

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT—EXCLUSIVE and NON-EXCLUSIVE

COVER PAGE

For PHS internal use only:

Patent License Application Number:
A-380-2003

Serial Number(s) of Licensed Patent(s) and/or Patent Application(s):

| <u>Country</u> | <u>Serial Number</u> | <u>Filing Date</u> | <u>DHHS ref</u> |
|----------------|----------------------|--------------------|---------------------|
| USA | 60/094,425 | 07/28/1998 | E-015-1998/0-US-01 |
| PCT | PCT/U599/17036 | 07/27/1999 | E-015-1998/0-PCT-02 |
| CA | 2336875 | 07/27/1999 | E-015-1998/0-CA-07 |
| EP | 99938819.2 | 07/27/1999 | E-015-1998/0-EP-08 |
| USA | 09/743,338 | 01/04/2001 | E-015-1998/0-US-10 |
| JP | 2000-562050 | 07/27R 999 | E-015-1998/0-JP-09 |
| KR | 7001236/2001 | 07/27/1999 | E-015-1998/0-KR-05 |
| AU | 5322199 | 07/27/1999 | E-015-1998/0-AU-06 |

Licensee:
Aridis Pharmaceuticals, LLC

Cooperative Research and Development Agreement (CRADA) Number (if applicable):

Additional Remarks:

Public Benefit(s): Vaccine against Rotavirus infection

This Patent License Agreement, hereinafter referred to as the “Agreement”, consists of this Cover Page, an attached Agreement, a Signature Page, Appendix A (List of Patent(s) and/or Patent Application(s)), Appendix B (Fields of Use and Territory and Biological Materials and Documentation), Appendix C (Royalties), Appendix D (Modifications), Appendix E (Benchmarks), Appendix F (Commercial Development Plan) and Appendix G (Plan for Developing Countries). The Parties to this Agreement are:

- 1) The National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), or the Food and Drug Administration (“FDA”), hereinafter singly or collectively referred to as “PHS”, agencies of the United States Public Health Service within the Department of Health and Human Services (“DHHS”); and

1

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- 2) The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as “Licensee”.

2

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

PHS PATENT LICENSE AGREEMENT—EXCLUSIVE and NON-EXCLUSIVE

PHS and Licensee agree as follows:

1. BACKGROUND

- 1.01 In the course of conducting biomedical and behavioral research, PHS investigators made inventions that may have commercial applicability.

- 1.02 By assignment of rights from **PHS** employees and other inventors, **DHHS**, on behalf of the United States Government, owns intellectual property rights claimed in any United States and/or foreign patent applications or patents corresponding to the assigned inventions. **DHHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.
- 1.03 The Secretary of **DHHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions.
- 1.04 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.05 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, and/or marketable products for public use and benefit.

2. DEFINITIONS

- 2.01 “**Benchmarks**” mean the performance milestones that are set forth in Appendix E.
- 2.02 “**Commercial Development Plan**” means the written commercialization plan attached as Appendix F.
- 2.03 “**First Commercial Sale**” means the initial transfer by or on behalf of Licensee or its sublicensees of Licensed Product(s) or the initial practice of a Licensed Process(es) by or on behalf of Licensee or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.
- 2.04 “**Government**” means the Government of the United States of America.
- 2.05 “**Licensed Fields of Use**” means the fields of use identified in Appendix B.
- 2.06 “**Licensed Patent Rights**” shall mean:
 - a) Patent applications (including provisional patent applications and PCT patent applications) and/or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

3

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above:
 - i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; iv) priority patent application(s) of a) above; and v) any reissues, reexaminations, and extensions of all such patents;
 - c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in a) above: all counterpart foreign and U.S. patent applications and patents to a) and b) above, including those listed in Appendix A.
- Licensed Patent Rights** shall not include b) or c) above to the extent that they claim new matter that is not the subject matter disclosed in a) above, except to the extent included under an amendment to this **Agreement** pursuant to a CRADA between **Licensee** and the **PHS** investigators. For any patent rights under b) or c) above having claims to subject matter disclosed in a) above and other claims to subject matter not disclosed in a) above, those claims corresponding to a) above shall be included in the **Licensed Patent Rights**.
- 2.07 “**Licensed Process(es)**” means processes which, in the course of being practiced would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction, and these same processes when practiced in conjunction with the **Biological Materials** and their derivatives.
 - 2.08 “**Licensed Product(s)**” means tangible materials which, in the course of manufacture, use, sale, or importation would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction and **Biological Materials** and their derivatives and pharmaceutical formulations made from said **Biological Materials** and their derivatives.
 - 2.09 “**Exclusive Licensed Territory**” means the geographical area identified in Appendix B.
 - 2.10 “**Non-Exclusive Licensed Territory**” means the geographical area identified in Appendix B.
 - 2.11 “**Licensed Territories**” mean **Exclusive Licensed Territory and Non-Exclusive Licensed Territory**.
 - 2.12 “**Net Sales**” means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of **Licensee** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by **Licensee**, or sublicensees, and on its payroll, or for the cost of collections.

4

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- 2.13 “**Practical Application**” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.
- 2.14 “**Research License**” means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or **Licensed Processes** as defined by the **Licensed Patent Rights** for purposes of research and not for purposes of commercial manufacture or distribution or in lieu of purchase.
- 2.15 “**Public Sector**” means the government of a **Developing Country**, or any entity empowered by the government of a **Developing Country** to act for said government in matters applicable to this **Agreement**, organizations within the United Nations system including the World Health Global Organization and UNICEF, and other non-profit agencies which may purchase drugs or vaccines for delivery, manufacture and/or sale in **Developing Countries**.
- 2.16 “**Private Sector**” means all other parties other than the **Public Sector**.
- 2.17 “**Developing Country**” means countries eligible for support from The Global Alliance for Vaccines and Immunization (GAVI) or successor organization, which at the effective date of this **Agreement** are those countries with a Gross National Product of less than US \$1,000 per capita per year, and at the effective date of this **Agreement** include the countries listed in Appendix G.
- 2.18 “**Biological Materials**” means the materials listed in Appendix B, which include human-bovine reassortment rotavirus strains. For the sake of clarification, some of the **Biological Materials** may have been generated under a CRADA between **PHS** and the original commercial developer of this technology, Wyeth Pharmaceuticals, Inc. (“**Wyeth**”) and may be subject to the terms and conditions of L-030-1987/1 and L-008-1989/1, which includes in part Paragraph 12.05 as related to **Wyeth** of this **Agreement**.

