

November 17, 2017

Dear SEC FOIA Office:

I am requesting a copy of

Exhibit 10.11 to Form 10-Q filed by Advanced Life Sciences Holdings Inc. on 11/06/2008.

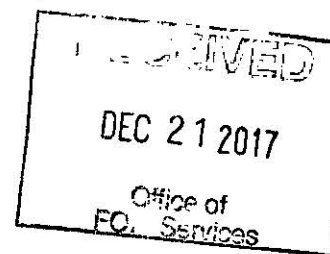
I am willing to pay up to \$61.00.

Thank you,

Diane Martin

**AUS Consultants Inc.**  
155 Gaither Dr, Suite A  
Mt. Laurel  
NJ 08054  
856.234.9200

18-01565-E





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

Office of FOIA Services

December 27, 2017

Ms. Diane Martin  
AUS Consultants, Inc.  
155 Gaither Dr., Suite A  
Mt. Laurel, NJ 08054

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-01565-E

Dear Ms. Martin:

This letter is in response to your request, dated and received in this office on December 21, 2017, for Exhibit 10.11 to Form 10-Q filed by Advanced Life Sciences Holdings Inc. on November 6, 2008.

In connection with a previous request, we identified and released Exhibit 10.11; as such, we have no objection to releasing this same exhibit to you. No fees have been assessed in this instance.

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

Sincerely,

*Kay Reid*

Kay Reid  
FOIA Lead Research Specialist

Enclosures

**DEVELOPMENT AND COMMERCIALIZATION  
AGREEMENT**

by and between

**WYETH**  
acting through its Wyeth Pharmaceuticals Division

and

**ADVANCED LIFE SCIENCES HOLDINGS, INC.**

September 29, 2008

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## DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Development and Commercialization Agreement (the “**Agreement**”) is entered into as of September 29, 2008 (the “**Effective Date**”), by and between Wyeth, a corporation organized and existing under the laws of the State of Delaware and having a place of business at 500 Arcola Road, Collegeville, Pennsylvania 19426 (“**Wyeth**”), acting through its Wyeth Pharmaceuticals Division, and Advanced Life Sciences Holdings, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 1440 Davey Road, Woodridge, Illinois 60517 (“**ADLS**”). Wyeth and ADLS may each be referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

WHEREAS, Wyeth is engaged in the research, development and commercialization of pharmaceutical and health care products;

WHEREAS, ADLS controls proprietary rights related to cethromycin, an antibiotic from the ketolide class;

WHEREAS, Wyeth and ADLS desire to collaborate to develop, manufacture and commercialize products for the Territory (as defined below) based on cethromycin, as described herein;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

### 1. DEFINITIONS.

**1.1. Abbott Agreement.** “**Abbott Agreement**” shall have the meaning set forth in Section 5.3.2 hereof.

**1.2. Additional Third Party License.** “**Additional Third Party License**” shall have the meaning set forth in Section 5.3.4 hereof.

**1.3. ADLS Indemnified Party.** “**ADLS Indemnified Party**” shall have the meaning set forth in Section 10.2 hereof.

**1.4. ADLS Know-How.** “**ADLS Know-How**” shall mean any Know-How, other than the Joint Know-How, that (i) ADLS or any of its Affiliates Controls as of the Effective Date or that comes into the Control of ADLS or any of its Affiliates during the Term (other than through the grant of a license by Wyeth) and (ii) is necessary or useful in the discovery, synthesis, research, use, Development, Manufacture or Commercialization of any Compound or any Product.

**1.5. ADLS Licensee.** “**ADLS Licensee**” or “**Licensee**” shall mean any Person who receives or has received, directly or indirectly, from ADLS, a license or



sublicense of any right to Develop, Manufacture or Commercialize any Compound or Product.

**1.6. ADLS Patent Rights.** “ADLS Patent Rights” shall mean any Patent Right, other than any Joint Patent Right, that (i) ADLS or any of its Affiliates Controls as of the Effective Date or that comes into the Control of ADLS or any of its Affiliates during the Term (other than through the grant of a license by Wyeth) and (ii) is necessary or useful in the discovery, synthesis, research, use, Development, Manufacture or Commercialization of any Compound or any Product. Those ADLS Patent Rights existing as of the Effective Date include without limitation those set forth on Exhibit 1.6 attached hereto.

**1.7. ADLS Product Data or Filings.** “ADLS Product Data or Filings” shall have the meaning set forth in Section 4.4.1.

**1.8. ADLS Study.** “ADLS Study” shall mean [the clinical study of the Current Product for the treatment of CAP, as summarized in Exhibit 1.8 attached hereto, to be conducted in South Korea and Taiwan (pursuant to Section 4.3.1) and other appropriate jurisdictions].

**1.9. ADLS Technology.** “ADLS Technology” shall mean, collectively, the ADLS Patent Rights and ADLS Know-How.

**1.10. ADLS Third Party Agreement(s).** “ADLS Third Party Agreement(s)” shall mean any agreement between ADLS and any Third Party under which ADLS obtains rights in or to any Licensed Right. Those ADLS Third Party Agreement(s) in existence as of the Effective Date are listed on Exhibit 1.10.

**1.11. Affiliate(s).** “Affiliate(s)” shall mean, with respect to any Person or entity, any other Person or entity that controls, is controlled by or is under common control with such Person or entity. A Person or entity shall be regarded as in control of another entity if it owns or controls more than fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority), provided, however, that the term “Affiliate” shall not include subsidiaries or other entities in which a Party or its Affiliates owns a majority of the ordinary voting power necessary to elect a majority of the board of directors or other managing authority, but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.

**1.12. Bankruptcy Code.** “Bankruptcy Code” shall have the meaning set forth in Section 2.6 hereof.

**1.13. Calendar Quarter.** “Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

**1.14. Calendar Year.** “**Calendar Year**” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

**1.15. CAP.** “**CAP**” shall mean community acquired pneumonia.

**1.16. Change of Control.** “**Change of Control**” shall mean, with respect to a Party, (i) a merger, reorganization or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation, (ii) a Third Party becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party or (iii) the sale or other transfer of all or substantially all of such Party’s business or assets to which this Agreement relates to a Third Party.

**1.17. [China] Study.** “[**China**] **Study**” shall mean [the clinical study of the Current Product for the treatment of CAP, as summarized in Exhibit 1.17 attached hereto, to be conducted in China (pursuant to Section 4.3.2)].

**1.18. Combination Product.** “**Combination Product**” shall mean any Product containing as active ingredients both (a) any Compound and (b) one or more other pharmaceutically active compounds or substances, in the same formulation.

**1.19. Combination Sale.** “**Combination Sale**” shall have the meaning set forth in Section 1.64 hereof.

**1.20. Commercial Events.** “**Commercial Events**” shall have the meaning set forth in Section 5.2 hereof.

**1.21. Commercialization.** “**Commercialization**” or “**Commercialize**” shall mean to use, have used, offer for sale, have offered for sale, sell, have sold, import, have imported and otherwise commercialize a product, including activities directed to obtaining pricing and reimbursement approvals for, marketing, promoting or distributing a product. Commercialization shall not include any activities related to Manufacturing or Development.

**1.22. Commercially Reasonable Efforts.** “**Commercially Reasonable Efforts**” shall mean, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. With respect to any objective relating to the Development, Manufacture or Commercialization of a Product by Wyeth, generally or with respect to any particular country in the Territory, “**Commercially Reasonable Efforts**” shall mean those efforts and resources normally used by Wyeth, in the Territory or in such country, as the case may be, with respect to a product owned or controlled by Wyeth, or to which Wyeth has



similar rights, which product is of similar market potential in the Territory or in such country, as the case may be, and is at a similar stage in its development or life as is such Product, taking into account issues of safety, efficacy, product profile, the likelihood of obtaining regulatory approvals, including satisfactory reimbursement or pricing approvals for such product in the Territory or such country, as the case may be, and the timing of such approvals, the current and projected competitiveness of the marketplace for such product in the Territory or in such country, as the case may be, the proprietary position and anticipated exclusivity of such product in the Territory or in such country, as the case may be, the existing or projected sales and profitability of such product in the Territory or such country, as the case may be, and other relevant commercial factors. To the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of the failing Party's failure shall be taken into account in determining whether the other Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

**1.23. Commercial Payment.** "Commercial Payment" shall have the meaning set forth in Section 5.2.3.

**1.24. Competing Product.** "Competing Product" shall mean, with respect to any Product, any product that contains an active ingredient that is substantially the same as a Compound (or any analog or other pharmaceutically acceptable form of a Compound, including, without limitation, any isomer, metabolite, hydrate, solvate, salt form or polymorph of a Compound). For the avoidance of doubt, an active ingredient shall not be considered to be separate, distinct and different from a Compound solely on the basis of its method of production, method of delivery or dosage level.

**1.25. Compound.** "Compound" means the compound set forth on Exhibit 1.25 attached hereto, also known as cethromycin, or any prodrug or other pharmaceutically acceptable form of such compound, including, without limitation, any isomer, metabolite, hydrate, solvate, salt form or polymorph of any of the foregoing.

**1.26. Confidential Information.** "Confidential Information" of a Party shall mean all Know-How or other information, including, without limitation, proprietary information and materials (whether or not patentable) regarding such Party's technology, products, business or objectives that is communicated in any way or form by the Disclosing Party to the Receiving Party, either prior to or after the Effective Date of this Agreement, and whether or not such Know-How or other information is identified as confidential at the time of disclosure. Subject to Section 7.3 below, the terms and conditions of this Agreement shall be considered Confidential Information of each Party.

**1.27. Continuing Party.** "Continuing Party" shall have the meaning set forth in Section 6.2.1(b) hereof.

**1.28. Control.** “Control” or “Controlled” shall mean with respect to any intellectual property right (including, without limitation, any Know-How, Patent Right or right regarding access or reference to Product Data or Filings or other data or information), possession of the ability (whether by sole or joint ownership, license or otherwise, other than pursuant to this Agreement) to grant, without violating the terms of any Control Limitation Agreement, a license, access or other right in, to or under such intellectual property right.

**1.29. Control Limitation Agreement.** “Control Limitation Agreement” shall mean any agreement or arrangement which limits the ownership rights of a Person with respect to, or limits the ability of a Person to grant a license, sublicense or other right in, to or under, any intellectual property right.

**1.30. Current Product.** “Current Product” shall mean the Product the formulation of which is described in IND number 57836.

**1.31. Debtor.** “Debtor” shall have the meaning set forth in Section 9.4.

**1.32. Declining Party.** “Declining Party” shall have the meaning set forth in Section 6.2.1(b) hereof.

**1.33. Develop.** “Develop” shall mean shall mean to discover, research or develop a product, including the use of any licensed right for the purpose of conducting any such discovery, research or development. When used as a noun, “Development” shall mean any and all activities involved in Developing. Develop and Development shall include, without limitation, conducting non-clinical and clinical research and development activities such as toxicology, pharmacology and other discovery efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre- and post-approval studies), regulatory affairs, pharmacovigilance and all activities directed to obtaining any Regulatory Approval.

**1.34. Development Program.** “Development Program” shall mean the Development of Products pursuant to the Global Development Plan.

**1.35. Disclosing Party.** “Disclosing Party” shall have the meaning set forth in Section 7.1 hereof.

**1.36. Divested Asset.** “Divested Asset” shall have the meaning set forth in Section 12.14.2 hereof.

**1.37. Effective Date.** “Effective Date” shall have the meaning set forth in the first paragraph of this Agreement.

**1.38. Executive Officers.** “Executive Officers” shall mean an appropriate senior level executive designated by Wyeth (or an executive of Wyeth or an

Affiliate of Wyeth designated by such senior level executive) and the President of ADLS (or an officer of ADLS or an Affiliate of ADLS designated by such President).

**1.39. FDA.** “FDA” shall mean the United States Food and Drug Administration or any successor agency thereto.

**1.40. FD&C Act.** “FD&C Act” shall mean the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*), as amended, and the rules and regulations promulgated thereunder.

**1.41. First Commercial Sale.** “First Commercial Sale” shall mean, with respect to any Product and any country of the Territory and any indication, the first sale of such Product under this Agreement by Wyeth, its Affiliates or its Sublicensees to a Third Party in such country, after such Product has been granted Regulatory Marketing Approval and Regulatory Pricing Approval for such indication by the competent Regulatory Authorities in such country. When used without reference to a specified indication, First Commercial Sale shall mean the First Commercial Sale for any indication.

**1.42. First Party.** “First Party” shall have the meaning set forth in Section 6.2.1(c).

**1.43. GAAP.** “GAAP” shall mean then current United States generally accepted accounting principles, consistently applied.

**1.44. Generic Product.** “Generic Product” shall mean any product containing Compound as an active ingredient.

**1.45. Global Development Plan.** “Global Development Plan” shall have the meaning as set forth in Section 4.2.

**1.46. IND.** “IND” shall mean an Investigational New Drug Application, as defined in the FD&C Act, that is required to be filed with the FDA before beginning clinical testing of a Product in human subjects, or an equivalent foreign filing.

**1.47. Indemnified Party.** “Indemnified Party” shall have the meaning set forth in Section 10.4 hereof.

**1.48. Indemnifying Party.** “Indemnifying Party” shall have the meaning set forth in Section 10.4 hereof.

**1.49. Joint Invention(s).** “Joint Invention(s)” shall have the meaning set forth in Section 6.1 hereof.

**1.50. Joint Know-How.** “Joint Know-How” shall have the meaning set forth in Section 6.1 hereof.

**1.51. Joint Patent Right(s).** “Joint Patent Right(s)” shall have the meaning set forth in Section 6.1 hereof.

**1.52. Joint Technology.** “Joint Technology” shall mean, collectively, the Joint Patent Rights, the Joint Inventions and the Joint Know-How.

**1.53. Know-How.** “Know-How” shall mean non-public, proprietary inventions, discoveries, data, information, processes, methods, techniques, materials, technology, results or other know-how, whether or not patentable.

**1.54. Label.** “Label” shall mean product labeling in accordance with all applicable Regulatory Approvals.

**1.55. Launch Events.** “Launch Events” shall have the meaning set forth in Section 5.2 hereof.

**1.56. Launch Payment.** “Launch Payment” shall have the meaning set forth in Section 5.2.1(a).

**1.57. Leading Party.** “Leading Party” shall have the meaning set forth in Section 6.2.2(c).

**1.58. Liability.** “Liability” shall have the meaning set forth in Section 10.2 hereof.

**1.59. Licensed Rights.** “Licensed Rights” shall mean the interest of ADLS or any of its Affiliates in the ADLS Patent Rights, the ADLS Know-How and the Joint Technology.

**1.60. Licensee Trademark.** “Licensee Trademark” shall have the meaning set forth in Section 2.1.3 hereof.

**1.61. Major Market.** “Major Market” [shall mean each of China, South Korea and Taiwan].

**1.62. Manufacturing.** “Manufacturing” or “Manufacture” shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product.

**1.63. Net Combination Sale Amount.** “Net Combination Sale Amount” shall have the meaning set forth in Section 1.64 hereof.

**1.64. Net Sales.** “Net Sales” shall mean the gross amount actually received for any sale of any Product by Wyeth, any Wyeth Affiliate or any Wyeth Sublicensee, as appropriate (a “Selling Person”), to a non-Affiliate of the Selling Person, less the following deductions, in each case to the extent specifically

related to the Product and taken by the Selling Person or otherwise paid for or accrued by the Selling Person (“**Permitted Deductions**”):

- (i) trade, cash, promotional and quantity discounts and wholesaler fees;
- (ii) taxes on sales (such as excise, sales or use taxes or value added taxes) to the extent imposed upon and paid directly with respect to the sales price (and excluding national, sales or local taxes based on income);
- (iii) freight, insurance, packing costs and other transportation charges to the extent included in the invoice price to the buyer;
- (iv) amounts repaid or credits taken by reason of damaged goods, rejections, defects, expired dating, recalls or returns or because of retroactive price reductions;
- (v) charge back payments and rebates granted to (a) managed healthcare organizations, (b) federal, state or provincial or local governments or other agencies, (c) purchasers and reimbursers, or (d) trade customers, including wholesalers and chain and pharmacy buying groups; and
- (vi) documented custom duties actually paid by the Selling Person.

Such Permitted Deductions shall be determined in accordance with GAAP.

Sales of Products between Wyeth, its Affiliates or Sublicensees for resale, or for use in the production or manufacture of Products, shall not be included within Net Sales; provided, however, that any subsequent sale of such Product (or Products produced or manufactured using such Product) by Wyeth or its Affiliate or Sublicensee to a non-Affiliate Third Party shall be included within Net Sales.

If a Product is sold as part of a Combination Product (in each case, a “**Combination Sale**”), the Net Sales amount for the Product sold in such a Combination Sale shall be that portion of the gross amount actually received for such Combination Sale (less all Permitted Deductions) determined as follows:

Except as provided below, the Net Sales amount for a Combination Product shall equal the gross amount actually received for the Combination Sale, reduced by the Permitted Deductions (the “**Net Combination Sale Amount**”), multiplied by the fraction  $A/(A+B)$ , where:

**A** is the Wholesale Acquisition Cost, in the country where such Combination Sale occurs, of the Product contained in the Combination Product, if sold as a separate Product in such country by the Selling Person, and **B** is the aggregate Wholesale Acquisition Cost(s), in such country, of such other products or active ingredients/components, as the

case may be, included in the Combination Product if sold separately in such country by the Selling Person.

In the event that the Selling Person sells the Product included in a Combination Product as a separate Product in a country, but does not separately sell all of the other products or active ingredients/components, as the case may be, included in such Combination Product in such country, the calculation of Net Sales resulting from such Combination Sale shall be determined by multiplying the Net Combination Sale Amount by the fraction  $A/C$  where:

**A** is the Wholesale Acquisition Cost, in the country where such Combination Sale occurs, of the Product contained in such Combination Product when sold as a separate Product by the Selling Person, and **C** is the Wholesale Acquisition Cost, in such country, charged by the Selling Person for the entire Combination Product.

In the event that the Selling Person does not sell the Product included in a Combination Product as a separate Product in the country where such Combination Sale occurs, but does separately sell all of the other products or active ingredients/components, as the case may be, included in the Combination Product in such country, the calculation of Net Sales resulting from such Combination Sale shall be determined by multiplying the Net Combination Sale Amount by the fraction  $(C-D)/C$ , where:

**C** is the Wholesale Acquisition Cost, in such country, charged by the Selling Person for the entire Combination Product, and **D** is the Wholesale Acquisition Cost, in such country, charged by the Selling Person for the other products or active ingredients/components, as the case may be, included in the Combination Product.

Where active ingredient portions of a Combination Product are sold separately as other products but in different dosage strengths than are in the Combination Product, the calculation of the Net Sales amount for such Combination Product shall be based on appropriate proration of the amounts of each active ingredient component included therein when applying the formulas set forth above.

