

PUBLIC HEALTH SERVICE

START-UP EXCLUSIVE EVALUATION OPTION LICENSE AGREEMENT

This **Agreement** is based on the model Start-Up Exclusive Option License Agreement adopted by the U.S. Public Health Service (“**PHS**”) Technology Transfer Policy Board for use by components of the National Institutes of Health (“**NIH**”), the Centers for Disease Control and Prevention (“**CDC**”), and the Food and Drug Administration (“**FDA**”), which are agencies of the **PHS** within the Department of Health and Human Services (“**HHS**”).

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

[Insert the full name of the IC]

an Institute or Center (hereinafter referred to as the “**IC**”) of the

[INSERT as appropriate: NIH, CDC, or FDA]

and

[Insert Company’s official name],

hereinafter referred to as the “**Licensee**”,

having offices at [Insert Company’s address],

created and operating under the laws of [Insert State of Incorporation].

Tax ID No.: _____

L#:

1. Definitions:
 - (a) “**Government**” means the government of the United States of America.
 - (b) “**Initial Commercial Development Plan**” means a preliminary business plan, attached as Appendix C, submitted to the **IC** by the **Licensee** that outlines the initial stages of development of the **Materials, Licensed Products** or inventions within the scope of the **Licensed Patent Rights** and the **Licensed Field of Use** under the terms of this **Agreement**.
 - (c) “**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 _____.
 - (d) “**Materials**” means _____, including all progeny, subclones, or unmodified derivatives thereof.
 - (e) “**Licensee**” means a start-up company having less than fifty (50) employees, in operation less than five (5) years, receiving less than five million dollars (\$5,000,000) in funding since incorporation, and is majority owned by individuals, hedge funds, or venture funds or by a company that is majority owned by individuals, hedge funds or venture funds.
 - (f) “**Licensed Products**” means _____ and **Materials** made by the **Licensee** within the scope of the **Licensed Patent Rights**.
 - (g) “**Licensed Field of Use**” means pre-clinical evaluation of human therapeutics/vaccines within the scope of the **Licensed Patent Rights**.
2. The **Licensee** desires to obtain an exclusive evaluation option license to evaluate the commercial applications of the **Materials, the Licensed Products** or any inventions within the scope of the **Licensed Patent Rights** within the **Licensed Field of Use**.
3. The **Licensee** represents that it has the facilities, personnel, and expertise to evaluate the commercial applications of the **Materials, the Licensed Products** or inventions within the scope of the **Licensed Patent Rights** within the **Licensed Field of Use** as outlined in the **Initial Commercial Development Plan**.
4. The **IC** hereby grants to the **Licensee** a start-up exclusive evaluation option license for evaluation purposes only to make and use, *but not to sell*, the **Materials** or the **Licensed Products** or inventions within the scope of the **Licensed Patent Rights** within the **Licensed Field of Use**. The **Licensee** agrees that any commercial or industrial use or sale of any such products or processes, other than for evaluation purposes, shall be made only pursuant to the terms substantially found in the **IC’s Start-Up Exclusive Patent License Agreement** to be negotiated in good faith by the parties and executed no later than the termination or expiration date of this **Agreement**. For the sake of clarity, this **Agreement** will be amended to the terms substantially found in the **IC’s Start-Up Exclusive Patent License Agreement**. The rights provided herein are provided for the *evaluation of commercial applications only and not for commercial use*.