3. GRANT OF RIGHTS

- 3.01 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** and the exclusive rights to use the **Biological Materials** in the **Exclusive Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import or to export any **Licensed Product** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**. During the term of this **Agreement**, **Biological Materials** shall not be provided by **PHS** to any third party except under written agreement prohibiting the practice of the rights granted hereunder in the **Exclusive Licensed Territory** for commercial purposes. For clarification, **Biological Materials** may be provided under **Research Licenses** as described in Paragraph 5.04.
- 3.02 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a non-exclusive license under the **Licensed Patent Rights** and non-exclusive right to use the **Biological Materials** in the **Non-Exclusive Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import or to export any **Licensed Product(s)** in the **Licensed Fields of Use**

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**. For the sake of clarification, the **Non-Exclusive Licensed Territory** includes (without limitation) Australia, Japan, and South Korea, where patents and patent applications under **Licensed Patent Rights** have been filed or issued.

- 3.03 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, the right to use the relevant documentation and information listed in Appendix B for development of, regulatory licensing of, and otherwise as related to exercise of **Licensee’s** rights to **Licensed Product(s)**.
- 3.04 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than **Licensed Patent Rights** in the **Licensed Territories** regardless of whether such patents are dominant or subordinate to **Licensed Patent Rights**. To the best of its knowledge, **PHS** represents that the **Licensed Patent Rights** and **Biological Materials** in the **Licensed Territories** can be exploited without infringing other patents or other intellectual property rights of **PHS** as of the effective date of this **Agreement**.

4. SUBLICENSING

- 4.01 Upon written approval by **PHS**, which approval shall not be unreasonably withheld, **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights** or to the **Biological Materials** in the **Exclusive Licensed Territory** or in the **Non-Exclusive Licensed Territory** if in the latter instance said sublicensing agreement is intended to support expeditious development and commercialization of **Licensed Product(s)** and expeditious distribution in developing countries, and if said sublicense is associated with **Licensee** know-how and added value to the licensed technology.
- 4.02 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.01-5.04, 8.01, 10.01, 10.02, 12.05, and 13.07-13.09 and the obligations to **Wyeth** of Paragraph 12.05 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.
- 4.03 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between such sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. Such conversion is subject to

PHS approval, not to be unreasonably withheld, and contingent upon acceptance by the sublicensee of the remaining provisions of this Agreement.

- 4.04 Licensee agrees to forward to PHS a copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of such agreement. To the extent permitted by law, PHS agrees to maintain each such sublicense agreement in confidence.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- 5.01 a) PHS reserves on behalf of the Government an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all inventions licensed under the Licensed Patent Rights throughout the world by or on behalf of the Government and on behalf of any foreign government or international organization pursuant to any existing or

6

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

future treaty or agreement to which the Government is a signatory. Prior to the First Commercial Sale, Licensee agrees to provide PHS reasonable quantities of Licensed Products or materials made through the Licensed Processes for PHS research use.

- b) In the event that Licensed Patent Rights are Subject Inventions made under a Cooperative Research and Development Agreement (CRA DA), Licensee grants to the Government, pursuant to 15 U.S.C. 3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice Licensed Patent Rights or have Licensed Patent Rights practiced throughout the world by or on behalf of the Government. In the exercise of such license, the Government shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. 552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party. Prior to the First Commercial Sale, Licensee agrees to provide PHS reasonable quantities of Licensed Products or materials made through the Licensed Processes for PHS research use.
- 5.02 Licensee agrees that products used or sold in the United States embodying Licensed Products or produced through use of Licensed Processes shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from PHS.
- 5.03 Licensee acknowledges that PHS may enter into future Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this Agreement. Licensee agrees not to unreasonably deny requests for a Research License from such future collaborators with PHS when acquiring such rights is necessary in order to make a Cooperative Research and Development Agreement (CRADA) project feasible. Licensee may request an opportunity to join as a party to the proposed Cooperative Research and Development Agreement (CRADA).
- 5.04 a) In addition to the reserved license of Paragraph 5.01 above, PHS reserves the right to grant nonexclusive Research Licenses directly or to require Licensee to grant nonexclusive Research Licenses on reasonable terms. The purpose of this Research License is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the Licensed Patent Rights, however, PHS shall consult with Licensee before granting to commercial entities a Research License in the Exclusive Licensed Territory or providing to them research samples of materials made through the Licensed Processes and shall, prior to providing such license or materials directly, provide Licensee the first opportunity to negotiate with commercial entities to provide them with such license or materials (For clarification, this right of Licensee to have the first opportunity to negotiate applies to Research Licenses for commercial entities only). If Licensee fails to offer such a Research License to commercial entities upon terms that are reasonable under the circumstances within sixty (60) days of submission of an application for such Research License, PHS may grant the Research License itself, under conditions consistent with this Agreement and with other Research Licenses granted by PHS for similar technologies and similar uses. In the event that Licensee can provide convincing written evidence to PHS that a commercial entity that has been granted a Research License to Licensed Patent Rights in the Exclusive Licensed Territory is developing the inventions for commercial manufacture or in lieu of purchase if the inventions are available as commercial products, then Licensee can

7

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

request that PHS terminate its Research License with such commercial entities, such request not to be unreasonably denied.

- b) In exceptional circumstances, and in the event that Licensed Patent Rights are Subject Inventions made under a Cooperative Research and Development Agreement (CRADA), the Government, pursuant to 15 U.S.C. 3710a(b)(1)(B), retains the right to require the Licensee to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use Licensed Patent Rights in Licensee's field of use in the Exclusive Licensed Territory on terms that are reasonable under the circumstances; or if Licensee fails to grant such a license, the Government retains the right to grant the license itself.

The exercise of such rights by the Government shall only be in exceptional circumstances and only if the Government determines (i) the action is necessary to meet health or safety needs that are not reasonably satisfied by Licensee; (ii) the action is necessary to meet requirements for public use specified by Federal regulations, and such requirements are not reasonably satisfied by the Licensee; or (iii) the Licensee has failed to comply with an agreement containing provisions described in 15 U.S.C. 3710a(c)(4) (B). The determination made by the Government under this Article is subject to administrative appeal and judicial review under 35 U.S.C. 203(2).