Where the calculation of Net Sales resulting from a Combination Sale in a country cannot be determined by any of the foregoing methods, the calculation of Net Sales for such Combination Sale shall be that portion of the Net Combination Sale Amount reasonably determined in good faith by Wyeth in consultation with ADLS as properly reflecting the value of the Product included in the Combination Product.

If a Product is sold as part of a bundle of distinct products (i.e., one price is charged for a number of distinct products that are not (i) packaged together with

another Product or (ii) in a Combination Product form alone), the Net Sales for such Product shall be based on the ratio of the Wholesale Acquisition Cost for such Product to the sum of the Wholesale Acquisition Costs for each product in such bundle. By way of example, if the Wholesale Acquisition Cost for such Product when sold separately is \$10, and the sum of the Wholesale Acquisition Costs for each product in such bundle when sold separately is \$40, then the Net Sales attributable to the Product when sold as part of the bundle would be twenty-five percent (25%) of the Net Sales of the bundle of products sold by the Selling Person.

Notwithstanding the foregoing, Net Sales shall not include any consideration received by Wyeth, its Affiliates or its Sublicensees in respect of the sale, use or other disposition of a Product in a country as part of a clinical trial prior to the receipt of all Regulatory Marketing Approvals required to commence commercial sales of such Product in such country.

Products provided by Wyeth, its Affiliates or Sublicensees free of charge, as samples, for administration to patients enrolled in clinical trials or distributed through a not-for-profit foundation or other compassionate use program at no charge to eligible patients, shall not be included in Net Sales, provided that Wyeth, its Affiliates or Sublicensees receive no cash consideration from such samples, clinical trials, not-for-profit foundation or program.

**1.65. Non-Disclosure Agreement.** “Non-Disclosure Agreement” shall have the meaning specified in Section 7.5.

**1.66. Offer.** “Offer” shall have the meaning specified in Section 12.15.

**1.67. Patent Rights.** “Patent Rights” shall mean any and all (a) patents, (b) pending patent applications, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation, supplementary protection certificates or the equivalent thereof, (d) inventor’s certificates, (e) any other form of government-issued right substantially similar to any of the foregoing; and (f) all United States and foreign counterparts of any of the foregoing.

**1.68. Permitted Deductions.** “Permitted Deductions” shall have the meaning set forth in Section 1.64 hereof.

**1.69. Person.** “Person” shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

**1.70. Product.** “**Product**” shall mean any pharmaceutical product containing a Compound, including, but not limited to, any formulation of any Compound (including, but not limited to, oral formulations, oral suspension formulations and intravenous formulations) and any Product Improvement. “Product” includes, without limitation, any Combination Product but does not include any separately formulated pharmaceutical product not containing a Compound, even if such product is sold together with a Product.

**1.71. Product Data or Filing.** “**Product Data or Filing**” shall mean (i) any pre-clinical or clinical data (including data from post-approval studies), clinical protocol, study, other data, information or result regarding any Compound or Product or the composition of or any method of making or using any Compound or Product or (ii) any IND, Regulatory Marketing Approval Application, Regulatory Marketing Approval or other regulatory filing regarding any Compound or Product.

**1.72. Product Improvement.** “**Product Improvement**” shall mean any alternative or improved dosage form of a Compound (e.g., a different dosage strength or a novel formulation technology) that ADLS may develop or license for a Compound.

**1.73. Product Trademark.** “**Product Trademark**” shall mean (i) any Trademark Controlled by ADLS and used by ADLS or its Affiliates anywhere in the world in connection with the Commercialization of Products, other than any corporate name or corporate logo of ADLS or its Affiliates or any Trademark used by ADLS or its Affiliates to identify products other than Products, or (ii) any Licensee Trademark.

**1.74. Prosecuting Party.** “**Prosecuting Party**” shall have the meaning set forth in Section 6.2.1(b).

**1.75. Recall.** “**Recall**” shall mean, with respect to any pharmaceutical product, a “recall,” “product withdrawal,” “stock recovery,” “seizure” or any similar term as utilized by any Regulatory Authority under such Regulatory Authority’s procedures regarding the recall of pharmaceutical products, as the same may be amended from time to time, and shall include any related post-sale warning or mailing of information regarding such product, including any warnings or mailings described in the Regulatory Authority’s product recall procedures.

**1.76. Receiving Party.** “**Receiving Party**” shall have the meaning set forth in Section 7.1 hereof.

**1.77. Regulatory Approval.** “**Regulatory Approval**” means any technical, medical, scientific or other license, registration, authorization or approval of any Regulatory Authority regarding the research, development, clinical testing, commercial manufacture, distribution, marketing, pricing, reimbursement,



promotion, offer for sale, use, import, export or sale of any pharmaceutical product or proposed pharmaceutical product.

**1.78. Regulatory Authority.** “**Regulatory Authority**” shall mean, with respect to any national, supra-national, regional, state or local regulatory jurisdiction, any agency, department, bureau, commission, council or other governmental entity involved in the granting of a Regulatory Approval for such jurisdiction.

**1.79. Regulatory Marketing Approval.** “**Regulatory Marketing Approval**” shall mean, with respect to any Product in any regulatory jurisdiction and for any indication, Regulatory Approval authorizing the marketing of such Product in such jurisdiction for such indication.

**1.80. Regulatory Marketing Approval Application.** “**Regulatory Marketing Approval Application**” shall mean, with respect to any Product in any regulatory jurisdiction for any indication, an application submitted to the appropriate Regulatory Authority for such regulatory jurisdiction seeking Regulatory Marketing Approval of such Product for use in such indication in such regulatory jurisdiction.

**1.81. Regulatory Pricing Approval.** “**Regulatory Pricing Approval**” shall mean, with respect to any Product in any regulatory jurisdiction, and for any indication, the achievement of all applicable pricing and reimbursement approvals with respect to such Product in such jurisdiction and for such indication.

**1.82. Right of First Offer.** “**Right of First Offer**” shall have the meaning specified in Section 12.15.

**1.83. Right of Reference.** “**Right of Reference**” shall mean a “Right of Reference,” as that term is defined in 21 C.F.R. § 314.3(b) and any comparable right existing under the laws or regulations of any foreign country.

**1.84. [Royalty Advance.** “**Royalty Advance**” shall have the meaning set forth in Section 5.3.6 hereof.]

**1.85. Royalty Rate.** “**Royalty Rate**” shall have the meaning set forth in Section 5.3.2.

**1.86. Royalty Term.** “**Royalty Term**” shall mean, on a country-by-country and Product-by-Product (but not indication-by-indication) basis, the period from the date of the First Commercial Sale of the Product in a country for any indication until the latest of (i) the end of any regulatory data exclusivity period for such Product in such country or (ii) the date on which there is no Valid Claim of any ADLS Patent Right which covers the use or sale of the Product in such country or (iii) ten (10) years after such First Commercial Sale of such Product in such Country.

**1.87. Second Party.** “Second Party” shall have the meaning set forth in Section 6.2.1(c).

**1.88. Selling Person.** “Selling Person” shall have the meaning set forth in Section 1.64 hereof.

**1.89. Steering Committee.** “Steering Committee” shall have the meaning set forth in Section 3.1.1 hereof.

**1.90. Stock Purchase Agreement.** “Stock Purchase Agreement” shall mean the Stock Purchase Agreement dated as of the Effective Date by and between Wyeth and ADLS in the form attached hereto as Exhibit 1.90.

**1.91. Sued Party.** “Sued Party” shall have the meaning set forth in Section 6.2.3(c) hereof.

**1.92. Supply Agreement.** “Supply Agreement” shall have the meaning set forth in Section 4.9.1 hereof.

**1.93. Term.** “Term” shall have the meaning set forth in Section 9.1.

**1.94. Territory.** “Territory” shall mean China, South Korea, Taiwan, Hong Kong, Afghanistan, Bangladesh, Bhutan, Brunei, Darussalam, Cambodia, Indonesia, Laos, Macau, Malaysia, Maldives, Mongolia, Myanmar, Nepal, North Korea, Pakistan, the Philippines, Singapore, Sri Lanka, Thailand, Vietnam and, if Wyeth accepts an Offer pursuant to Section 12.15, **[India]**.

**1.95. Territory Patent Right.** “Territory Patent Right” shall have the meaning set forth in Section 6.2.1(a).

**1.96. Third Party.** “Third Party” shall mean any Person other than Wyeth, ADLS and their respective Affiliates.

**1.97. Third Party IP Rights.** “Third Party IP Rights” shall have the meaning set forth in Section 6.2.3(b) hereof.

**1.98. Trademark.** “Trademark” shall mean any trademark, trade dress, design, logo, slogan, house mark or name used in connection with the marketing of a product, including, without limitation, any registration or application for registration of any of the foregoing.

**1.99. Transition Date.** “Transition Date” shall have the meaning set forth in Section 5.3.2 hereof.

**1.100. Valid Claim.** “Valid Claim” shall mean a claim of any unexpired issued patent that shall not have been dedicated to the public, disclaimed nor held invalid or unenforceable by a court or government agency of competent jurisdiction in an unappealed or unappealable decision.

**1.101. Wholesale Acquisition Cost.** “Wholesale Acquisition Cost” for any product shall mean the list price for wholesalers, distributors and other direct accounts before any rebates, discounts, allowances or other price concessions that might be offered by the supplier of the product.

**1.102. Wyeth Indemnified Party.** “Wyeth Indemnified Party” shall have the meaning set forth in Section 10.3 hereof.

**1.103. Wyeth Manufacturing Cost.** “Wyeth Manufacturing Cost” shall have the meaning set forth in Section 5.4.2.

**1.104. Wyeth Product Improvement.** “Wyeth Product Improvement” shall mean any Know-How (other than the Joint Know-How) Controlled by Wyeth or any of its Affiliates during the Term (other than through the grant of a license by ADLS) pertaining to the composition of, or any method of making or using, or any Patent Right (other than a Joint Patent Right) Controlled by Wyeth or any of its Affiliates during the Term (other than through the grant of a license by ADLS) that covers or claims, any alternative or improved dosage form of a Compound (e.g., a different dosage strength or a novel formulation technology) that Wyeth may Develop under this Agreement.

**1.105. Wyeth Sublicensee.** “Wyeth Sublicensee” or “Sublicensee” shall mean any Person who has received, directly or indirectly, from Wyeth, a sublicense of any right licensed to Wyeth by ADLS hereunder.

## **2. LICENSES AND RELATED GRANTS OF RIGHTS.**

### **2.1. Licenses Granted to Wyeth.**

**2.1.1. Licenses for Compounds and Products.** Subject to the terms and conditions of this Agreement, ADLS, effective as of the Effective Date, hereby grants to Wyeth under the Licensed Rights, with the right to grant sublicenses as set forth in Section 2.1.2, the following licenses:

(a) A non-exclusive license to Develop and have Developed, in all countries throughout the world, Compounds and Products for Commercialization in the Territory, and to Manufacture and have Manufactured, in all countries throughout the world, any such Compound or Product for use in such Development.

(b) An exclusive license (exclusive even as to ADLS and its Affiliates except as necessary to fulfill their obligations under this Agreement) to Commercialize Compounds and Products in the Territory and, subject to the obligation to purchase Product from ADLS pursuant to the Supply Agreement contemplated by Exhibit 4.9.1, to Manufacture and have Manufactured, in all countries throughout the world, Compounds and Products solely for use or sale in the Territory as part of such Commercialization.

**2.1.2. Sublicenses.** Wyeth may grant and authorize sublicenses within the scope of the rights conveyed to Wyeth pursuant to Section 2.1.1. Wyeth shall give ADLS prompt written notice of each such sublicense, identifying the applicable Sublicensee, Products sublicensed, territory and scope of rights granted. Wyeth shall be responsible to ensure that each Sublicensee complies with all applicable terms and conditions of this Agreement.

**2.1.3. Trademark License.** Subject to the terms and conditions of this Agreement, ADLS, effective as of the Effective Date, hereby grants to Wyeth an exclusive, royalty-free license to use any Product Trademark(s) solely in connection with Commercialization of Products in the Territory. With respect to any Trademark Controlled by a Licensee and used by such Licensee in connection with the Commercialization of Products in the United States or Europe, other than any corporate name or corporate logo of such Licensee or any Trademark used by such Licensee to identify products other than Products (each, a “**Licensee Trademark**”), ADLS shall use Commercially Reasonable Efforts to obtain from such Licensee a written agreement confirming ADLS' right to include such Trademark in the Product Trademarks licensed to Wyeth as provided in this Section 2.1.3.

**2.1.4. Direct Licenses to Affiliates.** Wyeth may at any time request and authorize ADLS to grant licenses directly to Affiliates of Wyeth by giving written notice designating to whom a direct license is to be granted. Upon receipt of any such notice, ADLS shall enter into and sign a separate agreement with such designated Affiliate of Wyeth conveying such direct license for so long as such Affiliate remains an Affiliate of Wyeth. All such direct license agreements shall be consistent with the terms and conditions of this Agreement, except for such modifications as may be required by the laws and regulations in the country in which the direct license will be exercised. In countries where validity of the direct license agreement requires prior government approval or registration, such direct license agreement shall not become binding between the parties thereto until such approval or registration is granted, which approval or registration shall be obtained by Wyeth. All out-of-pocket costs incurred in granting a direct license, including ADLS' reasonable attorneys' fees, under this Section 2.1.4 shall be borne by Wyeth. Wyeth shall cause any such Affiliate to make all payments required to be made to ADLS and to satisfy all other obligations of such Affiliate to ADLS under any such agreement and shall remain directly liable to ADLS for any breaches of any such agreement by its Affiliate. In the event that any such direct license results in the imposition on ADLS of any taxes in excess of those that would be imposed if Wyeth had granted a sublicense to such Affiliate, Wyeth shall be obligated to pay to ADLS such amounts as may be necessary to “gross up” payments to ADLS to account for such additional taxes. Any progress reports and royalty statements to be provided under



this Agreement shall be consolidated by Wyeth to one single report and statement for all Affiliates of Wyeth.

**2.2. Rights of Reference.** ADLS and Wyeth shall have Rights of Reference as set forth in Section 4.4.

**2.3. Technology Transfer.** ADLS shall provide reasonable assistance to Wyeth, as requested by Wyeth and at no additional cost to Wyeth, to effect the timely and orderly transfer of the ADLS Know-How to Wyeth in order for Wyeth to be able to Develop and Commercialize Compounds and Products as contemplated by this Agreement. All Know-How and other materials provided by or on behalf of ADLS may be subject to the obligations set forth in Section 7, and shall be used by Wyeth and its Affiliates and Sublicensees solely for the Development, Manufacture and Commercialization of Products for the Territory pursuant to the licenses set forth in Section 2.1.1 above.

**2.4. Licenses Granted to ADLS.**

**2.4.1. License for Compounds and Products.** Subject to the terms and conditions of this Agreement, Wyeth, effective as of the Effective Date, hereby grants to ADLS under any Wyeth Product Improvement, with the right to grant sublicenses as and to the extent provided in Section 2.4.2, the following royalty-free licenses:

(a) A non-exclusive license to Develop and have Developed, in all countries throughout the world, Products for future Commercialization outside the Territory, and to Manufacture and have Manufactured, in all countries throughout the world, any such Product for use in such Development.

(b) A non-exclusive license to Commercialize Products outside the Territory and to Manufacture and have Manufactured, in all countries throughout the world, Products solely for use or sale outside the Territory as part of such Commercialization.

**2.4.2. ADLS' Ability to Sublicense.** Subject to the terms of this Agreement, ADLS may sublicense any right licensed to ADLS by Wyeth in Section 2.4.1 to any ADLS Licensee. ADLS shall give Wyeth prompt written notice of each such sublicense, identifying the applicable ADLS Licensee, Products sublicensed, territory and scope of rights granted. ADLS shall ensure that each such ADLS Licensee complies with all applicable terms and conditions of this Agreement.

**2.5. Joint Technology.** The Parties may exploit Joint Technology as provided in Section 6.1.

**2.6. 365(n) of U.S. Bankruptcy Code.** All rights and licenses now or hereafter granted by ADLS to Wyeth under or pursuant to any Section of this

Agreement, including, without limitation, Sections 2.1, 2.2, 2.3 and 2.4 hereof, are rights to “intellectual property” (as defined in Section 101(35A) of Title 11 of the United States Code, as amended (such Title 11, the “**Bankruptcy Code**”). ADLS hereby grants to Wyeth and its Affiliates a right to access and to obtain possession of and to benefit from and, in the case of any biological material or other tangible item of which there is a fixed or limited quantity, to obtain a pro rata portion of, each of the following to the extent related to any Compound or Product, or otherwise related to any right or license granted under or pursuant to this Agreement: (i) copies of pre-clinical and clinical research data and results, (ii) all of the following (to the extent that any of the following are so related): cell lines, antibodies, assays, reagents and other biological materials, (iii) product samples and inventory, (iv) ADLS Technology, (v) laboratory notes and notebooks, (vi) data and results related to clinical trials, (vii) Product Data or Filings, and (viii) Rights of Reference in respect of regulatory filings and approvals, all of which constitute “embodiments” of intellectual property pursuant to Section 365(n) of the Bankruptcy Code, and (xi) all other embodiments of such intellectual property, whether any of the foregoing are in ADLS’ possession or control or in the possession and control of any Third Party but which ADLS has the right to access or benefit from and to make available to Wyeth. ADLS shall not interfere with the exercise by Wyeth or its Affiliates of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use Commercially Reasonable Efforts to assist Wyeth and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as reasonably necessary or desirable for Wyeth or its Affiliates to exercise such rights and licenses in accordance with this Agreement. The Parties hereto acknowledge and agree that the payments provided for under Section 5.2, and all other payments by Wyeth to ADLS hereunder, other than royalty payments pursuant to Section 5.3, do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder.

**2.7. No Implied Rights.** Except as expressly provided in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right with respect to any intellectual property of such Party.

### **3. DECISION MAKING AND DISPUTE RESOLUTION.**

#### **3.1. Steering Committee.**

**3.1.1. Formation of the Steering Committee.** ADLS and Wyeth shall establish a “**Steering Committee**” to facilitate communications regarding the Development of Products by the Parties and to oversee, direct and coordinate the activities of the Parties under this Agreement in regard to the Development Program. The Steering Committee shall also serve as a forum to facilitate communications between the Parties regarding

Development activities and Development of Products worldwide. The Steering Committee shall be comprised of up to four (4) representatives from each Party as appointed by such Party. The Steering Committee may change its size from time to time by mutual consent of its members. A Party may replace one or more of its representatives from time to time upon written notice to the other Party. Each Party, respectively, shall designate its initial members of the Steering Committee within thirty (30) days after the Effective Date. The Steering Committee shall exist until the completion of the ADLS Study, the [China] Study and any other studies included under the Global Development Plan, unless the Parties otherwise agree in writing. Following termination of the Steering Committee, each Party shall continue to have an approval right with respect to matters specified to be decided by the Steering Committee under this Agreement. In such event, if the Parties are unable to reach agreement on a matter specified in this Agreement to have been decided by the Steering Committee, the matter shall be resolved in accordance with Section 3.3.3 below.

