with respect to the manufacture of Products.

**13.7. Survival.** Any expiration or termination of this Agreement shall not preclude the terminating Party from exercising any other of those remedies to which it may be entitled under this Agreement or Applicable Law, or terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 2.3, 2.4, 2.5, 2.6, 3.6 (solely as to subsections 3.6.3-3.6.5 thereof and the first two sentences of Section 3.6 as they relate to such subsections (including, for clarity, LICENSEE's obligations under Schedule C), provided that Section 3.6 will not survive if this Agreement is terminated by LICENSEE under Section 13.3 because of material breach by PFIZER), 6, 7.1, 7.2, 7.4.3, 9, 10.4, 11 (as to claims arising with respect to activities occurring during the term of this Agreement), 12, 13.6, 13.7, 14.2, 15, 16, 17.1-17.8, and 17.10-17.15 shall survive expiration or termination of this Agreement.

## **14. PUBLICITY AND PUBLICATIONS**

### **14.1. Publicity.**

14.1.1. Subject to PFIZER's rights pursuant to Section 13.6.5(d) and except as expressly permitted in Section 14.1.2, neither Party (nor any of its Affiliates or

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agents) shall use the Trademarks of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance.

14.1.2. Each Party agrees not to issue any press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party, provided however, that (a) on the Closing Date, PFIZER at its option will, and LICENSEE will, each issue a global press release (collectively, the “**Global Press Releases**”), (b) contemporaneously with the issuance of the Global Press Releases, PFIZER will send on behalf of LICENSEE written communications to investigators of the Existing Trials (the “**Investigator Communications**”), and (c) neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or the rules and regulations of the SEC or any national securities exchange so long as the disclosing Party provides the other Party at least [\*\*\*] prior written notice (and the right to review and comment on the proposed disclosure), to the extent practicable, and only discloses information to the extent required by Applicable Law or the rules and regulations of the SEC or national securities exchange, as set forth in Section 9.3. The content of the Global Press Releases and Investigator Communications shall be reasonably agreed-upon by the Parties prior to the Closing Date and shall describe (i) the fact that the Existing Advanced Trial described in clause (a) of the definition of “Existing Advanced Trial” is being amended as set forth in Attachment C-1 to Schedule C and (ii) LICENSEE’s proposed development plan for Products.

- 14.2. Publications. LICENSEE acknowledges that PFIZER personnel may desire to publish in scientific journals or present at scientific conferences scientific, pre-clinical or clinical data derived from research and development related to the Compounds that was conducted by PFIZER prior to the Closing Date. PFIZER acknowledges that LICENSEE personnel may desire to publish in scientific journals or present at scientific conferences results of LICENSEE’s Development activities hereunder. Both Parties understand that a reasonable commercial strategy may require delay of publication of information or filing of patent applications. Accordingly, from and after the Closing Date, no such publication will be submitted and no such presentation shall be made without the prior written consent of the other Party. Any such publication or presentation shall be submitted in writing to the other Party for review by the other Party reasonably in advance of the proposed publication or presentation date. The reviewing Party will reasonably consider such publication or presentation request, but shall not be obligated to consent thereto, and such reviewing Party shall provide its consent to or denial of such request within thirty (30) days of its receipt of such proposed publication or presentation. The Parties will reasonably agree upon appropriate authorship of any publication to which the other Party consents. In addition, from and after the Closing Date, if any PFIZER publication resulting from research in which PFIZER exercises the PFIZER Retained Rights under Section 2.3 mentions

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the Neratinib Compound, PFIZER will notify LICENSEE in advance of publication and provide LICENSEE the opportunity to comment on such publication. The Parties will discuss their publications plans at Transition Committee meetings.