6. ROYALTIES AND REIMBURSEMENT

- 6.01 Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

- 6.02 **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty as set forth in Appendix C. The minimum annual royalty is due and payable on January 1 of each calendar year and may be credited against any other royalties (including all amounts listed in Appendix C as earned royalties, benchmark royalties, license issue royalties and sublicense royalties) accruing under Appendix C in that year. The minimum annual royalty due for the first calendar year of this **Agreement** may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.
- 6.03 **Licensee** agrees to pay **PHS** earned royalties as set forth in Appendix C.
- 6.04 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.
- 6.05 **Licensee** agrees to pay **PHS** sublicensing royalties as set forth in Appendix C.
- 6.06 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that a) the application has been abandoned and not continued, b) the patent expires or irrevocably lapses, or c) the claim has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
- 6.07 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- 6.08 On sales of **Licensed Products** by **Licensee** to sublicensees or on sales made in other than an arm's-length transaction, the value of the **Net Sales** attributed under this Article 6 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.
- 6.09 Within thirty (30) days of the earliest to occur of 1) the second anniversary of the effective date of this **Agreement**; 2) upon completion of the first round of financing in which a total of Five (5) million U.S. Dollars in equity investment is received by **Licensee**; or 3) the completion of a sublicensing agreement in the **Exclusive Licensed Territory**, **Licensee** will be obligated to pay **PHS** patent costs accumulated by them as follows: a) costs associated with the preparation, filing, prosecution, and maintenance of the PRV and PCT applications and **Licensed Patent Rights** in the **Non-Exclusive Licensed Territory** listed in Appendix A, said expenses being those incurred by **PHS** prior to the time that payment by **Licensee** under this Paragraph 6.09 is obligated and said expenses to be divided by the greater of 1) four (4), or 2) the number of relevant commercialization licenses of record as of the time payment is obligated; and b) one hundred percent (100%) of costs associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** listed in Appendix A in the **Exclusive Licensed Territory**.
- 6.10 With regard to expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** in the **Licensed Territories** incurred by **PHS** on or after the date on which expenses under Paragraph 6.09 become due, **PHS**, at its sole option, may require **Licensee**:
- a) to pay **PHS** on an annual basis, within sixty (60) days of **PHS's** submission of a statement and request for payment, a royalty amount equivalent to all such patent expenses incurred during the previous calendar year(s), said expenses to be calculated in the same way as in Paragraph 6.09; or
- b) to pay such expenses directly to the law firm employed by **PHS** to handle such functions, said expenses to be calculated in the same way as in Paragraph 6.09. However, in such event, **PHS** and not **Licensee** shall be the client of such law firm.
- 6.11 **Licensee** may elect to surrender its rights in any country of the **Licensed Territories** under any **Licensed Patent Rights** upon ninety (90) days written notice to **PHS** and owe no payment obligation under Paragraph 6.10 for patent-related expenses incurred in that country after ninety (90) days of the effective date of such written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

- 7.01 Except as otherwise provided in this Article 7, **PHS** agrees to take responsibility for, but to consult with, the **Licensee** in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**, shall furnish copies of relevant patent-related documents to **Licensee**, and shall provide **Licensee** sufficient opportunity to comment on any document that **PHS** intends to file or to cause to be filed with the relevant intellectual property or patent office; **Licensee's** comments shall be considered in good faith and suggestions not to be unreasonably

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- refused. Regarding **Licensed Patent Rights** in the **Non-Exclusive Licensed Territory**, **PHS** shall also consult with **Licensee** in the choice of countries in which protection shall be sought, giving good faith consideration to concerns of cost and efficiency.
- 7.02 Upon **PHS's** written request, **Licensee** shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** in the **Exclusive Licensed Territory** and shall on an ongoing basis promptly furnish copies of all patent-related documents to **PHS**. In such event, **Licensee** shall, subject to the prior approval of **PHS**, select

registered patent attorneys or patent agents to provide such services on behalf of **Licensee** and **PHS**. **PHS** shall provide appropriate powers of attorney and other documents necessary to undertake such actions to the patent attorneys or patent agents providing such services.

Licensee and its attorneys or agents shall consult with **PHS** in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Licensed Patent Rights** in the **Exclusive Licensed Territory** and shall provide **PHS** sufficient opportunity to comment on any document that **Licensee** intends to file or to cause to be filed with the relevant intellectual property or patent office. **PHS's** comments shall be considered in good faith and suggestions not to be unreasonably refused.

- 7.03 At any time, **PHS** may provide **Licensee** with written notice that **PHS** wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** in the **Exclusive Licensed Territory**. If **PHS** elects to assume such responsibilities, **Licensee** agrees to cooperate fully with **PHS**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights** in the **Exclusive Licensed Territory** and to provide **PHS** with complete copies of any and all documents or other materials that **PHS** deems necessary to undertake such responsibilities. **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of **PHS's** choice.
- 7.04 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

- 8.01 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. Such records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection at the expense of **PHS** by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and payments hereunder; any such inspection/audit to be on reasonable notice and not to occur more than once per year. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of seven and one half percent (7.5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported

10

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

royalties, including any late charges as required by Paragraph 9.08 of this **Agreement**. All payments required under this Paragraph shall be due within thirty (30) days of the date **PHS** provides **Licensee** notice of the payment due.

- 8.02 **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every five (5) years if annual sales of the **Licensed Products** or **Licensed Processes** are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalty funds owed to the **Government** under this **Agreement**, and whether the royalty amount owed has been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

- 9.01 Prior to signing this **Agreement**, **Licensee** has provided to **PHS** the **Commercial Development Plan** at Appendix F, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** and/or **Biological Materials** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix E.
- 9.02 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee's** public service activities that relate to the **Licensed Patent Rights** and/or **Biological Materials**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for such differences. In any such annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee's** performance under this **Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written consent by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if such request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 CFR 404.3(d). **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **PHS** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.
- 9.03 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix E and the **First Commercial Sale** in each country in the **Licensed Territories** within thirty (30) days of such occurrences.