**3.1.2. Chairperson; Secretary of the Steering Committee.** The chairperson and secretary of the Steering Committee shall rotate on an annual basis between the Parties. The chairperson and secretary shall not be from the same Party at the same time. The first chairperson shall be designated by Wyeth. The chairperson shall be responsible for scheduling meetings of the Steering Committee, preparing agendas for meetings and sending to all Steering Committee members notices of all regular meetings and agendas for such meetings at least five (5) business days before such meetings. The chairperson shall solicit input from both Parties regarding matters to be included on the agenda, and any matter either Party desires to have included on the agenda shall be included for discussion. Nothing herein shall be construed to prohibit the Steering Committee from discussing or acting on matters not included on the applicable agenda. The secretary shall record the minutes of the meeting, circulate copies of meeting minutes to the Parties and each Steering Committee member promptly following the meeting for review, comment and approval by the Steering Committee members and finalize approved meeting minutes. The chairperson shall be a member of the Steering Committee but the secretary need not be a member of the Steering Committee.

**3.1.3. Meetings.** It is currently contemplated that the Steering Committee shall meet at least once each Calendar Quarter until it has been terminated in accordance with Section 3.1.1 at dates and times mutually agreed by the Steering Committee, unless otherwise mutually agreed by the Parties. The initial meeting of the Steering Committee shall be held within ninety (90) days after the Effective Date. Either Party may call a special meeting of the Steering Committee on fifteen (15) days written notice to the other Party's members of the Steering Committee (or upon such shorter notice as exigent circumstances may require). Such written

notice shall include an agenda for the special meeting. In-person meetings, including, without limitation, special meetings, of the Steering Committee shall alternate between the offices of the Parties, unless otherwise agreed upon by the members of the Steering Committee. Meetings of the Steering Committee may be held telephonically or by video conference; provided however, that at least one (1) meeting per year shall be held in-person. Meetings of the Steering Committee shall be effective only if at least one (1) representative of each Party is in attendance or participating in the meeting. Members of the Steering Committee shall have the right to participate in and vote at meetings held by telephone or video conference. In addition, the Steering Committee may act on any matter or issue without a meeting if it is documented in a written consent signed by each member of the Steering Committee.

**3.2. Other Committees.** The Steering Committee may establish additional committees to oversee specific projects or activities or to perform certain other functions under this Agreement, and such committees shall always include equal representation from each Party.

**3.3. Decision Making.**

**3.3.1. Decisions by Consensus.** All decisions of the Steering Committee and all other committees established under this Agreement shall be made by unanimous agreement of both Parties' representatives. If the Steering Committee cannot or does not reach unanimous agreement on a matter within the purview of the Steering Committee, then such matter may be referred for resolution as set forth in Section 3.3.3 below.

**3.3.2. Lower Committee Escalation to Steering Committee.** If any other committee established by the Steering Committee cannot reach a decision on a matter, the lower committee shall refer the matter to the Steering Committee for resolution. A matter shall be considered referred to the Steering Committee as of the date that the lower committee or either Party provides each Steering Committee member a written description of the disputed matter. The Party referring such disputed matter to the Steering Committee shall use reasonable efforts to include in the written description the positions taken by each Party's members of the lower committee as to such matter, all other material information relevant to such matter and a copy of the minutes (if any) of the applicable lower committee meeting(s) at which such matter was discussed. Within fifteen (15) days after such matter is so presented to the Steering Committee, the Steering Committee shall meet to discuss and try to resolve the matter.

**3.3.3. Steering Committee Dispute Resolution.** If the Steering Committee cannot resolve any matter within its purview by unanimous agreement, the matter may be referred by either Party to the Executive Officers, who shall meet promptly (and in any event within ten (10) days



after such matter is referred to the Executive Officers) in an effort to resolve the matter. If, after discussion, the Executive Officers are unable to reach consensus on the matter, any matter as to which one Party has final decision making authority (as described below in Section 3.4) may thereafter be resolved as determined by such Party and any other matter may thereafter be resolved in accordance with Section 11.2 below.

**3.4. Allocation of Final Decision Making Authority.** Final decision making authority shall be allocated to ADLS and Wyeth in regard to certain matters, to the extent such matters are within the purview of the Steering Committee, as described below. Such final decision making authority may be exercised only after discussion by the Executive Officers as described in Section 3.3.3, in order to encourage the Parties to reach consensus on decisions at the Steering Committee level or lower committee levels. Each Party shall exercise its final decision making authority described herein in a manner consistent with the terms and conditions of this Agreement.

**3.4.1. ADLS.** To the extent decisions regarding any of the following fall within the purview of the Steering Committee, ADLS shall have final decision making authority as described in this Section 3.4 with respect to the following matters:

- (a) Any decision involving Development of any Compound or Product for use or sale outside the Territory;
- (b) Any decision regarding any filing related to any Compound or Product with any Regulatory Authority outside the Territory (other than filings related to Manufacture outside the Territory of Compounds or Products for use or sale in the Territory);
- (c) Any decision relating to Commercialization of any Product outside the Territory;
- (d) Any decision regarding the Manufacture of any Product for use or sale solely outside the Territory or in any clinical study undertaken for the sole purpose of obtaining any Regulatory Approval outside the Territory, except as otherwise provided in the Supply Agreement; and
- (e) Any decision involving the Label for a Product outside the Territory. ADLS will reasonably consider, but shall have no obligation to accept or act on, requests from Wyeth to modify the Label for a Product outside the Territory.

**3.4.2. Wyeth.** Wyeth shall have final decision making authority as described in this Section 3.4 with respect to the following matters:

- (a) Any decision regarding the Development of any Compound or Product for use or sale in the Territory;
- (b) Any decision regarding any filing related to any Compound or Product with any Regulatory Authority in the Territory (other than filings related to Manufacture in the Territory of Compounds or Products for use or sale outside the Territory);
- (c) Any decision relating to Commercialization of any Product in the Territory;
- (d) Any decision regarding the Manufacture by or on behalf of Wyeth or its Affiliate or Sublicensee of any Product for use or sale in the Territory or in any clinical study undertaken for the purpose of obtaining any Regulatory Approval in the Territory (other than Manufacture by ADLS or its Affiliate or suppliers of ADLS or its Affiliate of Compounds or Products, if any, to be supplied to Wyeth or its Affiliate, which supply, if any, shall be governed by the Supply Agreement); and
- (e) Any decision involving the Label for a Product inside the Territory. Wyeth will reasonably consider, but shall have no obligation to accept or act on, requests from ADLS to modify the Label for a Product inside the Territory.

**3.4.3. Limitation on Deciding Vote.** Notwithstanding Sections 3.4.1 and 3.4.2 above, (i) neither Party shall have the right to exercise its final decision making authority as described herein to obligate the other Party to expend money or undertake activities unless the other Party agrees in writing, and (ii) neither Party may exercise its final decision making authority in a manner inconsistent with this Agreement, including the Global Development Plan, or to amend the provisions of this Agreement or the Global Development Plan, or to convey licenses or rights to such Party beyond those rights and licenses expressly set forth in this Agreement.

**3.5. Alliance Managers.** In addition to the foregoing governance provisions, each of the Parties shall appoint a single individual to serve as that Party's Alliance Manager. The role of each Alliance Manager shall be to facilitate the relationship between the Parties as established by this Agreement. The Alliance Managers shall attend meetings of the Steering Committee and support the chairperson of such committee in the discharge of his or her responsibilities. Unless otherwise determined by the Steering Committee, a Party's Alliance Manager shall serve as secretary at each meeting of such committee for which the chairperson is a representative of the other Party. Alliance Managers shall be non-voting participants in such committee meetings. A Party may replace its Alliance Manager from time to time upon written notice to the other Party.

**4. PRODUCT DEVELOPMENT, REGULATORY MATTERS, DATA SHARING AND CROSS REFERENCE RIGHTS, MANUFACTURING, SUPPLY AND COMMERCIALIZATION.**

**4.1. General.** Subject to the terms and conditions of this Agreement (including the Parties' responsibilities under the Global Development Plan and Wyeth's responsibilities under Section 4.5.1 below), Wyeth shall have the sole authority and the exclusive right to undertake the Development of Compounds and Products for use or sale in the Territory. Subject to the terms and conditions of this Agreement (including the Parties' responsibilities under the Global Development Plan and ADLS' responsibilities under Section 4.5.2 below), ADLS shall have the sole authority and the exclusive right to undertake the Development of Compounds and Products for use or sale outside the Territory, provided, however, that, in connection with such activities, ADLS shall take into account their potential impact on Wyeth's Development and Commercialization of Compounds and Products for use or sale in the Territory. Except as expressly provided in this Agreement, each Party shall be solely responsible for the expenses of conducting such Development.

**4.2. Global Development Plan.** From time to time, in order to facilitate the Development of Products on a worldwide basis, a Party, acting through its representatives on the Steering Committee, may propose that certain Development activities be performed in coordination between the Parties in accordance with a written plan (the "**Global Development Plan**"). If approved by the Steering Committee for inclusion in the Global Development Plan, such Development activities shall be incorporated in appropriate detail into a written amendment of the Global Development Plan. If not approved by the Steering Committee for inclusion in the Global Development Plan, such Development activities may be performed by a Party to the extent in accordance with Section 4.1 above. Except as expressly provided in this Agreement or agreed in writing by the Parties, each Party shall be solely responsible for the expenses of performing its responsibilities under the Global Development Plan.

**4.2.1.** In addition, if ADLS or a Licensee decides to conduct any clinical studies with respect to any proposed future Product, ADLS shall give written notice of such decision to Wyeth with a brief description of the proposed Product and clinical studies. If, after receipt of such notice, Wyeth notifies ADLS that Wyeth has a good faith interest in Developing and Commercializing such Product in the Territory, then such clinical studies shall be added to the Global Development Plan pursuant to an amendment of the Global Development Plan to be approved by the Steering Committee in accordance with this Agreement.

**4.2.2.** During the Term, the Global Development Plan may be updated from time to time as deemed necessary by the Steering Committee.

**4.2.3.** Each Party shall provide to the other Party or the Steering Committee, as appropriate, such information in its Control and relevant to the Development of Products as may be necessary or appropriate in connection with updating the Global Development Plan. Each modification or update of the Global Development Plan shall be subject to review and approval of the Steering Committee.

**4.3. Initial Global Development Plan.** The initial Global Development Plan, which shall initially consist of the ADLS Study and the [China] Study, is attached hereto as Exhibit 4.3.

**4.3.1.** [For clarity, it is agreed that Wyeth's sole responsibilities under the ADLS Study shall be providing reasonable regulatory and clinical cooperation and support as requested by ADLS and providing the funding set forth in Section 4.5.2 below. In addition, for clarity, it is agreed that the ADLS Study shall include, without limitation, study sites and patients in South Korea and Taiwan to the extent and in accordance with a clinical study design sufficient, as reasonably determined by Wyeth, to meet the legal and regulatory requirements for obtaining Regulatory Marketing Approval and Regulatory Pricing Approval of the Current Product for the treatment of CAP in South Korea and Taiwan, respectively].

**4.3.2.** [For clarity, it is agreed that ADLS' sole responsibilities under the China Study shall be providing reasonable regulatory and clinical cooperation and support as requested by Wyeth and providing sufficient quantities of the Current Product as are necessary to complete the China Study in accordance with the Supply Agreement at no cost to Wyeth. In addition, for clarity, it is agreed that the China Study shall include, without limitation, study sites and patients in China to the extent and in accordance with a clinical study design sufficient, as reasonably determined by Wyeth, to meet the legal and regulatory requirements for obtaining Regulatory Marketing Approval and Regulatory Pricing Approval of the Current Product for the treatment of CAP in China.]

**4.4. Data Sharing.**

**4.4.1.** ADLS shall promptly disclose to and share with, or cause to be disclosed to and shared with, Wyeth, at no cost to Wyeth, each Product Data or Filing generated by or otherwise coming into the ownership or Control of ADLS, any of its Affiliates or any ADLS Licensee in connection with the Development, Manufacture or Commercialization of Compounds or Products worldwide (the "**ADLS Product Data or Filings**"). ADLS shall require each ADLS Licensee to allow ADLS to include in the ADLS Product Data or Filings to be provided to Wyeth under this Section 4.4.1 any Product Data or Filing generated by or otherwise coming into the ownership or Control of such ADLS Licensee in connection with the Development, Manufacture or Commercialization

of Compounds or Products. Upon request, ADLS shall promptly assign and transfer, or cause to be assigned and transferred, to Wyeth any ADLS regulatory filing filed with any Regulatory Authority in the Territory.

**4.4.2.** Wyeth shall promptly disclose to and share with, or cause to be disclosed to and shared with, ADLS, at no cost to ADLS, all Product Data or Filings generated by or otherwise coming into the ownership or Control of Wyeth, any its Affiliates or any Wyeth Sublicensee in connection with the Development, Manufacture or Commercialization of Compounds or Products pursuant to this Agreement.

**4.4.3.** Subject to Sections 4.3.1 and 8.1(e), each Party disclaims any representation or warranty that Product Data or Filings provided as set forth in this Section 4.4 will meet the requirements of any particular country, or that such Product Data or Filings will be adequate or usable by the other Party in connection with seeking any Regulatory Marketing Approval in any particular country.

**4.4.4.** Subject to Section 4.4.5, each Party and its Affiliates and Sublicensees or Licensees, as the case may be, shall have the right as set forth in this Section 4.4.4 to use, without additional payment, any and all Product Data or Filings provided pursuant to Section 4.4.1 or Section 4.4.2 to support any regulatory filings for Compounds or Products (i) in the Territory, in the case of Wyeth and its Affiliates and Wyeth Sublicensees, or (ii) outside the Territory, in the case of ADLS and its Affiliates and ADLS Licensees.

(a) ADLS hereby grants to Wyeth and its Affiliates a Right of Reference, for regulatory filings in the Territory (or for Manufacture, in countries outside the Territory, of Compounds or Products for sale in the Territory, or for clinical trials related to supporting or obtaining any Regulatory Approval in the Territory), to any ADLS Product Data or Filing to be provided or disclosed by ADLS or its Affiliates or Licensees pursuant to Section 4.4.1, and ADLS shall, and shall require its Affiliates and Licensees to, provide a signed statement to this effect, if requested by Wyeth. Wyeth may sublicense the Right of Reference set forth in this Section 4.4.4(a) to its Sublicensees in the Territory.

(b) Wyeth hereby grants to ADLS and its Affiliates a Right of Reference, for regulatory filings outside the Territory (or for Manufacture in the Territory of Compounds or Products for sale outside the Territory, or for clinical trials related to supporting or obtaining any Regulatory Approval outside the Territory) to any Product Data or Filing to be provided or disclosed by Wyeth or any of its Affiliates or Sublicensees pursuant to Section 4.4.2, and



Wyeth shall, and shall require its Affiliates and Sublicensees to, provide a signed statement to this effect, if requested by ADLS. ADLS may sublicense the Right of Reference set forth in this Section 4.4.4(b) to its Licensees solely for use in connection with the Development, Manufacture and Commercialization of Products outside the Territory.

**4.4.5.** Wyeth shall obtain from each Wyeth Sublicensee (i) an obligation by the Sublicensee to disclose to and share with Wyeth (for disclosure to and sharing with ADLS as set forth in Section 4.4.2) any and all Product Data or Filings generated by or otherwise coming into the ownership or Control of such Sublicensee, and (ii) the right of ADLS, its Affiliates and Licensees to disclose and to use such Product Data or Filings as set forth in Section 4.4.4(b).

**4.4.6.** ADLS shall obtain from each ADLS Licensee (i) an obligation by such Licensee to disclose to and share with ADLS (for disclosure to and sharing with Wyeth as set forth in Section 4.4.1) any and all Product Data or Filings generated by or otherwise coming into the ownership or Control of such Licensee, and (ii) the right of Wyeth, its Affiliates and Sublicensees to disclose and to use such Product Data or Filings as set forth in Section 4.4.4(a). Commencing upon the Effective Date, it shall be a condition to any Person becoming an ADLS Licensee that such Person agree in writing to the obligation and grant of rights by such ADLS Licensee as set forth in this Section 4.4.6.

#### **4.5. Development Diligence.**

**4.5.1.** Wyeth shall use Commercially Reasonable Efforts to Develop and obtain Regulatory Marketing Approval for the Current Product in each Major Market, provided that ADLS has successfully completed all Development activities to be performed by ADLS with respect to such Product pursuant to Section 4.5.2. In addition, Wyeth shall use Commercially Reasonable Efforts to perform its obligations under the Global Development Plan[, including, subject to Section 4.5.2, conducting the China Study, except to the extent that safety issues require modification or termination of such study. Without limiting the generality of the foregoing, it is agreed and understood that Wyeth's obligations with respect to the China Study are subject to ADLS making appropriate progress, because the China Study contemplates that any application for Regulatory Marketing Approval based on the China Study will be dependent on ADLS obtaining Regulatory Marketing Approval of the Current Product in the United States. Wyeth shall have the sole responsibility to pay for the China Study, except that ADLS shall be required to provide to Wyeth, at no cost to Wyeth, sufficient quantities of the Current Product as are necessary to complete the China Study. In the event that any additional pre-clinical studies are required by any



- Regulatory Authority or are otherwise necessary in connection with the Development of the Current Product for the treatment of CAP in China, ADLS shall use Commercially Reasonable Efforts to perform such studies, at its expense.] Wyeth shall have no diligence obligation, express or implied, with respect to the Development of Products except as provided in this Section 4.5.1.

**4.5.2.** ADLS shall use Commercially Reasonable Efforts to perform its obligations under the Global Development Plan[, including conducting the ADLS Study, except to the extent that safety issues require modification or termination of such study. ADLS shall pay for the ADLS Study, except that Wyeth shall contribute to the funding of the ADLS Study by making the following one-time payments to ADLS: (i) Five Hundred Thousand Dollars (\$500,000) within thirty (30) business days after Wyeth's receipt of written confirmation of the dosing of the first patients in both South Korea and Taiwan under the ADLS Study and (ii) Five Hundred Thousand Dollars (\$500,000) within thirty (30) business days after Wyeth's receipt of written confirmation that ADLS has enrolled under the ADLS Study at least fifty percent (50%) of the minimum number of patients in each of South Korea and Taiwan as mutually determined by ADLS and Wyeth in good faith, prior to enrollment of patients in the ADLS Study, to be necessary for obtaining Regulatory Marketing Approval and Regulatory Pricing Approval of the Current Product for the treatment of CAP in South Korea and Taiwan, respectively. Notwithstanding the foregoing, Wyeth shall not be obligated to make any of the payments under this Section 4.5.2, or to commence patient enrollment under the China Study, unless and until the Parties have executed and delivered the Supply Agreement in accordance with Section 4.9.1 and ADLS has entered into one or more binding written agreements with qualified Third Parties pursuant to and as necessary to support ADLS' obligations under the Supply Agreement. In the event that any additional pre-clinical studies are required by any Regulatory Authority or are otherwise necessary in connection with the Development of the Current Product for the treatment of CAP in South Korea and Taiwan, ADLS shall use Commercially Reasonable Efforts to perform such studies, at its expense.]

