

**PUBLIC HEALTH SERVICE**

**COMMERCIAL EVALUATION LICENSE AGREEMENT**

This **Agreement** is entered into between 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**") through the Office of Technology Transfer, National Institutes of Health, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and \_\_\_\_\_ ("**Licensee**"), a corporation of \_\_\_\_\_, having an office at \_\_\_\_\_.

1. Definitions:

- a. "**Licensed Patent Rights**" means PCT or U.S. patent application(s) (including provisional patent application(s)) and/or patents and all foreign counterparts as follows: U.S. Patent Application Serial No./U.S. Provisional Patent Application Serial No. \_\_\_\_/\_\_\_\_,\_\_\_\_, filed \_\_\_\_\_, entitled \_\_\_\_\_.
- b. "**Materials**" means \_\_\_\_\_, including any progeny, subclones, or derivatives thereof.
- c. "**Licensed Products**" means \_\_\_\_\_.

- 2. **Licensee** wishes to obtain a license to evaluate the commercial applications of the **Licensed Products** and any inventions claimed in the **Licensed Patent Rights**.
- 3. **Licensee** intends to conduct laboratory experiments under this **Agreement** to evaluate the suitability for commercial development of inventions encompassed by the **Licensed Patent Rights** and the **Licensed Products** in the **Field(s) of Use** of \_\_\_\_\_.
- 4. **Licensee** represents that it has the facilities, personnel, and expertise to evaluate the commercial applications of the **Licensed Products** and the inventions encompassed by the **Licensed Patent Rights**, and that it will expend reasonable efforts and resources on research and development of potential commercial products using the **Licensed Products** and the inventions encompassed by the **Licensed Patent Rights**.
- 5. **PHS** hereby grants to **Licensee** a nonexclusive license for evaluation purposes to make and use *but not to sell* the **Licensed Products** and products and processes encompassed within the scope of a claim in the **Licensed Patent Rights**. **Licensee** agrees that any commercial or industrial use or sale of any such products or processes, including any formalized in-house screening programs, other than for evaluation purposes, will be made only pursuant to the terms of a commercialization license to be negotiated in good faith by the parties. The rights provided herein are provided for the *evaluation of commercial applications only and not for commercial use*.
- 6. **PHS** agrees, after receipt of the payment required by Paragraph 9, to provide **Licensee** with samples of the **Materials** excluding progeny, subclones, and derivatives thereof ("**Supplied Materials**"), as available, and to replace such **Supplied Materials**, as available and at reasonable cost, in the event of their unintentional destruction.

7. **Licensee** agrees to retain control over the **Licensed Products** and the **Materials**, and not to distribute them to third parties without the prior written consent of **PHS**.
8. **Licensee** agrees that this **Agreement** does not preclude **PHS** from distributing the **Materials** or **Licensed Products** to third parties for research or commercial purposes.
9. In consideration of the grant in Paragraph 5, **Licensee** hereby agrees to pay **PHS** a royalty in the sum of U.S. \$\_\_\_\_\_ (\_\_\_\_\_ Dollars). Payment is due within thirty (30) days of **Licensee's** execution of this **Agreement**. This royalty 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 15251-6120. 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**. 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.
10. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement** and shall expire \_\_\_\_\_ (\_\_\_\_) months from its effective date. Upon termination or expiration of this **Agreement**, **Licensee** shall return all **Materials** and **Licensed Products** to **PHS** or provide **PHS** with certification of their destruction, unless **Licensee** has executed a commercialization license for the **Licensed Patent Rights**.
11. In the event that **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice of such default, **PHS** may terminate this **Agreement** by written notice.
12. **Licensee** acknowledges that third parties also may be evaluating the **Licensed Patent Rights**, the **Licensed Products**, or the **Materials** for a variety of commercial purposes, and no guarantee can be made, should **Licensee** apply for a license, that such a license would be available for any particular field of use. **PHS** agrees to notify **Licensee** promptly if it receives from another company an exclusive license application in the **Field(s) of Use** described in Paragraph 3.
13. **Licensee** is encouraged to publish the results of its research projects using the **Licensed Products** or the **Materials**. In all oral presentations or written publications concerning the **Licensed Products** or the **Materials**, **Licensee** will acknowledge the contribution by the named inventors to the **Licensed Products** or the **Materials**, unless requested otherwise by **PHS** or the named inventors.
14. **Licensee** agrees to submit in confidence a final report to **PHS** within thirty (30) days of termination or expiration of this **Agreement** outlining in general its results of commercial evaluation of the **Licensed Patent Rights**, the **Licensed Products**, and the **Materials** provided by this **Agreement**.
15. **PHS** agrees, to the extent permitted by law, to treat in confidence for a period of three (3) years from the date of disclosure any of **Licensee's** written information about the **Licensed Patent Rights**, the **Licensed Products**, or the **Materials** that is stamped "CONFIDENTIAL" except for information that was previously known to **PHS**, or that is or becomes publicly available, or that is disclosed to **PHS** by a third party without an obligation of confidentiality.
16. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE FITNESS FOR ANY PURPOSE OF THE **MATERIALS** OR **LICENSED PRODUCTS** PROVIDED TO **LICENSEE** UNDER

THIS AGREEMENT, OR THAT THE **LICENSED PATENT RIGHTS** MAY BE EXPLOITED WITHOUT INFRINGING OTHER PATENT RIGHTS. **LICENSEE** accepts license rights to the **Licensed Patent Rights**, the **Licensed Products**, and the **Materials** "as is", and **PHS** does not offer any guarantee of any kind.

17. **Licensee** agrees to indemnify and hold harmless **PHS** and the Government of the United States of America from any claims, costs, damages, or losses that may arise from the practice of the **Licensed Patent Rights** or through the use of the **Licensed Products** or the **Materials**.
18. Neither party shall have any obligation to take any action with regard to an infringement of **Licensed Patent Rights** by a third party.
19. **Licensee** agrees in its use of any **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** or the **Licensed Products** 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** or **Licensed Products** 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 United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
20. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.
21. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Licensed Patent Rights**, the **Licensed Products**, and the **Materials**.
22. 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 invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
23. Paragraphs 13, 15, 16, and 17 of this **Agreement** shall survive termination of this **Agreement**.

**SIGNATURES BEGIN ON NEXT PAGE**

**PHS COMMERCIAL EVALUATION LICENSE AGREEMENT**

**SIGNATURE PAGE**

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

\_\_\_\_\_  
Jack Spiegel, Ph.D.  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

\_\_\_\_\_  
Date

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:

\_\_\_\_\_  
Signature of Authorized Official

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title

Official and Mailing Address for Notices:

\_\_\_\_\_  
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\_\_\_\_\_  
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).