11

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- 9.04 **Licensee** shall submit to **PHS** within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territories**, the **Net Sales**, and the amount of royalty accordingly due. With each such royalty report, **Licensee** shall submit payment of the earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.10 to determine **Net Sales** made under Article 6 to determine royalties due.
- 9.05 **Licensee** agrees to forward semi-annually to **PHS** a copy of such reports received by **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to **PHS** by **Licensee** for activities under the sublicense.
- 9.06 Royalties due under Article 6 shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in The Wall Street Journal on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable, as appropriate, to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, P.O. Box 360120, Pittsburgh, PA 152516120. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.04 of this **Agreement** shall accompany each such payment, and a copy of such report shall also be mailed to **PHS** at its address for notices indicated on the Signature Page of this **Agreement**.
- 9.07 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay any such tax (deducting same from the total of royalties due) and be responsible for all filings, including tax exemption certificates for **PHS** (**PHS** to provide reasonable information and cooperation in obtaining such certificates), with appropriate agencies of foreign governments.
- 9.08 Interest and penalties may be assessed by **PHS** on any overdue payments in accordance with the Federal Debt Collection Act. The payment of such late charges shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.09 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of such records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. § 552 shall be subject to the pre-disclosure notification requirements of 45 CFR § 5.65(d).
10. PERFORMANCE
- 10.01 **Licensee** shall use its reasonable best efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable best efforts" for the purposes of this provision shall be determined by reference to the **Commercial**

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

Development Plan at Appendix F and performance of the **Benchmarks** at Appendix E. The efforts of a sublicensee shall be considered the efforts of **Licensee**.

- 10.02 Upon the **First Commercial Sale**, until the expiration of this **Agreement**, **Licensee** shall use its reasonable best efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

11. INFRINGEMENT AND PATENT ENFORCEMENT

- 11.01 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights** in the **Exclusive Licensed Territory**, as well as any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** in the **Exclusive Licensed Territory** of which either Party becomes aware.
- 11.02 Pursuant to this **Agreement** and the provisions of Chapter 29 of title 35, United States Code, **Licensee** may: a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the **Licensed Patent Rights** in the **Exclusive Licensed Territory**; b) in any such suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for infringement of the **Licensed Patent Rights** in the **Exclusive Licensed Territory** provided, however, that **PHS** and appropriate **Government** authorities shall also have the right to take such actions as set out herein: **Licensee** shall have the first right to initiate such suit, but in advance of initiating the suit shall notify **PHS** in writing of its intent, and consult with **PHS** and provide information to **PHS** relating to the suit. During **Licensee's** management of any such suit, it shall keep **PHS** informed regarding the progress of such suit and shall cooperate in good faith with **PHS** to address issues regarding the protection of **PHS** rights under this **Agreement** and in the **Licensed Patent Rights**, or to address any other concern regarding any **Government** interest in the action.

If **Licensee** elects not to initiate a suit or engage in settlement discussions with an infringer within a reasonable period after a written request by **PHS** to do so, then **PHS** shall have the right to initiate such action. **PHS** and **Licensee** shall have a continuing right to join in any suit by the other party. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such suit for patent infringement. **Licensee** may request the **Government** to initiate or join in any such suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any such suit, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action, including any and all costs incurred by the **Government** in opposing any such motion or other action. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHB** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

- 11.03 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** in the **Exclusive Licensed Territory** shall be brought against **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by **Licensee** under Paragraph 11.02, pursuant to this **Agreement** and the provisions of Chapter 29 of Title 35, United States Code or other

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

statutes, **Licensee** may: a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the **Licensed Patent Rights** in the **Exclusive Licensed Territory**; b) in any such suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights** in the **Exclusive Licensed Territory**-provided, however, that **PHS** and appropriate **Government** authorities shall also have the right to take such actions and shall have a continuing right to join in such suit according to the procedures set out in Paragraph 11.02. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any such declaratory judgment action. **Licensee** may request the **Government** to initiate or to join any such suit if necessary to avoid dismissal of the suit, which request shall not be unreasonably denied. Should the **Government** be made a party to any such suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of such motion or other action. If **Licensee** elects not to defend against such declaratory judgment action, **PHS**, at its option, may do so at its own expense. In all cases, **Licensee** agrees to keep **PHS** reasonably apprised of the status and progress of any litigation. Before **Licensee** commences an infringement action, **Licensee** shall notify **PHS** and give careful consideration to the views of **PHS** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.04 In any action under Paragraphs 11.02 or 11.03:

- a) If brought by **Licensee**, the expenses including costs, fees, attorney fees and disbursements, shall be paid by **Licensee**. If brought by **PHS**, the expenses including costs, fees, attorney fees and disbursements shall be paid by **PHS**. After reduction by the amount of all expenses including costs, fees, attorney fees and disbursements paid by the initiating party, the remaining value of any recovery made by either party through court judgment or settlement shall be treated as **Net Sales**, with appropriate earned royalties thereon deducted and paid to **PHS**, and the remainder paid to **Licensee**;
- b) Any party electing to join, follow or otherwise participate in any such action shall bear its own expenses, including costs, fees, attorney fees and disbursements (except that **Licensee** shall pay the **Government’s** expenses in the event that **Licensee** requests the **Government** to initiate or to join any such suit if necessary to avoid dismissal of the suit).

11.05 **PHS** shall cooperate fully with **Licensee** in connection with any action under Paragraphs 11.02 or 11.03. **PHS** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by **Licensee**.

11.06 With respect to **Licensed Patent Rights** in the **Non-Exclusive Licensed Territory**, **Licensee** and **PHS** shall notify each other if an infringement as in Paragraph 11.02 or a declaratory judgment as in Paragraph 11.03 has occurred and shall consult with each other and, if possible, with other licensees as to the appropriate course of action.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.01 **PHS** offers no warranties other than those specified in Article 1.