## 15. LICENSEE INSURANCE

- 15.1. Insurance Requirements.** LICENSEE will maintain at all times during the term of this Agreement immediately prior to the date that it becomes the sponsor of an IND for Product pursuant to Section 4.3.2, and until the later of: (a) [\*\*\*] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of the Product have expired, commercial general liability insurance from a minimum "A-" AM Bests rated insurance company, including contractual liability and product or clinical trials liability, if applicable, with coverage limits of not less than [\*\*\*] in the aggregate. LICENSEE has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on LICENSEE's liability hereunder. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to the PFIZER Indemnitees. Any deductibles for such insurance shall be assumed by LICENSEE.
- 15.2. Policy Notification.** LICENSEE shall provide PFIZER with certified copies of such policies or original certificates of insurance evidencing such insurance: (a) promptly following execution by both Parties of this Agreement, and (b) prior to expiration of any one type of coverage. LICENSEE shall provide to PFIZER at least [\*\*\*] written notice prior to cancellation, termination or any change to restrict the coverage or reduce the limits afforded ; provided that no such notice shall be required if LICENSEE does or will have other or additional coverage in place prior to such cancellation, termination or change that results in LICENSEE having overall insurance coverage that complies with Section 15.1.

## 16. DISPUTE RESOLUTION

- 16.1. General.** Except for disputes for which injunctive or other equitable relief is sought to prevent the unauthorized use or disclosure of proprietary materials or information or prevent the infringement or misappropriation of a Party's Intellectual Property Rights, the following procedures shall be used to resolve any dispute arising out of or in connection with this Agreement.
- 16.2. Dispute Escalation.** Promptly after the written request of either Party, except with respect to activities conducted pursuant to the Transition Plan or the Trial Completion Plan, or [\*\*\*], each of the Parties shall appoint a designated representative to meet in person or by telephone to attempt in good faith to resolve any dispute. If the designated representatives do not resolve the dispute within [\*\*\*] of such request, or if such dispute arises with respect to activities

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conducted pursuant to the Transition Plan or the Trial Completion Plan, or [\*\*\*], then the CEO of LICENSEE and the President of PFIZER's Oncology Business Unit (collectively, the **"DR Executives"**) shall meet in person or by telephone to review and attempt to resolve the dispute in good faith. The DR Executives shall have [\*\*\*] (except as provided in Section 16.4) to attempt to resolve the dispute.

- 16.3. Pursuit of Claims.** With respect to any dispute that is not resolved by the Parties as set forth above, except as expressly set forth in Section 16.4 and Section 16.5, each Party may pursue claims it has under applicable law, which may include filing suit in courts of competent jurisdiction.
- 16.4. Disputes Arising Under Transition Plan, Trial Completion Plan, or [\*\*\*].** Any disputes arising with respect to activities conducted pursuant to the Transition Plan or the Trial Completion Plan, or [\*\*\*], but no other disputes arising under this Agreement, shall be submitted for expedited resolution as provided in this Section 16.4 and Section 16.5 if applicable. First, such dispute shall be submitted directly for resolution by the DR Executives pursuant to Section 16.2, except that the [\*\*\*] time period shall be [\*\*\*]. If the DR Executives do not resolve such dispute within such [\*\*\*] time period, then either Party may submit the issue for resolution pursuant to Section 16.5.
- 16.5. Expedited Resolution of Transition Plan, Trial Completion Plan and [\*\*\*] Disputes.** Any disputes arising with respect to activities conducted pursuant to the Transition Plan or the Trial Completion Plan, or [\*\*\*], that remain unresolved after following the procedures set forth in Section 16.4, but no other issues arising under this Agreement, shall be submitted for resolution by expedited arbitration pursuant to this Section 16.5. Any arbitration under this Section 16.5 shall be conducted by [\*\*\*]. In such arbitration, [\*\*\*] shall select an independent expert with significant experience relating to the subject matter of such dispute in the life sciences industry, at a senior executive level, to advise the arbitrator with respect to the subject matter of the dispute. If the Parties are unable to agree on an arbitrator, the arbitrator shall be selected [\*\*\*]. The arbitrator and such expert shall be selected within [\*\*\*] after the matter is submitted for arbitration, and such arbitrator and expert shall issue their decision as promptly as practicable, but no later than [\*\*\*] after they have both been selected. The Parties agree that the arbitrator shall have the power to resolve any disputes to be resolved pursuant to this Section 16.5 based on principles of fairness and equity. Each Party shall bear its own costs and expenses in connection with the arbitration.