#### **4.6. Regulatory Approvals.**

**4.6.1.** Subject to ADLS' obligations under Section 4.5.2, Wyeth shall file, in its own name and at its own expense, all applications for Regulatory Approval in the Territory for Products where Wyeth, in its sole discretion (subject to Section 4.5.1), elects to do so, and all other applications for any approvals required for any clinical study or other study or action necessary or desirable to obtain such Regulatory Approval. Wyeth shall have the sole responsibility for communicating with any Regulatory Authority in the Territory regarding any application for Regulatory Approval or any Regulatory Approval once granted or any such other applications.

**4.6.2.** Subject to its diligence obligations under Section 4.5.2, ADLS shall have the sole right, in its sole discretion, to file and maintain, in its own name, all applications for Regulatory Approval outside the Territory for Products. Notwithstanding the foregoing, ADLS shall, or ADLS shall cause its Licensee to, as applicable, use Commercially Reasonable Efforts to obtain Regulatory Marketing Approval for the Current Product, and ADLS shall, or ADLS shall cause its Licensee to, as applicable, use Commercially Reasonable Efforts to maintain such Regulatory Marketing Approval for the Current Product, as well as any Regulatory Marketing Approval obtained from the FDA for any other Product. If ADLS or its Licensee, as applicable, elects not to continue to maintain any such Regulatory Marketing Approval, ADLS shall provide Wyeth with prompt written notice of the decision not to continue the maintenance of such Regulatory Marketing Approval in sufficient time to allow Wyeth to continue the maintenance of such Regulatory Marketing Approval in a timely manner. In such event, at Wyeth's request in its sole discretion, ADLS shall, or ADLS shall cause its Licensee to, as applicable, execute such documents and perform such acts, at no cost to Wyeth, as may be reasonably necessary (i) to assign and transfer to Wyeth all of the right, title and interest of ADLS or its Licensee, as applicable, in and to such Regulatory Marketing Approval and related files and (ii) to permit Wyeth to continue the maintenance of such Regulatory Marketing Approval. If Wyeth elects to obtain such assignment and/or continue the maintenance of such Regulatory Marketing Approval, Wyeth may deduct from any payment to be made to ADLS hereunder any expenses incurred by Wyeth in connection therewith, provided that such deductions in aggregate shall not exceed the aggregate payments to be made to ADLS hereunder. In addition, ADLS shall, or shall cause its Licensee to, consult with Wyeth in regard to, and provide Wyeth with copies of all regulatory correspondence and meeting minutes pertaining to, all regulatory filings relating to this Section 4.6.2.

**4.7. Regulatory Reporting.** Wyeth shall be responsible for filing, at its own expense, all reports required to be filed in order to maintain any Regulatory Approvals granted for Products in the Territory.

**4.8. Pharmacovigilance and Product Labeling.**

**4.8.1. Definitions.** Unless otherwise defined herein, the terms used surrounding adverse experiences will have the meaning set forth in U.S. Code of Federal Regulations (CFR), title 21 parts 312 and 314 and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use E2A as stated now and as may be revised in the future.

**4.8.2. Pharmacovigilance.** Wyeth shall be solely responsible for all of the following in the Territory: adverse experience reports; literature



review and associated reports; adverse experience follow-up reports; preparation and submission of all safety reports to the Regulatory Authorities as required; maintaining information regarding Compounds and Products for inclusion in the global safety database; all interactions with relevant Regulatory Authorities and investigators; periodic submissions; risk management; safety monitoring, signal detection and safety measures (e.g., clinical holds and restriction on distribution).

ADLS shall be solely responsible for all of the following outside the Territory or in connection with its clinical studies: adverse experience reports; literature review and associated reports; adverse experience follow-up reports; preparation and submission of all safety reports to the Regulatory Authorities as required; maintaining information regarding Compounds and Products for inclusion in the global safety database; all interactions with relevant Regulatory Authorities and investigators; periodic submissions; risk management; safety monitoring, signal detection and safety measures (e.g., clinical holds and restriction on distribution).

Notwithstanding the foregoing and until such time as a pharmacovigilance agreement is executed as provided in Section 4.8.4, to the extent either Party has or receives any information regarding any adverse experience which may be related to the use of the Compounds and Products, the Parties shall promptly forward such information as follows:

- Fatal or life-threatening serious adverse events/adverse drug reactions judged by either the investigator or sponsor to be reasonably related to the Compounds, Products or protocol shall be transmitted to the other Party within two (2) calendar days from the date received by the receiving Party.
- All other serious adverse events/adverse drug reactions not fatal or life-threatening but judged by either the investigator or sponsor to be reasonably related to the Compounds, Products or protocol shall be transmitted to the other Party within five (5) calendar days from the date received by the receiving Party.

If to Wyeth:

Facsimile: 610-989-5544

or

Overnight courier to:

Global Safety Surveillance Epidemiology & Labeling

Wyeth Research

GSSEL Triage Unit

Dock E

500 Arcola Road  
Collegeville, PA 19426

If to ADLS:

Facsimile: 630-739-6754

**or**

Overnight courier to:

Advanced Life Sciences Holdings, Inc.  
1440 Davey Road  
Woodridge, IL 60517  
Attn: Director of Regulatory Affairs

**4.8.3. Product Labeling.** Wyeth shall be solely responsible for the administrative aspects of preparing, updating and maintaining product labeling in connection with Commercialization of Product(s) in the Territory (and related Manufacturing of such Products, subject to ADLS' obligations under the Supply Agreement). Such labeling may include but is not limited to text and graphical contents of printed labels and labeling components, including but not limited to healthcare professional leaflets or inserts, patient leaflets or inserts and cartons.

ADLS shall be solely responsible for the administrative aspects of preparing, updating and maintaining product labeling in connection with Commercialization of Product(s) outside of the Territory (and related Manufacturing of such Products). Such labeling may include but is not limited to text and graphical contents of printed labels and labeling components, including but not limited to healthcare professional leaflets or inserts, patient leaflets or inserts and cartons.

The Parties agree to jointly develop the Developmental Core Data Sheet and Core Data Sheet for the Products in order to achieve global labeling consistency.

**4.8.4. Pharmacovigilance Agreement.** The Parties agree to meet promptly after the Effective Date to establish (if such agreement is mutually agreed to be necessary) a detailed pharmacovigilance agreement containing reasonable and customary terms that are mutually acceptable, outlining the responsibilities of each Party in connection with the collection and reporting of adverse experiences and Product labeling which will supersede this Section 4.8.

#### **4.9. Manufacture and Supply of Products.**

**4.9.1. Supply Agreement.** Within [one hundred eighty (180)] days after the Effective Date, the Parties shall negotiate, draft, execute and deliver, and the Parties shall thereafter perform their respective obligations under,

a supply agreement pursuant to which ADLS shall supply or have supplied Wyeth's clinical and commercial requirements for Products in bulk (tablet or other) form and containing the key terms set forth in Exhibit 4.9.1 attached hereto, as well as other reasonable and customary terms for an agreement of such type (the "**Supply Agreement**").

**4.9.2. Final Labeling and Packaging of Products.** Wyeth shall be responsible for the final labeling and packaging of Products supplied to Wyeth under the Supply Agreement for sale in the Territory.

**4.10. Commercialization.** Subject to the terms and conditions of this Agreement, Wyeth shall have the sole authority and the exclusive right in the Territory, at its expense, to Commercialize Products itself or through one or more Affiliates or Third Parties selected by Wyeth and shall have sole authority and responsibility in all matters relating to the Commercialization of Products in the Territory, including but not limited to: booking sales of all Products in the Territory, making decisions with respect to the pricing of each Product in each country in the Territory and making all decisions regarding marketing of and post-approval clinical studies for any Product in the Territory, provided, however, that prior to commencing any such post-approval clinical study, Wyeth shall consult with ADLS in regard to the development of such study. Wyeth shall use Commercially Reasonable Efforts to Commercialize the Current Product in each Major Market where Wyeth has obtained Regulatory Marketing Approval for such Product, provided that ADLS has successfully completed all Development activities to be performed by ADLS with respect to such Product pursuant to Section 4.5.2. Except for the foregoing, Wyeth shall have no other diligence obligations, express or implied, with respect to the Commercialization of Products. ADLS shall have the sole authority and the exclusive right outside the Territory, at its expense, to Commercialize Products itself or through one or more Affiliates or Third Parties selected by ADLS and shall have sole authority and responsibility in all matters relating to the Commercialization of Products outside the Territory, including but not limited to booking sales of all Products outside the Territory, making decisions with respect to the pricing of each Product in each country outside the Territory and making all decisions regarding marketing of and post-approval clinical studies for any Product outside the Territory.

**4.11. Product Recalls.** Wyeth shall be solely responsible for all contact with Regulatory Authorities relating to any Recall of any Product in the Territory and ADLS shall be solely responsible for all contact with Regulatory Authorities related to any Recall of any Product outside of the Territory. The responsible Party shall be solely responsible for implementing, directing and administering any Recall of any such Product required or recommended by any Regulatory Authority or court of competent jurisdiction, or determined by the responsible Party, in its sole discretion, to be necessary or advisable. Wyeth shall be responsible for the cost of any Recall of any Product in the Territory and ADLS

shall be responsible for the cost of any Recall of any Product outside of the Territory, except as otherwise provided in the Supply Agreement.

## 5. CONSIDERATION.

**5.1. Equity Investment.** Upon the Effective Date, Wyeth and ADLS shall each execute, deliver and consummate the purchase by Wyeth and sale by ADLS of shares of ADLS' common stock pursuant to the terms and conditions of the Stock Purchase Agreement, and thereafter Wyeth and ADLS shall perform their respective obligations thereunder.

**5.2. Milestone Payments.** In partial consideration of ADLS' contributions to the development of data useful for the Development of Products in the Territory, Wyeth shall be obligated to make a one-time, non-refundable payment upon the achievement of each of the applicable events described in Section 5.2.2 (the "**Launch Events**") and Section 5.2.3 (the "**Commercial Events**") by Wyeth or any Wyeth Affiliate or Sublicensee.

### 5.2.1. Timing of Payment.

(a) Wyeth shall promptly notify ADLS in writing of the achievement of each Launch Event, and Wyeth shall have thirty (30) business days following achievement of any Launch Event in which to pay the corresponding amount to ADLS (each, a "**Launch Payment**").

(b) Each Commercial Payment payable as provided below shall be payable with the royalty due for the fourth Calendar Quarter of the Calendar Year for which the Commercial Payment is earned.

(c) Each Launch Payment and Commercial Payment shall be payable one time only even if multiple Products achieve such event.

### 5.2.2. Launch Payments.

Launch Event	Launch Payment
[First Commercial Sale in China of the Current Product Labeled for the treatment of CAP ]	[\$[1,000,000]]
[First Commercial Sale in South Korea of the Current Product Labeled for the treatment of CAP ]	[\$[500,000]]
[First Commercial Sale in Taiwan of the Current Product Labeled for the treatment of CAP]	[\$[500,000]]



**5.2.3. Commercial Payments.** If the Net Sales of all Products within the Territory in any Calendar Year reach any of the following levels within the time period specified for such level, Wyeth shall make the one-time payment indicated below for achievement of such Commercial Event (each, a “**Commercial Payment**”). Each Commercial Payment set forth herein for Commercial Event shall be payable only once. If Net Sales of all Products within the Territory in an eligible Calendar Year exceed more than one level of Net Sales, a Commercial Payment shall be payable for each Commercial Event achieved during such Calendar Year. For avoidance of doubt, should Net Sales of Products first achieve any applicable Commercial Event in any Calendar Year ending after the applicable time period specified for achievement of such Commercial Event, under no circumstances shall any Commercial Payment be payable with respect to such achievement.

Commercial Event	Commercial Payment
[Net Sales of all Products in the Territory of at least \$50,000,000 in any Calendar Year during the period ending on the last day of the fifth (5th) full Calendar Year following the First Commercial Sale of any Product in the Territory]	[\$2,500,000]
[Net Sales of all Products in the Territory of at least \$100,000,000 in any Calendar Year during the period ending on the last day of the tenth (10th) full Calendar Year following the First Commercial Sale of any Product in the Territory]	[\$5,000,000]
[Net Sales of all Products in the Territory of at least \$150,000,000 in any Calendar Year during the period ending on the last day of the tenth (10th) full Calendar Year following the First Commercial Sale of any Product in the Territory]	[\$7,500,000]

### 5.3. Royalties.

**5.3.1. Product Royalties.** In consideration for the licenses granted to Wyeth under Section 2.1 hereof, Wyeth shall pay to ADLS royalties during the Royalty Term for the applicable Product in the applicable country as set forth in Section 5.3.2 below, subject to the adjustments provided in Sections 5.3.4 and 5.4.2 below.

**5.3.2. Royalty Rates.** Except as provided in Sections 5.3.4 and 5.4.2 below, Wyeth shall pay to ADLS royalties on a Product-by-Product and country-by-country basis in the amount of the applicable royalty rate set forth in the table below (the “**Royalty Rate**”) of the aggregate Net Sales obtained by Wyeth, its Affiliates or its Sublicensees from the sale of each Product in the Territory during the Royalty Term for such Product:



	<b>Royalty Rate (% of Net Sales)</b>
[For Net Sales Occurring before the Transition Date]	[30%]
[For Net Sales Occurring on or after the Transition Date]	[20%]

“**Transition Date**” shall mean [September 30, 2017] or, if later, the last date upon which there exists a Valid Claim, covering the use or sale of the applicable Product in the applicable country, under the ADLS Patent Rights licensed to ADLS pursuant to that certain License Agreement dated December 13, 2004 between ADLS and Abbott Laboratories, as amended (the “**Abbott Agreement**”), with respect to which ADLS is obligated to pay royalties under the Abbott Agreement, provided that ADLS shall have delivered written evidence of such later date to Wyeth at least thirty (30) days prior to [September 30, 2017].

Further, if, during the Royalty Term for a Product in any country within the Territory, (i) a Third Party commences commercial sales of a Generic Product in such country or (ii) there is no Valid Claim of any ADLS Patent Right which covers the use or sale of such Product in such country, then the Royalty Rate for such Product in such country shall be [twenty percent (20%)], effective for all Net Sales of such Product in such country during the Royalty Term for such Product in such country occurring on or after (a) the date of the first commercial sale of such Generic Product in such country (for so long as any Generic Product continues to be sold in such country) or (b) the first date upon which there is no such Valid Claim in such country (for so long as there is no such Valid Claim in such country).

**5.3.3. Expiration of Royalty Term.** After expiration of the Royalty Term for any Product in any country in the Territory, no further royalties shall be payable in respect of Net Sales of such Product in such country, and the licenses granted to Wyeth under Section 2.1 with respect to such Product in such country shall thereafter become fully paid-up, perpetual, irrevocable, royalty-free licenses.

**5.3.4. Royalty Adjustments for Additional Third Party Licenses.** In the event Wyeth determines, after good faith consultation with ADLS, that it is necessary to obtain a license under any intellectual property right from any Third Party in order to research, Develop, Manufacture or Commercialize any Compound or Products pursuant to rights granted to Wyeth under this Agreement (an “**Additional Third Party License**”), Wyeth shall be solely responsible for negotiating and obtaining any such Additional Third Party License, but shall not be obligated to do so. Wyeth shall use Commercially Reasonable Efforts to consult with ADLS regarding whether Wyeth should obtain such rights as part of an



agreement through which ADLS or its licensee obtains similar rights, provided, however, that Wyeth shall have no obligation to do so. Wyeth may deduct from the royalties payable under Section 5.3.2 on the Net Sales of any Product [a percentage, equal to the then applicable Royalty Rate for such Product, of the royalties on corresponding Product sales payable to Third Parties under Additional Third Party Licenses], provided that such deduction shall not reduce the royalties payable under Section 5.3.2 to less than [fifty percent (50%)] of the amount that would otherwise be payable to ADLS. [As an example of the foregoing, if Net Sales of a Product are \$100 during a period in which the applicable Royalty Rate for such Product is 30% and Wyeth owes royalties of \$10 to a Third Party with respect to corresponding sales of such Product under an Additional Third Party License, then the royalties payable to ADLS under this Agreement for such Product with respect to such period shall be \$27 (30% of \$100, minus 30% of \$10)]. Except for any permitted deduction described in this Section 5.3.4, Wyeth shall be solely responsible for all costs of any such Additional Third Party Licenses.

**5.3.5. Other Third Party Agreements.** ADLS shall be solely responsible for all payment obligations related to the ADLS Technology under its licenses and other agreements with Third Parties that are in effect as of the Effective Date, including, without limitation, those obligations arising under the ADLS Third Party Agreements. If after the Effective Date ADLS enters into any license or other agreement with a Third Party relating to any Compound or Product, ADLS shall use Commercially Reasonable Efforts to obtain in such license or other agreement the right to sublicense the rights granted under such license or other agreement to Wyeth under this Agreement. ADLS shall use Commercially Reasonable efforts to consult with Wyeth prior to entering into any such license or agreement and to allow Wyeth to obtain such rights either through ADLS or directly from such Third Party. Any payment made to such a Third Party or any additional payment made to ADLS in order to obtain such rights shall be treated as a payment made for an Additional Third Party License pursuant to Section 5.3.4.

**5.3.6. [Advance Against Royalties.** Wyeth will pay to ADLS as an advance (the “**Royalty Advance**”) against the royalties payable by Wyeth to ADLS under this Agreement an amount equal to \$0.10 per 150 mg tablet delivered under the Supply Agreement for all Current Product ordered by Wyeth under the Supply Agreement for delivery to Wyeth prior to the First Commercial Sale of the Current Product in the Territory and during the Calendar Quarter in which such First Commercial Sale occurs, payable in addition to, and on the same conditions and at the same time as, the transfer price payable under the Supply Agreement with respect to such tablets, and with the aggregate amount of such advance to be deducted by Wyeth from any royalties payable to ADLS under this Agreement as provided in Section 5.4.2.]



## 5.4. Reports and Payments.

**5.4.1. Cumulative Royalties.** The obligation to pay royalties under Section 5.3 above shall be imposed only once with respect to Net Sales of any single unit of a Product regardless of how many applicable Valid Claims included within the ADLS Patent Rights cover the Product in the applicable country.