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

12.02 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.03 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.04 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.05 **Licensee** shall indemnify and hold **PHS**, Wyeth and its affiliates, and their respective employees, students, fellows, agents, consultants, officers and directors harmless from and against all liability, demands, damages, deficiencies, judgements, assessments, costs, or expenses, including reasonable attorneys’ fees and costs of investigating and defending against lawsuits, complaints, actions, or other pending or threatened litigation, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of: a) the use by or on behalf of **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights** or documentation, information and materials, know-how, or the rights granted, transferred, or assigned to **PHS** by **Wyeth** under license agreements L-030-1987/1 and L-008-1989/1 as they relate to this **Agreement**; or b) the design, manufacture, distribution, use, or sale of any **Licensed Products**, **Licensed Processes** or **Biological Materials** by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights** or **Biological Materials**.

Prior to commencement of human clinical trials by **Licensee**, **Licensee** agrees to obtain and maintain a liability insurance program consistent with sound business practice, including commercial general liability and product liability insurance for **Licensed Products** utilizing documentation, information and materials, know-how, or the rights granted, transferred, or assigned to **PHS** by **Wyeth** under license agreements L-030-1987/1 and L-008-1989/1 as they relate to this **Agreement**, naming **PHS** and **Wyeth** and its affiliates, and their respective employees, students, fellows, agents, consultants, officers and directors as insured parties, sufficient to adequately provide such indemnification. **Wyeth** shall be given the right to enforce the indemnification and insurance rights and shall be named as a third party

beneficiary to this agreement for such purpose. **PHS** disclaims any and all liability for the failure of **Licensee**, its sublicensees or assigns or any other party to satisfy their obligation to **Wyeth**. However, in the event of any failure of any such party to indemnify or provide or maintain insurance, in addition to any other remedies it may have against such party, **Wyeth** retains its rights to terminate the licenses granted to **PHS** in license agreements L-030-1987/1 and L-008-1989/1 as they relate to this **Agreement**.

- 12.06 **Licensee's** acceptance of this **Agreement** shall not be deemed an admission by **Licensee** of the novelty or patentability of the **Licensed Patent Rights**.
- 12.07 Any materials provided by **Licensee** to **PHS** hereunder are provided for research purposes only and ARE NOT FOR USE IN HUMANS. **Licensee** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR

15

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

FITNESS FOR A PARTICULAR PURPOSE OF ANY MATERIALS PROVIDED TO **PHS** HEREUNDER.

- 12.08 **Licensee** does not represent that it will commence legal actions against third parties infringing the **Licensed Patent Rights**.
13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS
- 13.01 This **Agreement** is effective when signed by all parties and shall extend on a country-by-country basis until the later of (a) the expiration of all royalty obligations under **Licensed Patent Rights** where such rights exist or have existed or (b) eight (8) years from **First Commercial Sale** where such rights have ceased to exist or never existed unless terminated as provided in this Article 13 or by mutual agreement of **PHS** and **Licensee**. Upon expiration pursuant to this Paragraph 13.01, **Licensee** shall have a royalty-free, paid up, non-transferrable perpetual license to the **Biological Materials** transferred hereunder in the **Licensed Territories** and all derivatives and products made by **Licensee** therefrom.
- 13.02 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.05, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding amounts owed through procedures provided by the Federal Debt Collection Act.
- 13.03 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon written notice to **Licensee**, given the understanding that **PHS** shall first endeavor in good faith to assist **Licensee** in any efforts to emerge from bankruptcy by maintaining the present **License** in effect for a reasonable period of time not to exceed one (1) year from **Licensee's** receipt of written notice, unless otherwise deemed necessary to address an immediate public health need.
- 13.04 **Licensee** shall have a unilateral right to terminate this **Agreement** and/or any licenses in any country or territory by giving **PHS** sixty (60) days written notice to that effect.
- 13.05 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**: 1) is not executing the **Commercial Development Plan** consistent with the requirement of Paragraph 10.01 and the **Licensee** cannot otherwise demonstrate to **PHS's** reasonable satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**; 2) has not achieved the **Benchmarks** as may be modified under Paragraph 9.02, and the **Licensee** cannot otherwise demonstrate to **PHS's** reasonable satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to correct the failure to achieve the relevant **Benchmark** in order to achieve the relevant **Benchmark** within the earliest reasonably possible time; 3) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license **Agreement**; 4) has committed a material breach of a covenant or agreement

16

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

contained in the license; 5) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences; 6) cannot reasonably satisfy unmet health and safety needs; or 7) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.02 unless waived. In making this determination, **PHS** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.02. Prior to invoking this right, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS's** concerns as to the previous items 1) to 7). If **Licensee** fails to alleviate **PHS's** concerns as to the previous items 1) to 7) or fails to initiate corrective action to **PHS's** satisfaction, **PHS** may terminate or modify this **Agreement**.

- 13.06 When the public health and safety so require, and after written notice to **Licensee** providing **Licensee** a sixty (60) day opportunity to respond, **PHS** shall have the right to require **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights** in the **Exclusive Licensed Territory**, unless **Licensee** can reasonably demonstrate that the granting of the sublicense would not materially increase the availability to the public of the subject matter of the **Licensed Patent Rights** in the **Exclusive Licensed Territory**. **PHS** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with **Licensee**.

- 13.07 **PHS** reserves the right according to 35 U.S.C. § 209(0(4) to terminate or modify this **Agreement** if it is determined that such action is necessary to meet requirements for public use specified by federal regulations issued after the date of the license and such requirements are not reasonably satisfied by **Licensee**.
- 13.08 Within thirty (30) days of receipt of written notice of **PHS's** unilateral decision to modify or terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 CFR 404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.09 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **PHS** pursuant to Paragraph 4.03. Unless otherwise specifically provided for under this **Agreement**, upon any termination of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** in its possession to **PHS** or provide **PHS** with certification of the destruction thereof.

14. GENERAL PROVISIONS

- 14.01 Neither Party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of

17

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

that right by the **Government** or excuse a similar subsequent failure to perform any such term or condition by **Licensee**.

- 14.02 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights** and **Biological Materials**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.
- 14.03 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.04 If either Party desires a modification to this **Agreement**, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.05 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.
- 14.06 All notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party. Notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 14.07 This **Agreement** shall not be assigned by **Licensee** except: a) with the prior written consent of **PHS**, such consent not to be withheld unreasonably; or b) as part of a sale or transfer of substantially the entire business of **Licensee** relating to operations which concern this **Agreement**. **Licensee** shall notify **PHS** within ten (10) days of any assignment of this **Agreement** by **Licensee**, and **Licensee** shall pay **PHS**, as an additional royalty, [***] of the fair market value of any consideration received for any assignment of this **Agreement** within thirty (30) days of such assignment.
- 14.08 **Licensee** agrees in its use of **Biological Materials** and any other **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **DHHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the

18

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

- 14.09 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant Agency of the U.S.

