PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT – *START-UP EXCLUSIVE*

This **Agreement** is based on the model Patent License Exclusive 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 the

[Insert the full name of the IC]

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

NIH

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.:_____

For the **IC** internal use only:

License Number:

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

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

Additional Remarks:

Public Benefit(s):

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) or Patent Application(s) and Materials), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercialization Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options).

The **IC** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **IC** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **IC** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **IC**.

1.3 The Secretary of **HHS** has delegated to the **IC** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 The **IC** 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.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

1.6 The **Licensee** represents that it is a **Start-Up Company** on the **Effective Date** of this **Agreement**.

2. DEFINITIONS

2.1 "**Access Plan**" means the **Licensee**'s plan, and incorporating the plan(s) of its sublicensee(s), as applicable, that describes the **Licensee**'s strategy to support broad access to **Licensed Product(s)** or **Licensed Process(es)**. The **Access Plan** is part of the **Commercial Development Plan**, attached as Appendix E, and complies with the NIH Intramural Research Program Access Planning Policy.

2.2 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.3 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.4 "**Change of Control**" means i) any transaction or series of related transactions following which the holders of a majority of **Licensee**'s capital stock or membership or equity interests immediately prior to such transaction or series of related transactions entitled to (a) vote with respect to the election of directors (or positions having a similar function) or (b) receive the proceeds upon any sale, liquidation or dissolution of **Licensee**, and collectively no longer hold a majority of **Licensee**'s capital stock or membership or equity interests, (ii) a sale, transfer, or other disposition, in a single transaction or series of related transactions, of all or a material portion of **Licensee**'s interest in the **Licensed Product**(s) and/or **Licensed Process**(es) (iii) a sale, transfer, or other disposition, in a single transaction or series of related transactions, of all or a material portion of **Licensee**'s right, title, or interest in its assets taken as a whole, (iv) an initial public offering of the stock of **Licensee**; or (v) the merger of **Licensee** with a Third Party by operation of law or otherwise.

2.5 "**Commercial Development Plan**" means a written plan, including an **Access Plan**, which describes the **Licensee**'s formal approach to achieving **Practical Application** of the **Licensed Products** or **Licensed Processes** within the **Licensed Fields of Use**.

2.6 **"Commercial Evaluation Plan**" means the written evaluation plan which describes the **Licensee**'s plans for initial development of the **Licensed Products** or **Licensed Processes** within the **Licensed Fields of Use** under the terms of this **Agreement**.

2.7 "**Commercialization Plan**" means the **Commercial Development Plan** or **Commercial Evaluation Plan** stated in Appendix E and currently in effect under the terms of this **Agreement**.

2.8 "**CRADA"** means a Cooperative Research and Development Agreement.

2.9 "**Effective Date**" means the date when the last party to sign has executed this **Agreement**.

2.10 **"Extraordinary Expenditures**" means expenses arising from actions beyond the norms of typical preparation, filing, and prosecution of the **Licensed Patent Rights**, including, without limitation, interferences, reexaminations, reissues, oppositions, and defense.

2.11 "**FDA**" means the Food and Drug Administration.

2.12 "**First Commercial Sale**" means the initial transfer by or on behalf of the **Licensee** or its sublicensees of the **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.13 "**Government**" means the Government of the United States of America.

2.14 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.15 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.15(a):

(i) continuations-in-part of 2.15(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.15(a); and

(v) any reissues, reexaminations, and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.15(a): all counterpart foreign and U.S. patent applications and patents to 2.15(a) and 2.15(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.15(b) or 2.15(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.15(a).

2.16 "**Licensed Processes**" 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.

2.17 "**Licensed Products**" 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.

2.18 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.19 **"Materials"** means tangible materials provided to the **Licensee** by the **IC**, including all progeny, subclones and unmodified derivatives thereof**,** if applicable**,** as described in Appendix A.