**5.4.2. Royalty Statements and Payments.** Within [sixty (60) days] after the end of each Calendar Quarter [(or forty-five (45) days to that extent that ADLS is obligated to deliver royalty reports to Abbott Laboratories pursuant to the Abbott Agreement within forty-five (45) days after the end of each Calendar Quarter, after good faith efforts to extend such period to sixty (60) days)], Wyeth shall deliver to ADLS a report setting forth for such Calendar Quarter the following information, on a country-by-country basis: (a) the Net Sales of each Product in each country, (b) the basis for any adjustments to the royalty payable for the sale of each Product, (c) the royalty due hereunder for the sale of each Product and the resulting total royalty due for the sale of all Products during such Calendar Quarter, in each case prior to the application of the provisions of this Section 5.4.2, (d) the transfer price (determined as provided in Exhibit 4.9.1 attached hereto) paid by Wyeth to ADLS for the supply of Products under the Supply Agreement during such Calendar Quarter and any Wyeth Manufacturing Cost incurred during such Calendar Quarter, (e) [the amount, if any, of any Royalty Advance paid by Wyeth to ADLS during such Calendar Quarter] and (f) the withholding taxes, if any, required by law to be deducted in respect of the royalties payable to ADLS after giving effect to the provisions of this Section 5.4.2. The total royalty due for the sale of Products during any Calendar Quarter shall be reduced by [(i) the transfer price paid by Wyeth to ADLS for the supply of Products by ADLS to Wyeth under the Supply Agreement during such Calendar Quarter (or prior to such Calendar Quarter, in the case of the first Calendar Quarter with respect to which royalties are payable) and/or (ii) in the event that Wyeth elects to Manufacture or have Manufactured any Product due to a failure by ADLS to supply or have supplied such Product to Wyeth in breach of the Supply Agreement, any cost incurred by Wyeth during such Calendar Quarter in connection with such Manufacturing (the “Wyeth Manufacturing Cost”), as the case may be, and by the amount of any Royalty Advance not previously deducted from the royalties payable by Wyeth to ADLS under this Agreement. If, with respect to any Calendar Quarter, the amount of such transfer price or Wyeth Manufacturing Cost or Royalty Advance exceeds the total royalty due to ADLS, the amount of such excess shall be carried forward and applied against Wyeth’s future royalty obligations under this Agreement.] No report shall be required with respect to any Calendar Quarter in which both (x) there are no Net Sales of Products in the Territory and (y) there is no transfer price paid or payable by Wyeth to ADLS for the supply of

Products under the Supply Agreement or Wyeth Manufacturing Cost incurred by Wyeth. The royalty due for the sale of Products during any Calendar Quarter, determined in accordance with this Section 5.4.2, shall be remitted at the time the royalty report for such Calendar Quarter is delivered.

**5.4.3. Taxes and Withholding.** All payments under this Agreement shall be made in full without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by applicable laws or regulations. If Wyeth is so required to deduct or withhold, Wyeth will (a) promptly notify ADLS of such requirement, (b) pay to the relevant authorities the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against ADLS, (c) promptly forward to ADLS an official receipt (or certified copy) or other documentation reasonably acceptable to ADLS evidencing such payment to such authorities and (d) cooperate reasonably, as ADLS may request (at ADLS' expense), in efforts of ADLS to obtain a refund or otherwise recover such withheld taxes.

**5.4.4. Currency.** All amounts payable and all calculations made hereunder shall be paid and made in United States dollars. As applicable, Net Sales and any royalty deductions shall be converted into United States dollars in accordance with Wyeth's customary and usual currency conversion procedures, consistently applied.

**5.4.5. Method of Payment.** All payments by one Party to the other Party under this Agreement shall be made by wire transfer in immediately available funds to such account as the receiving Party shall designate before such payment is due (which account the receiving Party may from time to time change upon written notice to the paying Party).

**5.4.6. Additional Provisions Relating to Royalties.** Each Party acknowledges and agrees that nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) shall be construed as representing an estimate or projection of either (a) the number of Products that will or may be successfully Developed or Commercialized by either Party or (b) the anticipated sales or the actual value of any Product, and that the figures set forth in Section 5.2.3 or elsewhere in this Agreement or the exhibits hereto or that have otherwise been discussed by the Parties are merely intended to define Wyeth's payment obligations to ADLS in the event such sales performance is achieved. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT WYETH WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT WYETH WILL ACHIEVE ANY PARTICULAR SALES LEVEL OF SUCH PRODUCT(S).



## **5.5. Maintenance of Records; Audits.**

**5.5.1. Record Keeping.** Wyeth shall keep complete and accurate books and accounts of record in connection with the sale of Products, in sufficient detail to permit accurate determination of all figures and other information necessary for verification of royalties and other amounts to be paid hereunder. Wyeth shall maintain such books and records for a period of at least three (3) years after the end of the Calendar Year in which they were generated.

**5.5.2. Audits.** Upon thirty (30) days prior written notice from ADLS, Wyeth shall permit an independent certified public accounting firm of nationally recognized standing selected by ADLS and reasonably acceptable to Wyeth to examine, at ADLS' sole expense, the relevant books and records of Wyeth and Wyeth's Affiliates as may be reasonably necessary to verify the accuracy of the reports submitted by Wyeth in accordance with Section 5.4 and the payment of royalties and Commercial Payments hereunder based on Net Sales. An examination by ADLS under this Section 5.5.2 shall occur not more than once in any Calendar Year and shall be limited to the pertinent books and records for any Calendar Year ending not more than three (3) years before the date of the request. The accounting firm shall be provided access to such books and records at Wyeth's and Wyeth's Affiliate's facility(ies) where such books and records are normally kept and such examination shall be conducted during Wyeth's and Wyeth's Affiliate's normal business hours. Wyeth may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm access to Wyeth's and Wyeth's Affiliate's facilities or books and records. Upon completion of the audit, the accounting firm shall provide both Wyeth and ADLS a written report disclosing whether the reports submitted by Wyeth are correct or incorrect, whether the royalties and other amounts paid hereunder are correct or incorrect and, in each case, the amount of any discrepancies and specific details concerning each such discrepancy (if any).

**5.5.3. Underpayments/Overpayments.** If such accounting firm correctly concludes that additional royalties or Commercial Payment(s) were due to ADLS, Wyeth shall pay to ADLS such additional royalties or Commercial Payment(s) (together with applicable interest at [the prime rate then published in the Wall Street Journal]) within thirty (30) days of the date Wyeth receives such accountant's written report so concluding. In the case of such an underpayment, if such audit determines that the amount due is at least [five percent (5%)] more than the amount actually paid for the applicable period audited, Wyeth also shall reimburse ADLS for the out-of-pocket expenses incurred in conducting the audit. If such accounting firm concludes that Wyeth overpaid royalties or Commercial Payment(s) to ADLS, ADLS, within thirty (30) days of the date it receives



such accountant's report so concluding, will refund such overpayments to Wyeth.

**5.5.4. Confidentiality.** All financial information of Wyeth which is subject to review under this Section 5.5 shall be deemed to be Wyeth's Confidential Information subject to the provisions of Section 7 hereof, and ADLS shall not disclose such Confidential Information to any Third Party or use such Confidential Information for any purpose other than verifying payments to be made by Wyeth to ADLS hereunder, provided, however, that such Confidential Information may be disclosed by ADLS to Third Parties to the extent (but only to the extent) necessary to enforce ADLS' rights under this Agreement.

## **6. INTELLECTUAL PROPERTY.**

**6.1. Inventions.** Subject to the provisions of Section 2.1 hereof, any invention or Know-How made jointly by employees of both Parties (a "**Joint Invention**" or "**Joint Know-How**") and any Patent Right claiming any such Joint Invention or Joint Know-How (a "**Joint Patent Right**") shall be jointly owned by the Parties. All inventions and Know-How made solely by one or more employees of a Party shall be solely owned by such Party. All determinations of inventorship under this Agreement shall be made in accordance with the patent law of the United States. ADLS shall promptly disclose to Wyeth any invention or any newly acquired or licensed Patent Right or Know-How that is or may become a Licensed Right. Any Joint Invention or any Joint Know-How, including any resulting Joint Patent Right, shall be treated as Joint Technology under this Agreement.

During the Term and after termination of this Agreement, either Party may exploit and grant licenses under such Party's interest in any Joint Technology without accounting to or obtaining consent from the other Party, subject to the rights and obligations of the Parties with respect to Joint Technology under this Agreement, including the licenses of ADLS' interest under the Joint Technology granted by ADLS to Wyeth under Section 2.1.1.

### **6.2. Patent Rights.**

#### **6.2.1. Filing, Prosecution and Maintenance of Patent Rights.**

(a) **ADLS Patent Rights.** ADLS, at its expense, shall have the sole right but not the obligation to prepare, file, prosecute and maintain, throughout the world, all ADLS Patent Rights other than Territory Patent Rights using counsel of its choice. ADLS shall have the first right but not the obligation to file or continue prosecution or maintenance of any application for an ADLS Patent Right in the Territory (a "**Territory Patent Right**") using patent counsel selected by ADLS and reasonably acceptable to

Wyeth. Before filing any Territory Patent Right, ADLS shall give Wyeth a reasonable opportunity to review and comment upon the text of the application. ADLS shall consult with Wyeth with respect to any such application, shall not unreasonably refuse to address any of Wyeth's comments with respect to such application and shall supply Wyeth with a copy of each such application as filed, together with notice of its filing date and serial number. ADLS shall also keep Wyeth advised of the status of prosecution of all such patent applications included within the ADLS Patent Rights and shall reasonably consider timely comments of Wyeth with respect thereto, and provide Wyeth with a reasonable opportunity to comment on all material correspondence received from and all material submissions to be made to any government patent office or authority with respect to any such patent application or patent. In addition, if ADLS elects not to file in any country in the Territory a patent application on ADLS Know-How that, if filed, would be a Territory Patent Right, or to cease the prosecution or maintenance of any Territory Patent Right in the Territory, ADLS shall provide Wyeth with prompt written notice upon the decision to not file or continue the prosecution of such patent application or maintenance of such patent in sufficient time to allow Wyeth to file, continue prosecution of such application or maintain such patent in a timely manner. In such event, ADLS shall permit Wyeth, at Wyeth's sole discretion, to file or continue prosecution or maintenance of such Territory Patent Right in the applicable country on ADLS' behalf and at Wyeth's own expense. If Wyeth elects to make such filing and/or continue such prosecution or maintenance, Wyeth may deduct from any payment to be made to ADLS hereunder any expenses incurred by Wyeth in connection therewith.

**(b) Joint Patent Rights.** In the event the Parties make any Joint Invention, the Parties shall promptly meet to discuss and determine, based on the advice of patent counsel selected jointly by the Parties, whether to seek patent protection thereon. If the Parties jointly decide to seek patent protection on a Joint Invention, the Parties shall jointly appoint one of the Parties (the "**Prosecuting Party**") to have the obligation (subject to the opt out provisions of this Section 6.2.1(b)), to prepare, file, prosecute and maintain any Joint Patent Right throughout the world to the extent determined jointly by the Parties, using patent counsel selected by jointly the Parties. The Prosecuting Party shall give the other Party a reasonable opportunity to review the text of any application with respect to such Joint Patent Right before filing, shall consult with such other Party with respect thereto, shall not unreasonably refuse to address any timely comments of such

other Party with respect to such application and shall supply such other Party with a copy of the application as filed, together with notice of its filing date and serial number. The Prosecuting Party shall keep the other Party advised of the status of the actual and prospective patent filings (including, without limitation, the grant of any Joint Patent Rights), and shall provide such other Party with advance copies of any material official correspondence related to the filing, prosecution and maintenance of such patent filings. Subject to the opt-out provisions below, the Party other than the Prosecuting Party shall reimburse the Prosecuting Party for [fifty percent (50%)] of the out-of-pocket costs incurred by the Prosecuting Party in preparing, filing, prosecuting and maintaining such Joint Patent Rights, which reimbursement will be made pursuant to invoices submitted by the Prosecuting Party to the other Party no more often than once per Calendar Quarter. 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 thirty (30) days prior written notice to such effect, in which event the Declining Party shall (i) have no responsibility for any expenses incurred in connection with such Joint Patent Right in the applicable country after the end of such thirty (30) day period and (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 (x) to assign to the Continuing Party all of the Declining Party’s right, title and interest in and to such Joint Patent Right and (y) to permit the Continuing Party to file, prosecute and/or maintain such Joint Patent Right. Any such Joint Patent Right shall cease to be a Joint Patent Right and shall become a Patent Right of the Continuing Party.

(c) **No liability.** Neither Party (the “**First Party**”) shall have any liability to the other Party (the “**Second Party**”) for any actions taken or not taken after exercising any right granted to the First Party under the provisions of this Section 6.2.1 to file a patent application or to assume or continue the prosecution or maintenance of a Patent Right which (in the case of any such patent application or Patent Right) the Second Party has elected not to file or not to prosecute or maintain or, in the case of any Joint Patent Right, not to pay for.



**6.2.2. Enforcement of Patent Rights.**

(a) **Notice.** If either Wyeth or ADLS becomes aware of any infringement, anywhere in the world, of any issued patent within the ADLS Patent Rights or Joint Patent Rights, it will promptly notify the other Party in writing to that effect.

(b) **Patent Rights in the Territory.** In all cases where such infringement occurs in the Territory or represents infringement of any Territory Patent Right or Joint Patent Right in the Territory, except in cases where any existing ADLS Third Party Agreement grants the first or sole right to prosecute such infringement to a Third Party, Wyeth shall have the first right, but not the obligation, to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringer of such Patent Rights within [three (3) months] from the date of notice given pursuant to Section 6.2.2(a) and, with ADLS' consent or if ADLS is a necessary and indispensable party, to join ADLS as a party plaintiff. Wyeth shall bear all the expenses of any suit brought by it claiming infringement of any such Patent Rights. ADLS will cooperate with Wyeth in any such suit and shall have the right to consult with Wyeth and to participate in and be represented by independent counsel in such litigation at its own expense. Wyeth shall incur no liability to ADLS as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any of such Patent Rights invalid or unenforceable. If, after the expiration of the foregoing [three (3) month] period (or, if earlier, the date upon which Wyeth provides written notice that it does not plan to seek a discontinuance or bring suit), Wyeth has not obtained a discontinuance of infringement of such Patent Rights or filed suit against any such Third Party infringer of such Patent Rights, then ADLS shall have the right, but not the obligation, to bring suit against such Third Party infringer of such Patent Rights and to join Wyeth as a party plaintiff, provided that ADLS shall bear all the expenses of such suit. Wyeth will cooperate with ADLS in any such suit for infringement of such Patent Rights brought by ADLS against a Third Party, and shall have the right to consult with ADLS and to participate in and be represented by independent counsel in such litigation at its own expense. ADLS shall incur no liability to Wyeth as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any of such Patent Rights invalid or unenforceable. Neither Party shall have the right to settle any patent infringement litigation under this Section 6.2.2(b) in a manner that diminishes the rights or interests of the other Party without the prior written consent of such other Party, such

consent not to be unreasonably withheld, conditioned or delayed. Any recoveries obtained by either Party as a result of any proceeding against a Third Party infringer (where the infringement relates to the Manufacture, importation, use, offer for sale or sale of any Product) shall be allocated as follows:

(i) Such recovery shall first be used to reimburse each Party for all out-of-pocket costs in connection with such litigation paid by that Party;

(ii) [The Party bringing the action shall then estimate the sales of Product lost both inside and outside the Territory as a result of such infringement;]

(iii) [The remaining recovery shall then be allocated between Wyeth and ADLS based on the ratio of the estimated lost sales in the Territory (with such portion of the remaining recovery being further allocated between ADLS (X%, where X equals the then applicable Royalty Rate minus five (5) percentage points) and Wyeth (100% - X%)) to the estimated lost sales outside of the Territory (with such portion of the remaining recovery being 100% allocated to ADLS).]

(c) **Joint Patent Rights Outside the Territory.** With respect to any notice of a Third Party infringer of the Joint Patent Rights outside the Territory, the Parties shall meet as soon as reasonably practicable to discuss such infringement and determine an appropriate course of action, including an initial allocation of the fees and expenses of such course of action. The Parties jointly shall appoint one of the Parties (the “**Leading Party**”) to bring an action against such Third Party infringer or otherwise address such alleged infringement within [three (3) months] from the date of notice and to control such litigation or other means of addressing such infringement. The other Party shall cooperate with the Leading Party in any such suit brought by the Leading Party and shall have the right to consult with the Leading Party and participate in and be represented by independent counsel in such litigation at its own expense. The Leading Party shall not have the right to settle any patent infringement litigation under this Section 6.2.2(c) in a manner that diminishes the rights or interests of the other Party without the prior written consent of such other Party, such consent not to be unreasonably withheld or delayed. Any recoveries obtained by either Party shall be allocated as in Section 6.2.2(b).



### 6.2.3. Infringement and Third Party Licenses.

**(a) Notice of Potential Infringement of Third Party Rights.**

If the making, having made, importing, exporting, using, distributing, marketing, promoting, offering for sale or selling of any Product is alleged by a Third Party to infringe a Third Party's patent or other intellectual property rights, the Party becoming aware of such allegation shall promptly notify the other Party. Additionally, if either Party determines that, based upon the review of a Third Party's patent or patent application or other intellectual property rights, it may be desirable to obtain a license from such Third Party with respect thereto, such Party shall promptly notify the other Party of such determination.

**(b) Option to Negotiate.** In the event that a Party determines that it may be desirable to obtain a license under one or more patents or patent applications or other intellectual property rights Controlled by a Third Party (collectively, "**Third Party IP Rights**"), which Third Party IP Rights (i) relate to any Compound or any Product and (ii) if valid and issued, may, in the absence of a license from such Third Party, be infringed by the Development, Manufacture, use or Commercialization of any Compound or Product by or on behalf of Wyeth or any of its Affiliates or Sublicensees in the Territory or outside of the Territory pursuant to the exercise of rights granted by ADLS to Wyeth hereunder, such Party shall have the right, but not the obligation, to negotiate and enter into an agreement with such Third Party, whereby such Party is granted a license under such Third Party IP Rights permitting such Party to practice such Third Party IP Rights in connection with the Development, Manufacture, use or Commercialization of any Compounds or Products and the performance of any of its obligations or the exercise of any of its rights under this Agreement; provided, however, that if such Party proceeds in negotiating and entering into such license agreement with such Third Party, then (a) if such Party is Wyeth, and the license agreement with such Third Party includes the grant of rights outside of the Territory, Wyeth shall use Commercially Reasonable Efforts to obtain the right under such license agreement to sublicense such Third Party IP Rights outside of the Territory to ADLS, and (b) if such Party is ADLS, and the license agreement with such Third Party includes the grant of rights in the Territory, ADLS shall use Commercially Reasonable Efforts to obtain the right under such license agreement to sublicense such Third Party IP Rights in the Territory to Wyeth. The provisions of this Section 6.2.3(b) are subject to the provisions of Sections 5.3.4 and 5.3.5.