Government or written assurances by **Licensee** that it shall not export such items to certain foreign countries without prior approval of such agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

- 14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve **PHS** patent rights in such countries.
- 14.11 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the Government, **PHS**, any other Government organizational unit, or any **Government** employee. Additionally, Licensee shall not use the names of **NIH**, **CDC**, **PHS**, or **DHHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written consent of **PHS**.
- 14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any such unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.
- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Paragraphs 4.03, 8.01, 9.05-9.07, 12.01-12.05, 13.08, 13.09, and 14.12 and the indicated section of Appendix C of this **Agreement** shall survive termination of this **Agreement**.

SIGNATURES BEGIN ON NEXT PAGE

19

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

PHS PATENT LICENSE AGREEMENT—EXCLUSIVE

SIGNATURE PAGE

For **PHS**:

/s/ Steven M. Ferguson

Steven M. Ferguson
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices:

Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by: /s/ Eric Patzer

Signature of Authorized Official

Eric Patzer, Ph.D.

Printed Name

President

Title

Official and Mailing Address for Notices:

Aridis Pharmaceuticals, LLC

350 Cervantes Road

Portola Valley, CA 94028

USA

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

APPENDIX A—Patent(s) or Patent Application(s)

Patent(s) or Patent Application(s):

DHHS Technology Reference E-015-1998/0

| <u>Country</u> | <u>Serial Number</u> | <u>Filing Date</u> | <u>DHHS ref</u> |
|----------------|----------------------|--------------------|---------------------|
| USA | 60/094,425 | 07/28/1998 | E-015-1998/0-US-01 |
| PCT | PCT/US99/17036 | 07/27/1999 | E-015-1998/0-PCT-02 |
| CA | 2336875 | 07/27/1999 | E-015-1998/0-CA-07 |
| EP | 99938819.2 | 07/27/1999 | E-015-1998/0-EP-08 |
| USA | 09/743,338 | 01/04/2001 | E-015-1998/0-US-10 |
| JP | 2000-562050 | 07/27/1999 | E-015-1998/0-JP-09 |
| KR | 7001236/2001 | 07/27/1999 | E-015-1998/0-KR-05 |
| AU | 5322199 | 07/27/1999 | E-015-1998/0-AU-06 |

Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

APPENDIX B—Licensed Fields of Use and Territory and Biological Materials and Documentation

Licensed Fields of Use:

Human Rotavirus Vaccine based on Human-Bovine Rotavirus Reassortants

Exclusive Licensed Territory:

Europe, Canada and United States of America

Non-Exclusive Licensed Territory:

Worldwide excluding Europe, Canada, United States of America, India, Brazil, and China

For the sake of clarification, the Non-Exclusive Licensed Territory includes (without limitation) Australia, Japan, and South Korea, where patents and patent applications under Licensed Patent Rights have been filed or issued.

Biological Materials:

Rotaviruses:

- (1) Preseed BRota-HP-PSOI, Type ST3 (1 container with 15 ml of virus suspension)
- (2) Preseed BRota-HD-PS03, Type ST1 (1 container with 15 ml of virus suspension)
- (3) Preseed BRota-HDS I -PS03, Type ST2 (1 container with 15 ml of virus suspension)
- (4) Preseed BRota-ST3-PS02, Type ST4 (1 container with 15ml of virus suspension)

PHS and Licensee acknowledge that **Licensee** requests, for the following human-bovine reassortant strains (or strains derived therefrom), a sample of the Preseed, Master virus seed (FRhL2 cell adapted) and Master virus seed (Vero cell adapted). These samples will be provided by **PHS** and included under this **Agreement**, pending reasonable review by **PHS** for each to establish that **PHS** has legal access to the materials and the right to include same under this **Agreement**:

- | | |
|---|--------------|
| (1) HD x BRV-1, clone 47-1-1 (VP7:1 [D]) | ATCC VR-2617 |
| (2) HDS1 x BRV-1, clone 66-1-1 (VP7:2 [DS-1]) | ATCC VR-2616 |
| (3) HP x BRV-2, clone 22-1-1 (VP7:3 [P]) | ATCC VR-2611 |
| (4) HST3 x BRV-2, clone 52-1-1 (VP7:4 [ST3]) | ATCC VR-2612 |
| (5) IAL28 x UK, clone 33-1-1 (VP7:5 [IAL28]) | ATCC VR-2613 |
| (6) AU32 x UK, clone 27-1-1 (VP7:9 [AU32]) | ATCC VR-2614 |
| (7) KC-1 x UK, clone 32-1-1 (VP7:10 [KC-1]) | ATCC VR-2615 |

Antibodies:

- (1) Lot W1A1-anti IgG2a (serotype 1) [5 ml (5 vials x 1m1) of monoclonal antibody preparation]]
- (2) Lot 1C10A-anti IgA(serotype 2) [5 ml (5 vials x 1m1) of monoclonal antibody preparation]]
- (3) Lot RIA-anti IgG2b (Serotype 3) [5 ml (5 vials x 1m1) of monoclonal antibody preparation]]

- (4) Lot S4A- anti IgG1 (Serotype 4) [5 ml (5 vials x 1ml) of monoclonal antibody preparation]
(5) Rabbit Polyclonal Antisera [10 ml (1 tube x 10 ml) of sera]

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

Documentation:

BB-IND 7219: Human Bovine Reassortant Rotavirus (Book 1: Ser 000-008 (7/3/97-9/28/00))
BB - IND 8415
BB - IND — 7928

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

APPENDIX C—Royalties

ROYALTIES:

Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty in the amount of [***] as follows:

- [***] due three (3) months after effective date of this **Agreement**
- [***] due two (2) years after the effective date of this **Agreement**.
- [***] at the first to occur of:
 - 1) raising a cumulative [***] in financing, whether from individuals, venture capital, or through the formation of partnership/sublicensing, where such payment is due within thirty (30) days of this event; or
 - 2) a firmly underwritten initial public offering and sale of Licensee's Common Stock pursuant to an effective registration statement under the Securities Act of 1933, as amended, where such payment is due within sixty (60) days of this event. This clause shall survive termination or expiration of this Agreement.