## 17. GENERAL PROVISIONS

- 17.1. Assignment.** Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) PFIZER may assign to a Third Party its rights to receive some or all of the Milestone Payments and Royalties payable hereunder, provided that doing so does not adversely affect in any material respect the payment or other obligations of LICENSEE hereunder; (b) each Party may assign its rights and obligations

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under this Agreement to one or more of its Affiliates without the consent of the other Party, provided that such assignment does not increase materially the other Party's payment obligations (including without limitation such other Party's tax payment obligations) ; and (c) either Party may assign this Agreement to the successor entity in the event it undergoes a Change in Control. As used herein, "**Change in Control**" means the acquisition of a Party by a Third Party or the sale of all or substantially all of its business to which this Agreement relates. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.

**17.2. Severability.** Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such invalidity or unenforceability, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

**17.3. Governing Law; Exclusive Jurisdiction.**

17.3.1. This Agreement shall be governed by and construed under the laws in effect in the State of New York, US, without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result.

17.3.2. The courts of the State of New York, US, shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum, and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award, or the pursuit of injunctive or other equitable relief described in Section 16.1.

**17.4. Force Majeure.** Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a

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“**Force Majeure Event**”), provided that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for [\*\*\*], then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

- 17.5. Waivers and Amendments.** The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.
- 17.6. Relationship of the Parties.** Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between PFIZER and LICENSEE, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.
- 17.7. Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.
- 17.8. Notices.** All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt), (b) sent by fax (with written confirmation of receipt), provided that a copy is sent by an internationally recognized overnight delivery service (receipt requested), or (c) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to PFIZER:

Pfizer Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017  
Fax: 646-348-8157  
Attention: General Counsel

If to LICENSEE:

Puma Biotechnology, Inc.  
10940 Wilshire Blvd, Suite 600  
Los Angeles, CA 90024  
Attention: Alan Auerbach

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With a copy to:

Latham & Watkins  
650 Town Center Drive  
20th Floor  
Costa Mesa CA 92626-1925  
Fax: 714-755-8290  
Attention: Charles Ruck

**17.9. Further Assurances.** LICENSEE and PFIZER hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

**17.10. No Third Party Beneficiary Rights.** This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

**17.11. Entire Agreement; Confidentiality Agreement.**

- (a) This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, without limitation, that certain Confidentiality Agreement by and between the Parties, dated November 23, 2010 (the “CDA”). The Parties acknowledge and agree that, as of the Execution Date, all Confidential Information (as defined in the CDA) disclosed by PFIZER or its Affiliates pursuant to the CDA shall be considered PFIZER’s Confidential Information and subject to the terms set forth in this Agreement.
- (b) In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

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

**17.13. Cumulative Remedies.** Unless otherwise expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under applicable law.

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**17.14. Waiver of Rule of Construction.** Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

**17.15. Construction.** For purposes of this Agreement: (a) words in the singular shall be held to include the plural and vice versa as the context requires; (b) the words “including” and “include” shall mean “including, without limitation,” unless otherwise specified; (c) the terms “hereof,” “herein,” “herewith,” and “hereunder,” and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement; and (d) all references to “Section,” “Schedule” and “Exhibit,” unless otherwise specified, are intended to refer to a Section, Schedule or Exhibit of or to this Agreement.

**(Signatures on next page)**

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

**PUMA BIOTECHNOLOGY, INC.**By: /s/ Alan AuerbachName: Alan AuerbachTitle: CEO, President**PFIZER INC.**By: /s/ Garry NicholsonName: Garry NicholsonTitle: President, General Manager

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