(c) **Third Party Infringement Suit.** If a Third Party sues Wyeth or any of Wyeth's Affiliates or Sublicensees (the "**Sued Party**") alleging that the Sued Party's practice of any right granted by ADLS to Wyeth hereunder through the Development, Manufacture, use or Commercialization of any Compound or Product pursuant to this Agreement infringes or will infringe such Third Party's intellectual property, then, upon the Sued Party's request and in connection with the Sued Party's defense of any such Third Party infringement suit, ADLS shall provide reasonable assistance to the Sued Party for such defense at the Sued Party's expense. The Sued Party shall be solely responsible for expenses incurred in defending against any such suit and for payment of any damages or other rewards that may result therefrom, subject to Section 10.

**6.2.4. Patent Certifications.** Each Party shall immediately give written notice to the other of any certification of which it becomes aware filed pursuant to any statutory or regulatory requirement in any country in the Territory similar to 21 U.S.C. § 355(b)(2)(A) or § 355(j)(2)(A)(vii) (or any amendment or successor statute thereto) claiming that any ADLS Patent Right or Joint Patent Right covering any Compound or Product is invalid or that infringement will not arise from the Development, Manufacture, use or Commercialization in the Territory of such Compound or Product by a Third Party. Upon the giving or receipt of such notice, Wyeth shall have the first right, but not the obligation, to bring an infringement action against such Third Party. In such a case, Wyeth shall notify ADLS at least ten (10) days prior to the date set forth by statute or regulation of its intent to exercise, or not exercise, this right. Any infringement action against a Third Party arising under this Section 6.2.4 shall be governed by the provisions of Section 6.2.2(b) hereof.

**6.2.5. Patent Term Restoration.** During the Term, the Parties shall reasonably cooperate with each other in obtaining patent term restoration in any country in the Territory under any statute or regulation equivalent or similar to 35 U.S.C. § 156, where applicable to the ADLS Patent Rights and Joint Patent Rights. If any election with respect to seeking such patent term restoration is to be made in any country in the Territory during the Term with respect to such country, Wyeth shall make such election (including, without limitation, by filing supplementary protection certificates and any other extensions that are now or in the future become available) and ADLS shall abide by such election and cooperate, as reasonably requested by the Wyeth, in connection with the foregoing (including, without limitation, by providing appropriate information and executing appropriate documents).

**6.3. Recording.** If Wyeth deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other

appropriate government authorities in one or more jurisdictions in the Territory, ADLS shall reasonably cooperate to execute and deliver to Wyeth any documents accurately reflecting or evidencing this Agreement that are necessary or desirable, in Wyeth's reasonable judgment, to complete such registration or recordation. Wyeth shall reimburse ADLS for all reasonable out-of-pocket expenses, including attorneys' fees, incurred by ADLS in complying with the provisions of this Section 6.3.

**6.4. Trademarks.** Wyeth shall, in its sole discretion, select and own all product-related Trademarks and related copyrights to be used in connection with the Commercialization of any Product hereunder in the Territory, except to the extent that Wyeth in its discretion may determine to exercise the right granted to Wyeth by ADLS under the Trademark license provided for in Section 2.1.3. ADLS shall neither use nor seek to register, anywhere in the world, any Trademark which is confusingly similar to any Trademark used by or on behalf of Wyeth or its Affiliates or Sublicensees in connection with any Product commercialized hereunder (other than any Trademark rights to which were obtained by Wyeth from ADLS under Section 2.1.3; provided, however, that nothing in this Section 6.4 shall be construed to prevent ADLS from enforcing its own Trademark rights.

## 7. CONFIDENTIALITY.

**7.1. Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, for the Term and for [five (5) years] thereafter, each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder shall keep such Confidential Information confidential and shall not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement except for Confidential Information that the Receiving Party can establish:

- (a) was already known by the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party and such Receiving Party has documentary evidence to that effect;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, and other than through any act or omission of the Receiving Party in breach of this confidentiality obligation;

(d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) was independently discovered or developed by or on behalf of the Receiving Party without the use of or reference to the Confidential Information belonging to the Disclosing Party and the Receiving Party has documentary evidence to that effect.

## **7.2. Authorized Disclosure and Use.**

**7.2.1. Disclosure.** Notwithstanding the foregoing Section 7.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent such disclosure is reasonably necessary to:

(a) file or prosecute patent applications which the Receiving Party is authorized to file or prosecute hereunder, if the Disclosing Party consents to such disclosure (such consent not to be unreasonably withheld or delayed); provided that a disclosure of the Disclosing Party's Confidential Information under this Section 7.2.1(a) shall be treated as a publication under Section 7.4.4, and shall be subject to the requirements of advance notice, a review period and an opportunity to file patent application(s), as set forth in Section 7.4.4;

(b) prosecute or defend litigation;

(c) exercise rights hereunder provided such disclosure is covered by terms of confidentiality similar to those set forth herein;

(d) facilitate discussions with prospective licensees and sublicensees of the Receiving Party, subject to appropriate confidentiality agreements;

(e) facilitate discussions with potential financial investors in connection with an investment in or acquisition of the Receiving Party, subject to appropriate confidentiality agreements; or

(f) comply with applicable governmental laws, regulations and orders.

In the event that the Receiving Party shall reasonably deem it necessary to disclose, pursuant to Section 7.2.1(b) or 7.2.1(f), Confidential Information belonging to the Disclosing Party, the Receiving Party shall to the extent possible give reasonable advance notice of such disclosure to the Disclosing Party and take

reasonable measures to ensure confidential treatment of such information.

**7.2.2. Use.** Notwithstanding the foregoing Section 7.1, each Party shall have the right to use Confidential Information of the other Party in Developing, Manufacturing and Commercializing Compounds and Products as provided in this Agreement.

**7.3. SEC or Similar Filings.** Either Party may disclose the terms of this Agreement and events related to the Development or Commercialization of Products (including the achievement of Launch Events and Commercial Events and the payment and amount of corresponding payments, as well as the equity purchase described in Section 5.1) to the extent reasonably required to comply with applicable laws, rules and regulations, including, without limitation, the rules and regulations promulgated by the United States Securities and Exchange Commission, comparable foreign regulatory organizations and self-regulatory organizations (such as securities exchanges). Subject to the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 7.3, the Parties will reasonably consult with one another on the terms of this Agreement to be redacted in making any such disclosure. If a Party discloses this Agreement or any of the terms hereof in accordance with this Section 7.3, such disclosing Party agrees, at its own expense, to seek confidential treatment of portions of this Agreement, or such terms, as may be reasonably and timely requested by the other Party.

**7.4. Public Announcements; Publications.**

**7.4.1. Coordination.** The Parties agree on the importance of coordinating their public announcements respecting this Agreement and the subject matter thereof (other than academic, scientific or medical publications that are subject to the publication provision set forth below). Subject to Section 7.3, ADLS and Wyeth shall, from time to time, and at the request of the other Party, discuss and agree on the general information content relating to this Agreement which may be publicly disclosed (including, without limitation, by means of any printed publication or oral presentation).

**7.4.2. Announcements.** Except as may be expressly permitted under Sections 7.3, 7.4.3 and 7.4.4, or as may be appropriate for either Party to make in connection with its Development or Commercialization activities as contemplated hereunder, subject to Sections 7.1 and 7.2 hereof, neither Party will make any public announcement regarding this Agreement or the Development, Manufacturing or Commercialization of any Product without the prior written approval of the other Party.

**7.4.3. Press Releases.** Each Party may issue, if it determines to do so, a press release reasonably approved by the other Party, announcing the



execution of this Agreement. Such press release to be issued by ADLS shall be in the form of Exhibit 7.4.3 attached hereto.

**7.4.4. Publications.** During the Term, each Party will submit to the other Party for reasonable prior review and approval all proposed academic, scientific and medical publications and public presentations relating to the Development, Manufacture or Commercialization of any Product, or any proposed disclosure under Section 7.2.1(a) (but excluding marketing, sales and promotional materials and presentations used for Commercialization), for review in connection with preservation of Patent Rights or to determine whether any of such other Party's Confidential Information should be modified or deleted. Without limiting the foregoing, if such proposed publication or presentation contains information or data that should reasonably be reviewed for the preservation of Patent Rights, written copies of such proposed publication or presentation shall be submitted to the non-publishing Party no later than sixty (60) days before submission for publication or presentation and the non-publishing Party shall provide its comments with respect to such publication or presentation within thirty (30) business days of its receipt of such written copy. The review period may be extended for an additional ninety (90) days in the event the non-publishing Party can demonstrate reasonable need for such extension, including, but not limited to, the preparation and filing of patent applications. By mutual agreement, this period may be further extended. Wyeth and ADLS will each comply with standard academic practice regarding authorship of scientific publications and recognition of the contribution of other parties in any publications relating to the Development, Manufacture or Commercialization of any Product.

**7.5. Termination of Prior Non-Disclosure Agreement.** This Agreement supersedes the Non-Disclosure Agreement between the Parties dated July 18, 2007 (the "**Non-Disclosure Agreement**"), including any amendments thereto, provided, however, that the foregoing shall not limit any remedies available to either Party with respect to any breach of the Non-Disclosure Agreement which occurred prior to the Effective Date. All Information (as defined in the Non-Disclosure Agreement) exchanged between the Parties under the Non-Disclosure Agreement shall be deemed to be Confidential Information under this Agreement and shall be subject to the terms of this Section 7.

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

**8.1. Representations, Warranties and Covenants of Each Party.** Each of ADLS and Wyeth hereby represents, warrants and covenants to the other Party as follows:

- (a) it is a corporation duly organized and validly existing under the laws of the state of its incorporation;

(b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and does not require any stockholder action or approval;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its certificate of incorporation or bylaws; or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) it shall use Commercially Reasonable Efforts to conduct all human clinical trials of Products in accordance with current Good Clinical Practices, as defined by regulations promulgated by the FDA and corresponding ICH Guidelines, and shall use Commercially Reasonable Efforts to cause its Affiliates and Licensees (in the case of ADLS) and Sublicensees (in the case of Wyeth) to conduct such clinical trials in such manner; and

(f) it shall at all times comply in all material respects with all laws and regulations applicable to its activities under this Agreement.

**8.2. Additional Representations, Warranties and Covenants of ADLS.** In addition to the representations, warranties and covenants made by ADLS elsewhere in this Agreement, ADLS hereby represents, warrants and covenants to Wyeth that:

(a) except as disclosed in Exhibit 8.2(a), as of the Effective Date, the ADLS Patent Rights and the ADLS Know-How are existing and, to its knowledge, are not invalid or unenforceable, in whole or in part;

(b) it has the full right, power and authority to grant the licenses granted or to be granted to Wyeth under this Agreement;

(c) except as disclosed in Exhibit 8.2(c) attached hereto, as of the Effective Date, no Third Party has any right, title or interest in or to any of the ADLS Patent Rights or ADLS Know-How or any of ADLS' interest in the Joint Know-How or Joint Patent Rights

that would preclude the grant to Wyeth of the licenses set forth herein;

(d) except as disclosed in Exhibit 8.2(c) attached hereto, ADLS is the sole and exclusive owner of the ADLS Patent Rights listed on Exhibit 1.6 attached hereto and the ADLS Know-How existing as of the Effective Date, all of which are free and clear of any liens, charges or encumbrances;

(e) except as set forth in Exhibit 8.2(e) attached hereto, no ADLS Patent Right and no portion of the ADLS Know-How existing as of the Effective Date and relating to any Compound or Product is subject to any funding agreement with the United States government or any of its agencies;

(f) to its knowledge, as of the Effective Date, neither the Development, Manufacture, use or Commercialization of any Compound or Product infringes or would infringe any existing issued patent owned or possessed by any Third Party;

(g) to its knowledge, as of the Effective Date, there are no Third Party pending patent applications which are not included in the ADLS Patent Rights and, if issued, would cover the Development, Manufacture, use or Commercialization of any Compound or Product;

(h) to its knowledge, as of the Effective Date, there are no claims, judgments or settlements against or owed by ADLS or any of its Affiliates, or pending or threatened claims or litigation, in each case relating to the ADLS Patent Rights listed in Exhibit 1.6 attached hereto or the ADLS Know-How;

(i) during the Term, ADLS will use diligent efforts not to diminish the rights under the ADLS Patent Rights or the ADLS Know-How granted to Wyeth hereunder, including, without limitation, by not committing or permitting any actions or omissions which would cause ADLS to breach any ADLS Third Party Agreement; ADLS will provide Wyeth promptly with written notice of any such breach or any allegation of any such breach; and as of the Effective Date, ADLS is in compliance in all respects with each ADLS Third Party Agreement;

(j) the ADLS Third Party Agreements are in full force and effect; to ADLS' knowledge, as of the Effective Date, no other party to such agreements is in breach or default thereunder; and ADLS has not waived or allowed to lapse or terminate any of its

rights relating to any Compound or Product under the ADLS Third Party Agreements;

(k) ADLS has provided a true and complete copy of each ADLS Third Party Agreement to Wyeth, including any amendment(s) thereto;

(l) ADLS will not during the Term amend such ADLS Third Party Agreements in a manner that would adversely affect the rights, obligations or economic interests of Wyeth under this Agreement without Wyeth's prior written consent;

(m) ADLS shall furnish Wyeth with copies of all notices received by ADLS relating to any alleged breach or default by ADLS under ADLS Third Party Agreements within five (5) business days after ADLS' receipt thereof. In the event ADLS does not resolve any such alleged breach, it shall notify Wyeth within a sufficient period of time before the expiration of the cure period for such breach under such ADLS Third Party Agreement such that Wyeth, in its sole discretion, is able to cure or otherwise resolve such alleged breach. If Wyeth makes any payments to a Third Party in connection with the cure or other resolution of such alleged breach of ADLS, then Wyeth may credit the amount of such payments against any royalties or other payments payable to ADLS pursuant to this Agreement;

(n) ADLS shall promptly furnish Wyeth with copies of all (i) amendments of the ADLS Third Party Agreements and (ii) correspondence (or in the case of oral discussions, a summary of such discussions) with or from and reports received from or provided to licensors under the ADLS Third Party Agreements to the extent material to Wyeth or its rights granted under this Agreement;

(o) except as disclosed in Exhibit 8.2(o) attached hereto, as of the Effective Date, ADLS is not a party to or otherwise subject to any Control Limitation Agreement limiting Wyeth's access to or rights with respect to any Licensed Right or any other intellectual property right that would, but for such Control Limitation Agreement, be included in the Licensed Rights;

(p) except as may otherwise be expressly permitted by the terms of this Agreement, during the Term, ADLS will not enter into or otherwise allow itself to be subject to any Control Limitation Agreement limiting Wyeth's access to or rights with respect to any Licensed Right or any other intellectual property



right that would, but for such Control Limitation Agreement, be included in the Licensed Rights;

(q) as of the Effective Date, there are no ADLS Licensees, and ADLS will provide Wyeth promptly with written notice in the event that any Person becomes an ADLS Licensee and a copy of any document pursuant to which such Person is granted a license or sublicense of any right to Develop, Manufacture or Commercialize any Compound or Product, which copy may be redacted with respect to financial terms;

(r) it has complied with the "Right of First Negotiation" as defined in Section 5.6 of the Abbott Agreement, including the notice and negotiation provisions thereof, with respect to the transactions contemplated by this Agreement;

(s) [at no cost to Wyeth, it shall enter into, within six (6) months after the Effective Date, an amendment of the Abbott Agreement providing that the patent rights licensed to ADLS pursuant to the fourth amendment of the Abbott Agreement dated November 13, 2007 shall include all foreign counterparts of the patents listed in Exhibit D attached to such fourth amendment; and]

(t) [at no cost to Wyeth, it shall use Commercially Reasonable Efforts to enter into, within six (6) months after the Effective Date, an amendment of the Abbott Agreement providing that U.S. Patent No. 6,075,011, and all foreign counterparts thereof, shall be included among the patent rights licensed to ADLS pursuant to the fourth amendment of the Abbott Agreement dated November 13, 2007].

**8.3. Representation by Legal Counsel.** Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

**8.4. No Inconsistent Agreements.** Neither Party has in effect and after the Effective Date neither Party shall enter into any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement.

**8.5. Disclaimer.** EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND

PARTICULARLY THAT PRODUCTS WILL BE SUCCESSFULLY DEVELOPED HEREUNDER, AND IF PRODUCTS ARE DEVELOPED, WITH RESPECT TO SUCH PRODUCTS, THE PARTIES DISCLAIM ALL IMPLIED WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

## 9. TERM AND TERMINATION.

**9.1. Term.** The term of this Agreement (the “**Term**”) will commence on the Effective Date and shall extend, unless this Agreement is terminated earlier in accordance with this Section 9, on a Product-by-Product and country-by-country basis until such time as the Royalty Term with respect to the sale of such Product in such country expires.

**9.2. Termination by Either Party for Cause.** Either Party may terminate this Agreement, in its entirety or, at the terminating Party’s option, on a Product-by-Product and country-by-country basis, at any time during the Term by giving written notice to the other Party in the event that the other Party commits a material breach of its obligations under this Agreement and such breach remains uncured for [ninety (90) days] (or [thirty (30) days] in the case of the breach of a payment obligation, other than any payment obligation that the payor is disputing in good faith), measured from the date written notice of such breach is given to the breaching Party; provided, however, that if such breach is not susceptible of cure within the stated period and the breaching Party uses active and continuous, diligent, good faith efforts to cure such breach, the stated period will be extended by an additional [ninety (90) days]. Notwithstanding the foregoing, a Party shall not have the right to terminate this Agreement in part pursuant to this Section 9.2 with respect to an individual Product or country unless the other Party’s material breach giving rise to such termination right specifically relates to such Product or country, as applicable.

### 9.3. Termination by Wyeth At Will or For Safety.

**9.3.1. Termination At Will.** Wyeth shall have the right, exercisable upon [ninety (90) days] prior written notice to ADLS, to terminate this Agreement either (a) in its entirety or (b) on a Product-by-Product basis. Notwithstanding the foregoing, in no event shall such termination at will by Wyeth relieve it of its obligation to fully satisfy its payment obligations under this Agreement, to the extent accrued prior to such termination, and stock purchase obligations under Section 5.1.

**9.3.2. Termination for a Material Safety Issue.** Wyeth shall have the right to terminate this Agreement, at any time, either in its entirety or on a Product-by-Product and country-by-country basis, by giving [ten (10) days] prior written notice to ADLS in the event of any safety issue that would reasonably be expected to have a material adverse effect on Wyeth’s ability to Develop, Manufacture or Commercialize any



Compound or Product, as determined in Wyeth's reasonable judgment and according to Wyeth's standard internal procedures for evaluating such safety issues.