Licensee agrees to pay to PHS a nonrefundable minimum annual royalty in the amount of:

- [***] for years one through three (1-3)
- [***] for years four (4) through the year in which the First **Commercial Sale** occurs
- [***] after the year in which the First Commercial Sale occurs through the remainder of this **Agreement**.

Minimum annual royalties shall be creditable as provided in Paragraph 6.02 of this Agreement.

Licensee agrees to pay PHS earned royalties on Net Sales by or on behalf of Licensee and its sublicensees as follows:

- [***] in the **Exclusive Licensed Territory** where **Licensed Patent Rights** exist
- [***] in the **Non-Exclusive Licensed Territory** where **Licensed Patent Rights** exist
- [***] in the **Exclusive Licensed Territory** where no **Licensed Patent Rights** exist
- [***] in the **Non-Exclusive Licensed Territory** where no **Licensed Patent Rights** exist

The above earned royalties shall be reduced, on a **Licensed Product-by-Licensed Product**, country-by-country, and year-to-year basis by [***] for every [***] paid as royalties for third party licenses required to sell **Licensed Product** or **Licensed Process** where said royalties for the third party license exceed [***] and provided that such reduction in earned royalties owed to PHS shall never be reduced below [***] of the earned royalties rates specified above.

Licensee agrees to pay PHS benchmark royalties within ninety (90) days after accomplishment of the following **Benchmarks**, whether achieved by Licensee or sublicensee:

- [***]— upon completion of Phase 11 clinical trials necessary for the first complete regulatory license application for a **Licensed Product**.
- [***]— upon commencement of a Phase 111 clinical trial for the evaluation of safety of a **Licensed Product**;

*Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- [***]— upon completion of the Phase 111 clinical trials necessary for the first complete regulatory license application for a **Licensed Product**.
- [***]— upon launch of the first **Licensed Product**.

Licensee agrees to pay PHS additional sublicensing royalties as follows:

[***] of the fair market value of any consideration received for granting each sublicense, excluding earned royalties received for **Net Sales of Licensed Products**, for which the earned royalties noted above shall accrue.

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

APPENDIX D—Modifications

PHS and **Licensee** agree to the following modifications to the Articles and Paragraphs of this **Agreement**:

Modifications made to the model language have been incorporated into the body of this **Agreement**.

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

APPENDIX E—Benchmarks and Performance

Licensee agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

- IND filing: January 2009.
- Phase I clinical trial completion: November 2010.
- Phase II clinical trial completion: November 2012.
- Phase III clinical trial completion: May 2016.
- Biological License Application (BLA) submission: May 2017.
- BLA approval: November 2018.
- **First Commercial Sale**: January 2019.

For the sake of clarification, the above benchmarks can be modified from time to time per Paragraph 9.02 in the **Agreement**.

- Developing world access

Within six (6) months of NDA/BLA equivalent approval in any **Licensed Territory**, **Licensee** shall send a written report to **PHS** detailing the potential **Public Sector** market to fulfill the public health need for the approved **Licensed Product** in **Developing Countries**, including the impact of any approved competing **Licensed Product**. The report shall also include **Licensee’s** amendment to the **Commercial Development Plan**, Appendix F, to satisfy said potential **Public Sector** market either directly with **Licensee’s** own resources and/or through joint ventures with third parties. Acceptance of this report and amendment is required by **PHS** in writing, such acceptance will not be unreasonably denied.

Licensee agrees:

- a) To the extent that **Licensee** shall satisfy the potential **Public Sector** market through its own resources, and provided there is a commercially reasonable market therefore, **Licensee** shall make commercially reasonable efforts to deliver the first allotment of a safe and effective **Licensed Product** to the **Public Sector** for distribution and/or sale in **Developing Countries** within two (2) years of **First Commercial Sale** and thereafter **Licensee** agrees to use commercially reasonable efforts to meet any delivery date and in the quantities required in an order placed by the **Public Sector**.
- b) To the extent that **Licensee** shall satisfy the potential **Public Sector** market through joint ventures with third parties, **Licensee** shall:
 - (i) Within one (1) year after **First Commercial Sale**, make commercially reasonable efforts to negotiate with third parties in order to effect joint ventures or other partnership agreements to make and sell the **Licensed Products** and **Licensed Processes** and (or to assist in development of similar third party licensed products or processes made under license directly between the third party and **PHS** for the technology covered by the **Agreement** [hereinafter “Third Party Products”]) to provide know-how and effect technology transfer to said third parties that will allow them to manufacture a safe and effective **Licensed Product** (or Third Party Products) for distribution and/or sale in **Developing Countries**.

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

- (ii) Within two (2) years of **First Commercial Sale**, and provided there is a commercially reasonable market therefore, make commercially reasonable efforts to have entered into at least one (1) joint venture or other partnership agreement with at least one (1) third party for the purpose of manufacturing a safe and effective **Licensed Product** or Third Party Product for distribution and/or sale in **Developing Countries**.
- (iii) Subject to (ii) above, Within four (4) years of **First Commercial Sale**, ensure that any said third party(ies) have made commercially reasonable efforts to have delivered a first allotment of a safe and effective **Licensed Product** or Third Party Product

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

APPENDIX F—Commercial Development Plan

Background

This project will use the four monovalent human-bovine UK reassortant rotavirus strains designated D x UK (VP 7 serotype 1), DS-1 x UK (VP 7 serotype 2), P x UK (VP 7 serotype 3) and ST3 x UK (VP 7 serotype 4) previously tested in clinical trials that established the safety and immunogenicity of the orally administered quadrivalent mixture.

Proof of Concept Studies

This previous quadrivalent vaccine was a mixture of four serotype-specific human-bovine reassortants, which were individually produced in DBS FRhL2 cells at titers ranging from 1053 to 1058 pfu/mL, and then stored frozen. The four reassortants were thawed and combined immediately prior to administration. A Vero cell manufacturing process was developed by Wyeth, which represents an attractive alternative cell substrate with significant manufacturing advantages (titers ranging from 1075 to 108° pfu/mL). Proof of concept studies will be performed with Vero cell produced material, which will continue into development, unless deficiencies in this material compared to the previously tested DBS FRhL2 cell material are identified.