2.20 "**Net Sales**" means the total invoiced amount to a third party for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee, Affiliates** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others, less returns and allowances, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately listed on the invoice), and cash discounts in amounts not to exceed amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or sublicensees and on its payroll, payments for any service received, or for the cost of collections. **Net Sales** for any sale or disposition of **Licensed Products** invoiced at zero or not invoiced shall be calculated at the average invoiced amount to a third party

2.21 "**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 these 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.

2.22 "**Research License**" means a nontransferable, nonexclusive license to make and to use the **Licensed Products** or the **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.

2.23 "**Start-up Company"** means a company operating for fewer than seven (7) years, having received less than fifteen million dollars ($15,000,000.00) since incorporation (exclusive of non-dilutive grant funding), and that is majority owned by individuals or by a company that is majority owned by individuals.

2.24 "**Term Extension Amendment**" means a written amendment to this **Agreement**, mutually acceptable to the **IC** and the **Licensee**, comprising at least the following features:

(a) A **Commercial Development Plan**, extending from the then-current development status of the **Licensed Products** and/or **Licensed Processes** to **Practical Application**. The **Commercial Development Plan** shall be incorporated into Appendix E;

(b) An **Access Plan**, which shall be incorporated into Appendix E

(c) A field of use no broader than the **Licensed Fields of Use**, commensurate with the **Commercial Development Plan**, which shall be incorporated into Appendix B;

(d) An updated set of **Benchmarks,** corresponding to the **Commercial Development Plan** and the **Access Plan**, which shall be incorporated into Appendix D;

(e) Updated financial benchmarks, corresponding to the **Commercial Development Plan**, which shall be incorporated into Appendix C-Section V;

(f) An amendment to Paragraph 9.1 whereby the present text is replaced with the following:

(i) "Prior to executing the **Term Extension Amendment**, the **Licensee** has provided the **IC** with the **Commercial Development Plan** and **Access Plan** stated in Appendix E, under which the **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. Based on these plans, performance **Benchmarks** were determined as specified in Appendix D."

(g) An amendment to Paragraph 13.1 whereby the present text is replaced with the following:

(i) "This **Agreement** is effective as of the **Effective Date**, unless the provisions of Paragraph 14.16 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights,** unless sooner terminated as provided in this Article 13."

2.25 "**Third Party Collaborator(s)**" means an academic and/or non-profit third party with whom **Licensee** has entered into a *bona fide* collaboration agreement (*i.e*., work under the collaboration reflects contribution from both the **Licensee** and third party) for purposes of conducting research and development activities.

2.26 "**Third Party Contractor(s)**" means a third-party organization, acting with, on behalf and for the benefit of **Licensee** for consideration provided by the **Licensee** on a fee-for-service basis to conduct experiments specified by the **Licensee**.

3. GRANT OF RIGHTS

3.1 The **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Process(es)** in the **Licensed Fields of Use**.

3.2 The **Licensee** is entitled to authorize its **Third-Party Contractor(s)** to make, have made and to use, but not to sell **Materials** and **Licensed Products** on **Licensee**'s behalf solely in the **Licensed Field(s) of Use** and in the **Licensed Territory**. **Licensee** may, without prior written permission, transfer the **Materials** and **Licensed Products** to **Third Party Collaborator(s)** solely for internal research purposes within the **Licensed Field(s) of Use**. **Licensee** shall ensure that such **Third-Party Collaborator(s)**, and **Third-Party Contractor(s)** comply with the terms and obligations of this **Agreement** with respect to their use of the **Materials** and/or the **Licensed Products**.

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **IC** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by the **IC** and which shall not be unreasonably withheld, the **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights**.

4.2 The **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to the **IC** of Paragraphs 5.1-5.4, 8.1, 10.1, 10.2, 12.5, and 13.8-13.10 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and the **IC**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **IC** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 The **Licensee** agrees to forward to the **IC** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, the **IC** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 (a) the **IC** 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 future treaty or agreement to which the **Government** is a signatory. Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **IC** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **IC** research use; and

(b) in the event that the **Licensed Patent Rights** are Subject Inventions made under **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Licensed Patent Rights** or have the **Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this 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**, the **Licensee** agrees to provide the **IC** with reasonable quantities of the **Licensed Products** or materials made through the **Licensed Processes** for **IC** research use.