**9.4. Termination on Insolvency of ADLS.** ADLS shall be deemed a "Debtor" under this Agreement if, at any time during the Term (i) a case is commenced by or against ADLS under the Bankruptcy Code, (ii) ADLS files for or is subject to the institution of bankruptcy, reorganization, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (iii) ADLS assigns all or a substantial portion of its assets for the benefit of creditors, (iv) a receiver or custodian is appointed for ADLS' business or (v) a substantial portion of ADLS' business is subject to attachment or similar process; provided, however, that in the case of any involuntary case under the Bankruptcy Code, ADLS shall not be deemed a Debtor if the case is dismissed within [sixty (60) days] after the commencement thereof. In the event that ADLS is deemed a Debtor, Wyeth may terminate this Agreement by providing written notice to ADLS. In accordance with Section 2.6 above, all licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in Section 101 of the Bankruptcy Code, and Wyeth shall have such rights as are provided under the Bankruptcy Code in the event of the bankruptcy of ADLS.

**9.4.1. Licenses.** If a case is commenced under the Bankruptcy Code by or against ADLS, ADLS (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall:

- (a) as Wyeth may elect in a written request, immediately upon such request:
  - (i) perform all of the obligations provided in this Agreement to be performed by ADLS, including, where applicable, providing to Wyeth portions of intellectual property licensed hereunder (including embodiments thereof) held by ADLS and/or such successors and assigns or otherwise available to them; or
  - (ii) provide to Wyeth all such intellectual property (including all embodiments thereof) held by ADLS and/or such successors and assigns or otherwise available to them; and
- (b) not interfere with Wyeth's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

**9.4.2. Rights to Intellectual Property.** If (i) a case under the Bankruptcy Code is commenced by or against ADLS, (ii) this Agreement is rejected as provided in the Bankruptcy Code and (iii) Wyeth elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, then ADLS (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) shall provide to Wyeth all intellectual property licensed hereunder (including all embodiments thereof) held by ADLS and/or such successors and assigns, or otherwise available to them, immediately upon Wyeth's written request. Whenever ADLS or any of its successors or assigns provides to Wyeth any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 9.4.2, Wyeth shall have the right to perform the obligations of ADLS hereunder with respect to such intellectual property, but neither such provision nor such performance by Wyeth shall release ADLS from liability resulting from rejection of the license or the failure to perform such obligations.

**9.4.3. Additional Rights.** All rights, powers and remedies of Wyeth provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

- (a) the right of access to any intellectual property (including all embodiments thereof) of ADLS, or any Third Party with whom ADLS contracts to perform an obligation of ADLS under this Agreement, and, in the case of the Third Party, which is necessary for the Development, Manufacture, Commercialization or use of Products; and
- (b) the right to contract directly with any Third Party to complete the contracted work.

## **9.5. Effects of Termination.**

**9.5.1. Effect of Termination by Wyeth for Cause.** If Wyeth terminates this Agreement with respect to any one or more Products in any one or more countries pursuant to Section 9.2 (Termination by either Party for Cause):

- (a) All licenses conveyed by ADLS to Wyeth with respect to the applicable terminated Product in the applicable terminated country shall become irrevocable and perpetual, Wyeth's rights under Sections 4.4, 4.6.2, 6.2.1(a), 6.2.2(a) and (b), 6.2.4, 6.2.5 and 8.2(i), (l), (m), (n), (p) and (q) with respect to such Product



shall remain in effect and Wyeth shall have no further obligations to ADLS under this Agreement with respect to such Product in such country other than (i) an obligation to pay royalties with respect to Net Sales of such Product in such country in an amount equal to [fifty percent (50%)] of the amount that would otherwise have been payable under this Agreement, such amount to be paid in accordance with and subject to the other terms of this Agreement governing the payment of royalties, and (ii) those obligations that expressly survive termination in accordance with Section 9.6 hereof;

(b) Such termination shall not be construed to limit ADLS' right to receive payments that accrued before the effective date of such termination;

(c) Wyeth shall have the right to offset, against any payment owing to ADLS as provided for under Section 9.5.1(a), any damages found or agreed by the Parties to be owed by ADLS to Wyeth;

(d) For the avoidance of doubt, all licenses and other rights granted by Wyeth to ADLS under Sections 2.4 and 4.4, and any rights granted by ADLS under such rights to any Affiliate or ADLS Licensee, with respect to such Product(s) shall terminate as of the effective date of such termination; and

(e) Nothing in this Section 9.5.1 shall limit any other remedy Wyeth may have for ADLS' breach of this Agreement.

**9.5.2. Effect of Termination by Wyeth on Insolvency of ADLS.** If Wyeth terminates this Agreement pursuant to Section 9.4 (Termination on Insolvency of ADLS):

(a) All licenses granted to Wyeth shall become irrevocable and perpetual, Wyeth's rights under Sections 4.4, 4.6.2, 6.2.1(a), 6.2.2(a) and (b), 6.2.4, 6.2.5 and 8.2(i), (l), (m), (n), (p) and (q) shall remain in effect and Wyeth shall have no further obligations to ADLS under this Agreement other than (i) those obligations that expressly survive termination in accordance with Section 9.6 hereof and (ii) an obligation to pay royalties with respect to Net Sales of Products in an amount equal to [fifty percent (50%)] of the amount that would otherwise have been payable under this Agreement, such amount to be paid in accordance with and subject to the other terms of this Agreement governing the payment of royalties;

(b) Such termination shall not be construed to limit ADLS' right to receive payments that accrued before the effective date of such termination;

(c) Wyeth shall have the right to offset, against any payment owing to ADLS as provided for under Section 9.5.2(a), any damages found or agreed by the Parties to be owed by ADLS to Wyeth;

(d) For the avoidance of doubt, all licenses and other rights granted by Wyeth to ADLS under Sections 2.4 and 4.4, and any rights granted by ADLS under such rights to any Affiliate or ADLS Licensee, shall terminate as of the effective date of such termination; and

(e) Nothing in this Section 9.5.2 shall limit any other remedy Wyeth may have for any breach by ADLS of this Agreement.

**9.5.3. Effect of Termination by ADLS for Cause or by Wyeth At Will or For Safety.**

(a) If ADLS terminates this Agreement in its entirety pursuant to Section 9.2 (Termination by Either Party for Cause), or if Wyeth terminates this Agreement in its entirety pursuant to Section 9.3 (Termination by Wyeth At Will or For Safety), then the following shall apply:

(i) All licenses granted by ADLS to Wyeth shall automatically terminate; and

(ii) Such termination shall not be construed to limit ADLS' right to receive payments that accrued before the effective date of such termination.

(b) If this Agreement is not terminated in its entirety, but (i) ADLS terminates this Agreement with respect to any one or more Products in any one or more countries pursuant to Section 9.2, (ii) Wyeth terminates this Agreement pursuant to Section 9.3.1 with respect to any one or more Products or (iii) Wyeth terminates this Agreement pursuant to Section 9.3.2 with respect to any one or more Products in any one or more countries, then the following shall apply:

(i) All licenses granted by ADLS to Wyeth under Section 2.1 with respect to such Product(s) in such countr(y/ies) shall terminate, provided that the licenses to Wyeth with respect to all remaining Products and in all other countries in the Territory shall remain in effect; and

(ii) Such termination shall not be construed to limit ADLS' right to receive payments that accrued before the effective date of such termination.

(c) Nothing in this Section 9.5.3 shall limit any other remedy ADLS may have for Wyeth's breach of this Agreement.

**9.5.4. Disposition of Inventories of Products.** Following termination of this Agreement with respect to one or more Products by ADLS pursuant to Section 9.2, or by Wyeth pursuant to Section 9.3.1, ADLS shall have the right but not the obligation to purchase from Wyeth, at Wyeth's cost, Wyeth's then existing inventory of such Product or Products. Wyeth, its Affiliates and its Sublicensees shall have the right to continue to sell in the Territory any amounts of their existing inventories of such Products that ADLS does not elect to purchase as described in this Section 9.5.4 for a period not to exceed [one (1) year] after the effective date of any such termination of this Agreement with respect to one or more Products, and Wyeth shall pay any royalties payable in connection with such sales in accordance with Sections 5.3 and 5.4. and, if applicable, any Commercial Payment payable with respect to such sales in accordance with Section 5.2.3.

**9.6. Survival of Certain Obligations.** Expiration or termination of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination. The following provisions shall survive expiration or termination of this Agreement: Section 1 (Definitions) (to the extent definitions are embodied in the following Sections); Section 4.7 (Regulatory Reporting); Section 4.8.2 (Pharmacovigilance); Section 4.11 (Product Recalls) (solely with respect to Products sold prior to such expiration or termination); Section 5.5 (Maintenance of Records; Audits); Section 6.1 (Inventions); Section 7 (Confidentiality); Section 10 (Liability, Indemnification and Insurance); Section 11 (Dispute Resolution); and Section 12 (Miscellaneous) (other than Sections 12.14 (Change of Control of ADLS) and 12.15 (Right of First Offer)).

## **10. LIABILITY, INDEMNIFICATION AND INSURANCE.**

**10.1. Liability.** Except with respect to liability arising from a breach of Section 6 or 7, from any willful misconduct or intentionally wrongful act, or to the extent such Party may be required to indemnify the other Party under this Section 10, neither Party nor its respective Affiliates shall be liable to the other for special, punitive or consequential damages, whether based on contract or tort, or arising under applicable law or otherwise, in connection with this Agreement.

**10.2. Indemnification by Wyeth.** Wyeth will indemnify, defend and hold harmless ADLS and its Affiliates, Licensees and each of their respective employees, officers, directors and agents (each, an "**ADLS Indemnified Party**") from and against any and all liability, loss, damage, expense (including



reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") that the ADLS Indemnified Party may be required to pay to one or more Third Parties to the extent resulting from or arising out of (i) any claims of any nature, including product liability claims, arising out of the Development, Manufacture or Commercialization of Compounds or Products by, on behalf of or under the authority of Wyeth (other than by ADLS, its Affiliates or Licensees or any of their respective employees, officers, directors and agents), or (ii) any breach by Wyeth of any representation, warranty or covenant set forth in this Agreement, except, in each case, to the extent caused by the negligence or willful misconduct of ADLS or any ADLS Indemnified Party or any breach by ADLS of any representation, warranty or covenant set forth herein.

**10.3. Indemnification by ADLS.** ADLS will indemnify, defend and hold harmless Wyeth and its Affiliates, Sublicensees and distributors and each of its and their respective employees, officers, directors and agents (each, a "**Wyeth Indemnified Party**") from and against any and all Liabilities that the Wyeth Indemnified Party may be required to pay to one or more Third Parties to the extent resulting from or arising out of (i) any claims of any nature, including product liability claims, arising out of the Development, Manufacture or Commercialization of any Compound or Product by, on behalf of or under the authority of ADLS (other than by Wyeth, its Affiliates or Sublicensees or any of their respective employees, officers, directors and agents), or (ii) any breach by ADLS of any representation, warranty or covenant set forth in this Agreement, except, in each case, to the extent caused by the negligence or willful misconduct of Wyeth or any Wyeth Indemnified Party or any breach by Wyeth of any representation, warranty or covenant set forth herein.

**10.4. Procedure.** Each Party will notify the other promptly in the event it becomes aware of a claim for which indemnification may be sought hereunder. In furtherance and not in limitation of the preceding sentence, in case any proceeding (including any governmental investigation) shall be instituted involving any Wyeth Indemnified Party or ADLS Indemnified Party in respect of which indemnity may be sought pursuant to this Section 10, ADLS (if such proceeding is initiated against an ADLS Indemnified Party) or Wyeth (if such proceeding is initiated against a Wyeth Indemnified Party) (such Party referred to as the "**Indemnified Party**") shall promptly notify the other Party (the "**Indemnifying Party**") in writing within fifteen (15) days after the Indemnified Party first becomes aware of such proceeding and the Indemnifying Party and Indemnified Party shall then promptly meet to discuss how to respond to any claims that are the subject matter of such proceeding. The Indemnifying Party shall have the right to assume the defense of any Third Party claim subject to indemnification obligations hereunder. The Indemnifying Party, upon assuming the defense of the claim, shall retain counsel reasonably satisfactory to the Indemnified Party to conduct the defense of the claim and shall pay the fees and expenses of such counsel related to such proceeding. The Indemnified Party agrees to cooperate fully with the Indemnifying Party in the defense of any such claim, action or proceeding, or any litigation resulting from any such claim. In



any such proceeding, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party unless (a) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (b) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses shall be reimbursed as they are incurred. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent, the Indemnifying Party agrees to indemnify the Indemnified Party from and against any loss or liability by reason of such settlement. The Indemnifying Party shall not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding.

**10.5. Insurance.** ADLS shall obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers to cover its indemnification obligations under Section 10.3, with limits of not less than [Five Million Dollars (\$5,000,000.00)] per occurrence and in the aggregate. Insurance shall be procured with carriers having an A.M. Best Rating of A-VII or better.

## 11. DISPUTE RESOLUTION

**11.1. General.** Any controversy, claim or dispute arising out of or relating to this Agreement shall be settled, if possible, through good faith negotiations between the Parties. However, subject to Section 3.3 with respect to decisions of the Steering Committee and other committees established under this Agreement, if the Parties are unable to settle such dispute after good faith negotiations, the matter shall be referred to the Executive Officers (having authority to bind the Parties with respect to such dispute, subject to obtaining any necessary corporate or management approvals) to be resolved by negotiation in good faith as soon as is practicable but in no event later than thirty (30) days after referral. The resolution, if any, of a referred matter shall be reduced to writing signed by such Executive Officers and thereafter shall be final and binding on the Parties.

**11.2. Failure of Officers to Resolve Dispute.** If the Executive Officers are unable to settle the dispute after good faith negotiation in the manner set forth above, either Party may seek resolution of the dispute through any remedies available at law or in equity from any court of competent jurisdiction as provided in Section 12.9 below.

**12. MISCELLANEOUS.**

**12.1. Assignment.** Neither this Agreement nor any interest hereunder shall be assignable by either Party, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except a Party may make an assignment of its entire interest in this Agreement without the other Party's consent to an Affiliate or to a successor to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets, exclusive transfer of technology or other transaction, provided that, in the case of assignment to an Affiliate, the assigning Party shall guarantee the performance of this Agreement by such Affiliate. Each successor or permitted assign shall promptly provide the other Party written notice of its agreement to be bound by the terms and conditions of this Agreement. This Agreement shall be binding upon the successors and permitted assigns of the Parties, and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 12.1 shall be void. In addition, ADLS shall not assign any interest in the Licensed Rights to any Third Party or Affiliate unless such assignee agrees in writing that such assignment is subject to the terms and conditions of this Agreement and the rights granted to Wyeth hereunder.

**12.2. Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

**12.3. Force Majeure.** Neither Party shall be liable to the other for delay or failure in the performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to circumstances beyond its control which it could not have avoided by the exercise of reasonable diligence. Such Party shall notify the other Party promptly should such circumstances arise, giving an indication of the likely extent and duration thereof, and shall use all Commercially Reasonable Efforts to resume performance of its obligations as soon as practicable, provided, however, that neither Party shall be required to settle any labor dispute or disturbance.

**12.4. Correspondence and Notices.**

**12.4.1. Ordinary Notices.** Subject to Section 12.4.2, correspondence, reports, documentation and any other communication in writing between the Parties in the course of ordinary implementation of this Agreement shall be delivered by hand, sent by facsimile transmission (receipt verified), sent by registered or certified mail (return receipt requested) postage prepaid or sent using a nationally recognized express courier service, in each case to the employee or representative of the other Party

who is designated by such other Party to receive such written communication.

**12.4.2. Extraordinary Notices.** Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including, without limitation, any notice of force majeure, breach, termination, change of address, etc.) shall be in writing and shall be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), five (5) days after deposited in the mail if mailed by registered or certified mail (return receipt requested) postage prepaid, or on the next business day if sent by overnight delivery using a nationally recognized express courier service and specifying next business day delivery (receipt verified), to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as shall be specified by like notice, provided, however, that notices of a change of address shall be effective only upon receipt thereof):

All correspondence to Wyeth shall be addressed as follows:

Wyeth  
500 Arcola Road  
Collegeville, Pennsylvania 19426  
Attn: Senior Vice President, Corporate Business  
Development  
Fax: (484) 865-6476

with a copy to:

Wyeth  
5 Giralda Farms  
Madison, New Jersey 07940  
Attn: Executive Vice President and General Counsel  
Fax: (973) 660-7156

All correspondence to ADLS shall be addressed as follows:

Advanced Life Sciences Holdings, Inc.  
1440 Davey Road  
Woodridge, IL 60517  
Attn: Chief Legal Counsel  
Fax: (630) 739-6754

with a copy to:

Winston & Strawn LLP  
35 West Wacker Drive  
Chicago, IL 60601  
Attn: R. Cabell Morris, Jr.  
Fax: (312) 558-5700

**12.5. Amendment.** No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

**12.6. Waiver.** No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

**12.7. Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable law.

**12.8. Descriptive Headings.** The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

**12.9. Governing Law; Venue.** This Agreement shall be governed by and interpreted in accordance with the substantive law of the state of New York, without regard to conflict of law principles thereof. Subject to Section 11 hereof, any action based upon a controversy, claim or dispute arising out of or relating to this Agreement shall be brought only in a federal court of competent jurisdiction (or a state court if no federal court has jurisdiction) located in New York, New York and the Parties hereby submit to the exclusive jurisdiction and venue of such courts.

**12.10. Entire Agreement of the Parties.** This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, among the Parties respecting the subject matter hereof.



**12.11. Independent Contractors.** Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

**12.12. Counterparts.** This Agreement may be executed in two counterparts, each of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.

**12.13. Interpretation.** Except where the context requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation,” (c) the word “will” shall be construed to have the same meaning and effect as the word “shall,” (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person shall be construed to include the Person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Exhibits shall be construed to refer to Sections or Exhibits of this Agreement, and references to this Agreement include all Exhibits hereto, (h) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), and (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof.

**12.14. Change of Control of ADLS.**

**12.14.1. Change of Control Notice.** ADLS shall notify Wyeth in writing promptly (and in any event within two (2) business days) following the entering into of a definitive agreement with respect to a Change of Control of ADLS.