In the initial proof of concept testing, we will prepare bulk vaccine in 1-10L microcarrier cultures of Vero cells based on a process developed by Wyeth using human-bovine reassortants. Formulations, drying processes and milling conditions will be screened to generate dried powders with each individual strain, which will be subsequently tested for stability. Once satisfactory results are obtained with each individual reassortant, the stability of the combined quadrivalent mixture will be verified.

From the studies by Wyeth with Rotashield®, it is known that about 90 mg of buffer (sodium bicarbonate and citric acid) is required in the final formulation to allow rotavirus to survive the acid environment of the stomach and transit to its final destination in the upper small intestine. Similar amounts of buffer will be incorporated into the dried powder and then the powder will be fabricated into a quick dissolving tablet using standard powder mixing and tableting processes.

Preclinical Testing

Animal models that can provide relevant data with bovine rotavirus strains are restricted to a murine model with a limited ability to predict human safety and immunogenicity. Additionally, the quadrivalent human-bovine reassortant vaccine already has been tested in humans. Consequently, we do not anticipate that significant animal testing of the stabilized quadrivalent vaccine will be required prior to clinical testing. We will perform extensive stability testing to demonstrate that the infectivity of the rotavirus vaccine doesn’t change during storage. In addition, a battery of in vitro tests will be performed to demonstrate product purity, safety, identity and consistency of manufacture and that the key physical, chemical and immunological characteristics of the rotavirus strains are comparable to the previously tested strains.

Clinical Testing

The clinical program of the stabilized vaccine will exploit the prior human safety, immunogenicity and dose ranging data with individual monovalent reassortants and combined quadrivalent vaccine. The initial phase 1 study will compare the safety of a single dose of the stabilized quadrivalent vaccine in 10 adults to the previous formulation of quadrivalent vaccine in 10 adults. If the vaccines have similar safety profiles, we will proceed to phase 2 clinical testing of a single dose of stabilized quadrivalent vaccine in

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

10 young children (2-5 years) followed by testing of two doses of the stabilized quadrivalent vaccine administered to 200 young infants at 2 and 4 months of age for safety and immunogenicity (ELISA IgG and IgA and plaque reduction neutralization). The progression from adults to children and then infants will necessarily require close coordination and careful review of safety data with the FDA.

It is estimated that preclinical and phase 1 and 2 clinical testing can be completed within 7.5 years.

If the immunogenicity or reactogenicity profile of the reassortants in the stabilized vaccine are not the same as the previously tested vaccine, then subsequent phase 2 testing will include dose ranging (starting at lower doses) to define the dose of the reassortants in the stabilized vaccine that exhibits similar levels of reactogenicity and immunogenicity (5). These studies may require an additional 6-12 months to complete.

The phase 3 trial in 1,000 infants will be designed to obtain efficacy data in one rotavirus season; however, the trial will be extended for more than one year to gather data on the persistence of protection during subsequent rotavirus seasons. To obtain sufficient clinical safety data for regulatory approval, a large-scale safety trial (up to 60,000 subjects) is planned that will require —2.5 years to complete.

During phase 3 clinical testing a bridging/consistency trial in 1,000 infants has been included to allow a transfer from a clinical pilot plant to a commercial manufacturing facility or a technical transfer to a partner’s manufacturing facility. This trial will be completed concurrently with the other phase 3 clinical studies. The table below lists the major phases of development and the time for each phase. Total time for product development from project initiation to first commercial sale is estimated to require about 13.7 years.

Market and Competition: There are two competitors (Merck and GSK) developing rotavirus vaccines. The Aridis vaccine will be competitively superior to both, because no refrigeration will be required and administration will be as a 2 dose quick dissolving wafer assuring full dose receipt. Both competitor vaccines require refrigeration, administration as a liquid (with inherent inconsistencies in dosing), and either a 3-dose regimen or lengthy mixing procedures. We will identify an established marketing partner, who in combination with a superior product will allow us to capture a large share of the rotavirus vaccine market.

Project Timelines for Quadrivalent Vaccine:

| Project Phase | Years |
|--|-------|
| 1. Preclinical development (culminating in IND filing) | 3.7 |
| 2. Phase 1 clinical (safety) | 1.8 |
| 3. Phase 2 clinical in children & infants (safety & immunogenicity) | 2.0 |
| 4. Phase 3 clinical development (efficacy, expanded safety, mfg consistency, bridging) | 3.5 |
| 5. File BLA | 1.0 |
| 6. Regulatory review & approval | 1.5 |
| 7. First commercial sale | 0.2 |
| Total Time | 13.7 |

*Portions of this Exhibit, indicated by the mark “[***],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended*

APPENDIX G—Developing Countries

For the purpose of this Agreement, Developing Country will include the following countries:

- 1 Afghanistan
- 2 Albania
- 3 Angola
- 4 Armenia
- 5 Azerbaijan
- 6 Bangladesh
- 7 Benin
- 8 Bhutan
- 9 Bolivia
- 10 Bosnia & Herzegov
- 11 Burkina Faso
- 12 Burundi
- 13 Cambodia
- 14 Cameroon
- 15 Central Afr Rep
- 16 Chad
- 17 Comoros
- 18 Congo, Dem Rep
- 19 Congo, Rep
- 20 Cote d’Ivoire
- 21 Cuba
- 22 Djibouti
- 23 Eritrea
- 24 Ethiopia
- 25 Gambia
- 26 Georgia
- 27 Ghana
- 28 Guinea
- 29 Guinea-Bissau
- 30 Guyana
- 31 Haiti
- 32 Honduras
- 33 Indonesia
- 34 Kenya
- 35 Korea, DPR
- 36 Kyrgyz Republic
- 37 Lao PDR
- 38 Lesotho
- 39 Liberia
- 40 Madagascar
- 41 Malawi
- 42 Mali
- 43 Mauritania
- 44 Moldova
- 45 Mongolia
- 46 Mozambique
- 47 Myanmar
- 48 Nepal

