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PUBLIC HEALTH SERVICE

COMMERCIAL EVALUATION LICENSE AGREEMENT

This **Agreement** is entered into between the National Institutes of Health (“**NIH**”) 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 (“**HHS**”) through the Office of Technology Transfer, **NIH**, 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)) or patents and all foreign counterparts as follows: U.S. Patent Application Serial No. XX/XXX,XXX or U.S. Provisional Patent Application Serial No. XX/XXX,XXX, filed _____, entitled _____.
- (b) “**Materials**” means _____, including all progeny, subclones, or unmodified derivatives thereof.
- (c) “**Licensed Products**” means _____ and **Materials** made by **Licensee** within the scope of the **Licensed Patent Rights**.
- (d) “**Licensed Field of Use**” means _____.

- 2. **Licensee** desires to obtain a license to evaluate the commercial applications of the **Materials** and 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, Materials** or **Licensed Products** in the **Licensed Field of Use**.
- 4. **Licensee** represents that it has the facilities, personnel, and expertise to evaluate the commercial applications of the **Materials** and the **Licensed Products** and the inventions encompassed by the **Licensed Patent Rights**, and that it shall expend reasonable efforts and resources on research and development of potential commercial products using the **Materials** or the **Licensed Products** and the inventions encompassed by the **Licensed Patent Rights**.
- 5. **PHS** hereby grants to **Licensee** a nonexclusive license for evaluation purposes only, within its research facilities, to make and use *but not to sell* the **Materials** or 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, shall 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*.

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6. **PHS** agrees, after receipt and verification of the license issue royalty, as required by Paragraph 9(a), to provide **Licensee** with samples of the **Materials**, as available, and to replace the **Materials**, as available, and at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** at **Licensee's** expense and as specified in Appendix A.
7. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS**.
8. 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:
 - (a) **Licensee** hereby agrees to pay **PHS** a license issue royalty of _____ dollars (\$X) and payment is due within sixty (60) days of the effective date of this **Agreement**.
 - (b) This license issue royalty shall be paid in U.S. dollars and payment options are listed in Appendix B. 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.
 - i) 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**; and
 - ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties 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**, unless the provisions of Paragraph 24 are not fulfilled, and shall expire _____ (X) months from its effective date. Within thirty (30) days of the termination or expiration of this **Agreement**, **Licensee** shall return all **Materials** and **Licensed Products** to **PHS** or provide **PHS** with written 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 the 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 **Licensed Field of Use** described in Paragraph 3.

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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** shall 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**, or the **Materials** provided by this **Agreement**. **Licensee** shall submit the report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page. **Licensee** may not be granted additional **PHS** licenses if this final reporting requirement is not fulfilled.
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**, 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 THE **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 **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** 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 C.F.R. Part 50](#) and [45 C.F.R. Part 46](#). **Licensee** agrees not to use the **Materials** or the **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 shall 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 **Materials** and the **Licensed Products**.

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PHS Commercial Evaluation License Agreement (CEL)
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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, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
23. Paragraphs 10, 13, 14, 15, 16, and 17 of this **Agreement** shall survive termination of this **Agreement**.
24. The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

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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**:

_____ **DRAFT** _____
Richard U. Rodriguez
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health
Date

Mailing Address or E-mail Address for **Agreement** notices and reports:

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

E-mail: LicenseNotices_Reports@mail.nih.gov

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:

_____ **DRAFT** _____
Signature of Authorized Official
Date

Printed Name

Title

I. Official and Mailing Address for **Agreement** notices:

Name

Title

Mailing Address

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Email Address: _____

Phone: _____

Fax: _____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

Name

Title

Mailing Address:

Email Address: _____

Phone: _____

Fax: _____

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).

APPENDIX B – ROYALTY PAYMENT OPTIONS

The OTT License Number **MUST** appear on payments, reports and correspondence.

Automated Clearing House (ACH) for payments through U.S. banks only

The NIH encourages our licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: **<https://www.pay.gov>**. Locate the "NIH Agency Form" through the Pay.gov "Agency List".

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender **MUST** supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	NIH 75080031 License Number (L-XXX-XXXX) Name of Licensee
Detail of Charges (line 71a):	Charge Our

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Checks

All checks should be made payable to “NIH Patent Licensing”

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (NIH)
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (NIH)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852