**12.14.2. Disposition Upon Divestiture.** If, in connection with any Change of Control of ADLS, any governmental agency requires ADLS (including, but not limited to, pursuant to a consent decree) to divest its interest in any Product or this Agreement (the “**Divested Asset(s)**”), Wyeth shall have the right to purchase ADLS’ interest in the Divested Asset(s) for fair consideration. ADLS shall propose in writing a purchase price for the Divested Asset(s) within [thirty (30) days] after receiving notice of such divestiture requirement. Wyeth shall have [thirty (30) days] after receipt of such written proposal to accept or reject the proposed price for the Divested Asset(s). If Wyeth rejects the proposed price, ADLS shall be free to offer the Divested Asset(s) for sale to a Third Party for [one hundred eighty (180) days on terms no less favorable to ADLS than those offered to Wyeth]. If no sale to a Third Party is consummated within such [one hundred eighty (180) day] period, the provisions of this Section 12.14.2 requiring ADLS to first offer the Divested Assets to Wyeth shall again apply.

**12.14.3. Right to Terminate if Confirmation of Continued Priority Not Received.** Wyeth may terminate this Agreement in its entirety or with respect to any one or more Product(s) upon any Change of Control of ADLS unless, within [ninety (90) days] following the closing of such Change of Control, Wyeth has received from ADLS, and any Third Party who is acquiring or has acquired control of ADLS, written confirmation reasonably satisfactory to Wyeth to the effect that (i) after such Change of Control, the Development, Manufacture and Commercialization of Products as contemplated by this Agreement will have a priority for ADLS or its successor following such Change of Control which is equal to or greater than the priority that such Development, Manufacture and Commercialization had for ADLS prior to such Change of Control; and (ii) ADLS will continue to meet all of its obligations under this Agreement following such Change of Control. Any termination by Wyeth under this Section 12.14.3 shall be treated as a termination for cause under Section 9.2.

**12.14.4. Rights if Acquiror Has Competing Product.** Furthermore, in the event that a Change of Control of ADLS results in ADLS or any Affiliate of ADLS having, immediately following the Change of Control, marketing or royalty rights to, or any other substantial financial interest in, any Competing Product, Wyeth may, in its sole discretion, regardless of any assurances provided by ADLS, terminate this Agreement in its entirety or with respect to any one or more Product(s). Any termination by Wyeth under this Section 12.14.4 shall be treated as a termination for cause under Section 9.2.

**12.14.5. No Relief from Obligation.** Nothing in this Section 12.14 shall relieve ADLS of any of its obligations under this Agreement.

**12.15. Right of First Offer.** Wyeth is hereby granted a Right of First Offer (as hereinafter defined) to Develop and Commercialize Products in [India]. The “**Right of First Offer**” shall mean a written offer (the “**Offer**”) presented by ADLS to Wyeth to exclusively Develop and Commercialize Products in [India]. The Offer shall be presented to Wyeth before any such rights to Develop and Commercialize Products in [India] are offered or granted by or on behalf of ADLS to any Third Party. The Offer shall disclose the proposed terms and conditions of the arrangement and any other material facts relating to the Offer. Wyeth shall have [forty-five (45) days] after receipt of the Offer to accept or reject it in writing. In the event that Wyeth accepts such Offer, the Parties shall negotiate in good faith and enter into a written agreement containing the terms of such Development and Commercialization in [India]. Except for any terms and conditions expressly set forth in the Offer, such agreement between the Parties for [India] shall be substantially on the terms and conditions of this Agreement. If Wyeth rejects the Offer, ADLS shall be free to make similar offers to Third Parties for a period of [one (1) year] on terms and conditions, on the whole, no less favorable to ADLS than those offered to Wyeth. If, after such [one (1) year] period, ADLS has not entered into a written agreement with a Third Party granting to such Third Party rights to Develop and Commercialize Products in [India], ADLS shall not offer or grant to a Third Party any rights to Develop or Commercialize Products in [India] without again complying with the provisions of this Section 12.15.

*(The remainder of this page is intentionally left blank. The signature page follows.)*

**IN WITNESS WHEREOF**, duly authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.

**WYETH,**

**acting through its  
Wyeth Pharmaceuticals Division**

By: \_\_\_\_\_  
Name:  
Title:

**ADVANCED LIFE SCIENCES  
HOLDINGS, INC.**

By: \_\_\_\_\_  
Name:  
Title:



## EXHIBIT 1.6

ADLS PATENT RIGHTS

Country	Application No.	Filing Date	Patent No.	Expiration Date
Australia	41780/97	09/02/1997	729348	09/02/2017
Brazil	PI1100639-0	05/13/1997		
Bulgaria	103292	09/02/1997	63547	09/02/2017
Canada	2263972	09/02/1997		
China	97199334.3	09/02/1997		
Croatia	P970473A	09/03/1997		
Czech Republic	PV685-99	09/02/1997		
Europe	97939765.0	09/02/1997	EP 929563-B1	
Austria				
Belgium				
Denmark				
Finland				
France				
Germany				
Great Britain				
Greece				
Ireland				
Italy				
Luxembourg				
Netherlands				
Portugal				
Spain				
Sweden				
Switzerland				
Hong Kong	00100346.1	09/02/1997		
Hungary	P9902869	09/02/1997		
Israel	128681	09/02/1997		
Japan	512858/98	09/02/1997		
Korea	10-1999-7001803	09/02/1997		
Mexico	992161	09/02/1997		
New Zealand	334272	09/02/1997	334274	09/02/2017
1. Norway	1991022	09/02/1997	314230	09/02/2017
2. Pakistan	793/97	10/13/1997	136010	10/13/2013
Philippines	I-57773	09/02/1997		
Poland	P-332009	09/02/1997		
Romania	98-00228	09/02/1997		
Russian Federation	99106778	09/02/1997	2192427	09/02/2017
Singapore	9900750-2	09/02/1997	64049	09/02/2017

South Africa	97/7474	08/20/1997	97/7474	08/20/2017
Slovak Republic	PV286--99	09/02/1997		
Slovenia	P9720062	09/02/1997	20023	09/02/2017
Taiwan	86112756	09/25/1997	NI-142118	09/24/2017
Turkey	1999/01127	09/02/1997	TR01127B	09/02/2017
3. Ukraine	99041886	09/02/1997	51730	09/02/2017
United States	08/888,350	07/03/1997	5866549	09/04/2016
United States	10/752,438	01/06/2004	RE 39591	09/04/2016

## EXHIBIT 1.8

### ADLS STUDY

[The ADLS Study will be a Phase 3, double-blinded, randomized parallel group, multi-center, multi-national non-inferiority comparator study in subjects with moderate community-acquired pneumonia (CAP). Subjects will be randomly assigned to one of two treatment arms to receive either the Current Product at a dose of 300 mg QD for 7 days or a comparator at the comparator's approved/marketed dose for 7 days. The study will be statistically powered for efficacy.]

An appropriate number of subjects will be enrolled in Europe, South Africa, and Asia. Ambulatory males and females at 18 years of age or older are eligible for enrollment into the study if they are clinically diagnosed to have moderate CAP that does not require hospitalization.

The primary endpoint will be clinical response at the test of cure visit. Secondary endpoints will include bacteriological response, radiographic response, and resolution of signs and symptoms of pneumonia.

Safety will be evaluated throughout the study by physical examinations, medical history, measurement of vital signs, ECGs, laboratory tests, recording of other and supplemental medications, and through the monitoring of adverse events.

The exact study design and the number of patients required in this study will be discussed with and approved by the US FDA prior to the initiation of the study. ]

**EXHIBIT 1.10**

**ADLS THIRD PARTY AGREEMENT(S)**

1. License Agreement, dated December 13, 2004, by and between Abbott Laboratories and Advanced Life Sciences Holdings, Inc.
2. First Amendment to License Agreement, dated April 27, 2005, by and between Abbott Laboratories and Advanced Life Sciences Holdings, Inc.
3. Second Amendment to License Agreement, dated August 2, 2005 by and between Abbott Laboratories and Advanced Life Sciences Holdings, Inc.
4. Third Amendment to License Agreement, dated August 10, 2005, by and between Abbott Laboratories and Advanced Life Sciences Holdings, Inc.
5. Fourth Amendment to License Agreement dated as of November 13, 2007 by and between Abbott Laboratories and Advanced Life Sciences, Inc.
6. Fifth Amendment to License Agreement expected to be executed on or around September 30, 2008 by and between Abbott Laboratories and Advanced Life Sciences, Inc.



**EXHIBIT 1.17****[CHINA] STUDY**

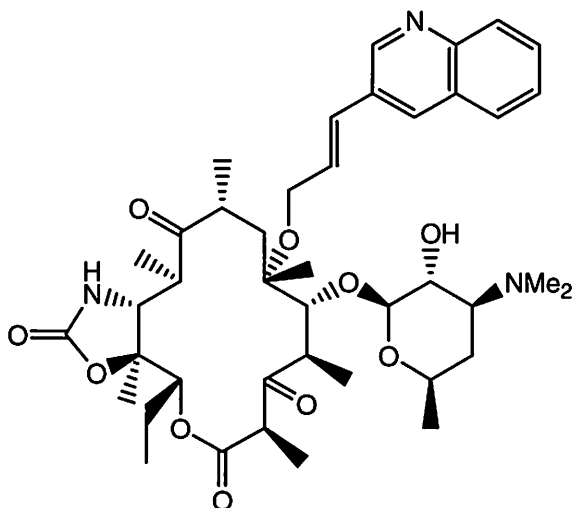
[The China Study will be designed as a bridging study that together with the ADLS Study and US CPP of the Current Product will meet the requirements for the regulatory approval of the Current Product in China. Its design and protocol will be based on the ADLS Study. It will be a Phase 3, double-blinded, randomized parallel group, multi-center, Chinese comparator study in subjects with moderate community-acquired pneumonia (CAP). Subjects will be randomly assigned to one of two treatment arms to receive either the Current Product at a dose of 300 mg QD for 7 days or a comparator at the comparator's approved/marketed dose for 7 days. Safety, tolerability and efficacy data will be collected to support pivotal phase 3 studies; however this study is not independently powered for efficacy. An additional PK study may be performed in parallel or may be required before any other studies are initiated if Chinese regulators feel that Japanese population PK data are insufficiently robust.]

An appropriate number of subjects will be enrolled at sites located within China. Ambulatory males and females at 18 years of age or older are eligible for enrollment into the study if they are clinically diagnosed to have moderate CAP that does not require hospitalization

The primary endpoint will be clinical response at the test of cure visit. Secondary endpoints will include bacteriological response, radiographic response, and resolution of signs and symptoms of pneumonia.

Safety will be evaluated throughout the study by physical examinations, medical history, measurement of vital signs, ECGs, laboratory tests, recording of other and supplemental medications, and through the monitoring of adverse events.

The ultimate design of this study will be reviewed and approved by China's State Food and Drug Agency (sFDA). The discussion with China's sFDA will occur after the ADLS Study design and protocol is approved by the US FDA. ]

**EXHIBIT 1.25****COMPOUND****Structural Formula****Chemical Name**

[3aS,4R,7R,9R,10R,11R,13R,15R,15aR]-4-ethyloctahydro-3a,7,9,11,13,15-hexamethyl-11-[[3-(3-quinolinyl)-2E-propenyl]oxy]-10-[[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopranosyl]oxy]-2H-oxacyclotetradecino [4,3-d] oxazole-2,6,8,14(1H,7H,9H)-tetrone.

**Molecular Formula**

C<sub>42</sub>H<sub>59</sub>N<sub>3</sub>O<sub>10</sub>

**Molecular Weight**

765.93

**EXHIBIT 1.90**

**STOCK PURCHASE AGREEMENT**

**EXHIBIT 4.3**

**INITIAL GLOBAL DEVELOPMENT PLAN**

[The Global Development Plan will initially consist of two clinical trials, the ADLS Study and the China Study, and in the future may be supplemented with additional or updated studies or other activities in accordance with the Agreement.]



**EXHIBIT 4.9.1****KEY TERMS OF THE SUPPLY AGREEMENT**

1. Rolling Forecasts. [At the time of entering into the Supply Agreement, Wyeth shall prepare and deliver to ADLS its good faith, non-binding estimate of its current anticipated launch quantities and annual requirement of the Current Product, which non-binding estimate shall be updated at regular intervals to the extent Wyeth obtains further information regarding the market that would result in a material change to the previously delivered estimates. Thereafter, commencing no later than six (6) months prior to such First Commercial Sale, on or prior to the first day of each calendar month thereafter during the Term, Wyeth will update such forecast by providing ADLS with a written estimate of the monthly quantities of Products it will require for the twenty-four (24) calendar month period commencing ninety (90) days from each such update. Wyeth shall use its Commercially Reasonable Efforts to ensure the accuracy of such forecasts. The first three (3) months of each such rolling forecast shall be binding, and the remaining twenty-one (21) months shall be good faith, non-binding estimates only; provided, however, that no portion of the forecast referred to in the first sentence of this paragraph shall be binding.]
2. Inventory; Launch. ADLS shall at all times maintain an inventory of each Product (in bulk tablet form) equal to [one hundred twenty percent (120%)] of the estimate provided to ADLS under Section 1 above for the next [three (3) calendar months]. ADLS shall at all times maintain an inventory of the API for each Product, and/or such Product in bulk tablet form, sufficient to support supply of [one hundred fifty percent (150%)] of the estimate for such Product provided to ADLS under Section 1 above for the next [four (4) calendar months]. Such inventory shall be maintained by ADLS at no charge to Wyeth. The Supply Agreement shall also contain appropriate provisions with respect to launch quantities of Products.
3. Shelf Life. Each shipment of Products shall have, as of the date of receipt by Wyeth, at least [twenty-four (24) months] of remaining shelf life.
4. Third Party Manufacturers. At all times during the Term and as provided in Section 9 below, ADLS shall satisfy its supply obligations to Wyeth hereunder through binding written agreements with qualified Third Parties engaged to perform services or supply facilities or goods in connection with the Manufacture of Products, provided that ADLS shall not enter into any such agreement unless prior thereto ADLS shall have given Wyeth a written summary identifying the proposed manufacturer and the principal terms of such proposed agreement and Wyeth shall not have reasonably objected thereto in writing within ten (10) days after receipt of such summary. Upon reasonable request, ADLS shall permit and arrange for Wyeth to conduct due diligence inspections of any proposed Third Party manufacturers.



5. Changes. Except as otherwise permitted under the change control procedures to be specified in the Supply Agreement, ADLS shall not modify or change the process, specifications, materials, suppliers, facilities or analytical testing methods used in connection with the Manufacture of Products, regardless of whether such modification or change requires the approval of any Regulatory Authority, without the prior written consent of Wyeth, which consent shall not be unreasonably withheld. ADLS shall provide Wyeth with a written summary of all proposed modifications or changes and must receive the written approval of Wyeth prior to the implementation thereof, which approval shall not be unreasonably withheld. The detailed provisions reflecting this Section 5 shall be set forth in a quality agreement on reasonable and customary terms, and complying with applicable regulatory requirements, to be negotiated and entered into by the Parties in connection with the Supply Agreement (the "**Quality Agreement**").
6. Failure to Supply. ADLS shall give Wyeth prompt written notice if ADLS becomes aware that it will not be able to satisfy Wyeth's requirements for Products in any material way. In such event, or in the event that, without such prior notice, ADLS actually fails to materially satisfy Wyeth's requirements for Products, Wyeth and ADLS shall promptly work together, in good faith, to devise and implement measures to cure such failure to supply or to identify an appropriate alternative source of Products. In addition, in the event of an uncured failure to supply, if Wyeth determines to utilize an alternative source of Products, at Wyeth's request, ADLS shall promptly transfer to Wyeth or its designee, at no cost to Wyeth, all Know-How and other technical information necessary or useful to permit Wyeth to make or have made Products, provided that, pending the full transfer of supply to an alternative source, ADLS shall use best efforts to continue to supply Wyeth's requirements for Products until such time as Wyeth determines, in its sole reasonable discretion, that such alternative supplier is fully able to supply all such requirements. Until such time, available quantities of Products shall be allocated pro-rata among Wyeth's requirements hereunder for the Territory and ADLS' requirements for outside the Territory based upon their relative sales of the applicable Products for the immediately preceding [twelve (12) month] period, or if such shortages occur during or prior to the first [twelve (12) month] period of sales for a Product, then such pro-rata allocation shall be based upon the Parties' then current relative annualized projected requirements for such Product.
7. Transfer Price. The transfer price for commercial supplies of the Current Product purchased by Wyeth during the Royalty Term shall be [\$0.10 per 150 mg tablet]. The transfer price for commercial supplies of other Products purchased by Wyeth during the Royalty Term shall be as mutually agreed by the Parties, but shall in no event exceed [ten percent (10%) of Wyeth's estimated average Net Sales price per unit of such Product in the Major Markets. Clinical supplies of Products shall be provided free of charge].

8. Inspection and Other Rights. Wyeth shall have reasonable and customary (a) rights to routinely inspect the facilities (including with respect to compliance with applicable regulatory requirements) and books and records of ADLS and its Third Party manufacturers relating to Products and (b) rights to information, consultation and participation with respect to regulatory inspections of ADLS and its Third Party manufacturers relating to Products.
9. Survival. In the event that Wyeth terminates the Agreement with respect to any Product pursuant to Section 9.2 or 9.4 of the Agreement, at Wyeth's option the Supply Agreement shall remain in effect with respect to any such Product until such time as ADLS and Wyeth are able to transfer all Third Party supply arrangements relating to such Product directly to Wyeth and, pending such transfer, ADLS shall use best efforts to ensure Wyeth's continued supply of any such Product from any applicable Third Party manufacturer(s).
10. Qualification of Back-Up Manufacturers. Wyeth shall have the right to qualify potential back-up manufacturers (for both API and Products) for use in the event that Wyeth elects to Manufacture or have Manufactured any Product due to a failure by ADLS to supply or have supplied such Product to Wyeth.
11. Stability Studies. ADLS, at its expense, shall perform stability studies with respect to each Product in accordance with ICH Guidelines and meeting the requirements of Regulatory Authorities in the Territory, as applicable, as necessary to establish a shelf life of at least [twenty-four (24) months] for each Product in a final packaged form (as will be agreed upon and set forth in further detail in the Supply Agreement or the Quality Agreement). The detailed provisions reflecting this Section 11 shall be set forth in the Quality Agreement.
12. Term. The Supply Agreement shall remain in effect with respect to each Product supplied thereunder during the Royalty Term for such Product.

**EXHIBIT 7.4.3**

**ADLS PRESS RELEASE**



**EXHIBIT 8.2(a)**

**INFORMATION RELATED TO ADLS IP**

[Reference is made to the matters described in that certain letter dated as of September 26, 2008 from Advanced Life Sciences Holdings, Inc. to Wyeth.]

**EXHIBIT 8.2(c)**

**THIRD PARTY RIGHTS RELATED TO ADLS IP**

Please refer to Exhibit 1.10.

**EXHIBIT 8.2(e)**

**GOVERNMENT FUNDING**

None.

**EXHIBIT 8.2(o)**

**CONTROL LIMITATION AGREEMENTS**

Please refer to Exhibit 1.10.