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5. The **IC** agrees, after receipt and verification of the license issue royalty, as required by Paragraph 7 of this **Agreement**, to provide the **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. The **IC** shall provide the **Materials** to the **Licensee** at the **Licensee's** expense and as specified in Appendix A.
6. The **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties, except (a) contractors working directly for the **Licensee** or (b) academic or non-profit collaborators, who may support the evaluation of **Materials**, **Licensed Products** or inventions within the scope of the **Licensed Patent Rights** within the **Licensed Field of Use**, without the prior written consent of the **IC**.
7. In consideration of the grant in Paragraph 4, the **Licensee** hereby agrees to pay the **IC** a license issue royalty of two thousand dollars (\$2,000) and payment is due within sixty (60) days of the effective date of this **Agreement**. 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. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**.
8. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 20 are not fulfilled, and shall expire twelve (12) months from its effective date. Within sixty (60) days of the termination or expiration of this **Agreement**, unless a **IC Start-Up Exclusive Patent License** has been executed for the **Licensed Patent Rights** in the **Licensed Field of Use** as stipulated in Paragraph 4 of this **Agreement**, the **Licensee** shall return all **Materials** and **Licensed Products** to the **IC** or provide the **IC** with written certification of their destruction.
9. In the event that the **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, the **IC** may terminate this **Agreement** by written notice.
10. The **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**, the **Licensee** shall acknowledge the contribution by the named inventors to the **Licensed Products** or the **Materials**, unless requested otherwise by the **IC** or the named inventors.
11. The **Licensee** agrees to submit in confidence a final report to the **IC** within sixty (60) days of termination or expiration of this **Agreement**, unless a **IC Start-Up Exclusive Patent License** has been executed for the **Licensed Patent Rights** in the **Licensed Field of Use**, outlining, in general, its results of commercial evaluation of the **Licensed Patent Rights**, the **Licensed Products**, or the **Materials** provided by this **Agreement**. The **Licensee** shall submit the report to the **IC** at the Mailing Address for **Agreement** notices indicated on the Signature Page.
12. The **IC** 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 the **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 the **IC**, that is or becomes publicly available, or that is disclosed to the **IC** by a third party without an obligation of confidentiality.

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13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE FITNESS FOR ANY PURPOSE OF THE **MATERIALS** OR THE **LICENSED PRODUCTS** PROVIDED TO THE **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **LICENSED PATENT RIGHTS** MAY BE EXPLOITED WITHOUT INFRINGING OTHER PATENT RIGHTS. The **Licensee** accepts license rights to the **Licensed Patent Rights**, the **Licensed Products**, and the **Materials** “as is”, and the **IC** does not offer any guarantee of any kind.
14. The **Licensee** agrees to indemnify and hold harmless the **IC** and the **Government** 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**.
15. Neither party shall have any obligation to take any action with regard to an infringement of **Licensed Patent Rights** by a third party.
16. 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**. The **Licensee** agrees to be subject to the jurisdiction of U.S. courts.
17. This **Agreement** constitutes the entire understanding of the **IC** and the **Licensee** and supersedes all prior agreements and understandings with respect to the **Licensed Patent Rights**, the **Materials** and the **Licensed Products**.
18. 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**.
19. Paragraphs 7, 8, 10, 11, 12, 13, 14 and 19 of this **Agreement** shall survive termination of this **Agreement**.
20. The terms and conditions of this **Agreement** shall, at the **IC**'s sole option, be considered by the **IC** to be withdrawn from the **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 the **IC** within sixty (60) days from the date of the **IC** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

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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 the **IC**:

_____ **DRAFT** _____
Name _____ Date _____
Title _____
Office _____
National Institutes of Health

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

License Compliance and Administration
Monitoring & Enforcement
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.IC.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **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 (the **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 A – SHIPPING INFORMATION

The Licensee’s Shipping Contact: information or questions regarding shipping should be directed to the Licensee’s Shipping Contact at:

Shipping Contact’s Name	Title	
Phone: () _____	Fax: () _____	E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

Company Name & Department

Address:

The Licensee’s shipping carrier and account number to be used for shipping purposes:

APPENDIX B – ROYALTY PAYMENT OPTIONS

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

Credit and Debit Card Payments

Credit and debit card payments can be submitted for amounts up to \$29,999. Submit your payment through the U.S. Treasury web site located at: <https://www.pay.gov/public/form/start/28680443>.

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

The IC encourages its 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/public/form/start/28680443>. Please note that the IC “only” accepts ACH payments through this U.S. Treasury web site.

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 the 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 the Licensee
Detail of Charges (line 71a):	Charge Our

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:

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National Institutes of Health
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
Office of Technology Transfer
License Compliance and Administration
Royalty Administration
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

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APPENDIX C – INITIAL COMMERCIAL DEVELOPMENT PLAN

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