5.2 The **Licensee** agrees that products used or sold in the United States embodying the **Licensed Products** or produced through use of the **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **IC**.

5.3 The **Licensee** acknowledges that the **IC** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **IC** when acquiring these rights is necessary in order to make a **CRADA** project feasible. The **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4 (a) in addition to the reserved license of Paragraph 5.1, the **IC** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Licensed Patent Rights**, however, the **IC** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) in exceptional circumstances, and in the event that the **Licensed Patent Rights** are Subject Inventions made under a **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 the **Licensed Patent Rights** in the **Licensed Field of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these 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 the **Licensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these 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); and

(c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **IC** a non-creditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 The **Licensee** agrees to pay the **IC** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **IC** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **IC** benchmark royalties as set forth in Appendix C.

6.5 The **Licensee** agrees to pay the **IC** a **Change of Control** royalty as set forth in Appendix C.

6.6 The **Licensee** agrees to pay the **IC** sublicensing royalties as set forth in Appendix C.

6.7 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 patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.8 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.9 On sales of the **Licensed Products** by the **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 this 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 this transaction.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **IC** on or after the **Effective Date** of this **Agreement**, the **Licensee** shall, on an annual basis, pay the **IC** within sixty (60) days of the **IC's** submission of a statement and request for payment the lesser of the following:

(a) Fifty percent (50%) of such unreimbursed expenses;

(b) A pro-rata share of such unreimbursed expenses, whereby if the **IC** has granted a commercialization license under the **Licensed Patent Rights** to one or more third parties, then the **Licensee** shall pay the **IC** a portion of such unreimbursed expenses calculated by dividing the total patent costs paid during the previous calendar year(s) by the number of commercialization licensees of record whose licenses include the development of therapeutic or diagnostic products within the scope of the **Licensed Patent Rights** and remains effective as of the date of this statement (hereafter a "Pro-Rata Share"); or

(c) _____ dollars ($_____).

6.11 Upon occurrence of the earliest of the following triggering events, (i) **Change of Control**; (ii) grant of a sublicense; (iii) **First Commercial Sale**; or (iv) the first anniversary of the effective date of the **Term Extension Amendment**, the **Licensee** shall pay the **IC**, as additional royalties, within sixty (60) days of the **IC's** submission to the **Licensee** of a statement and request for payment:

(a) All unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **IC** prior to the **Effective Date** of this **Agreement.** As of (___date___), these expenses are approximately _____ dollars ($_____);

(b) The remaining unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **IC** on or after the **Effective Date** of this **Agreement** up until the date of the triggering event; and

(c) With respect to the unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **IC** on or after the date of the triggering event, the lesser of:

(i) One-hundred percent (100%) of such unreimbursed expenses; or

(ii) A Pro-Rata Share of such unreimbursed expenses.

6.12 The **IC** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **IC** has requested payment from the **Licensee** under Paragraphs 6.10 and 6.11. The **Licensee** agrees that all information provided by the **IC** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.13 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon ninety (90) days written notice to the **IC** and owe no payment obligation under Paragraphs 6.10 and 6.11 for patent-related expenses paid in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 The **IC** 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** and shall furnish copies of relevant patent-related documents to the **Licensee**. The foregoing notwithstanding, prior to execution of a **Term Extension Amendment** the **Licensee** acknowledges that the following conditions apply:

(a) If the **IC** anticipates the possibility of **Extraordinary Expenditures**, the **IC** will provide prompt written notice to the **Licensee**. The **Licensee** may request that the **IC** incur such **Extraordinary Expenditures** at the **Licensee**'s expense, which shall require approval by the **IC**. In the absence of an agreement between the parties regarding reimbursement the **Extraordinary Expenditures**, the **IC** may elect to abandon the elements of the **Licensed Patent Rights** responsible for such **Extraordinary Expenditures**.

7.2 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 the **Licensed Patent Rights**, which comments and suggestions shall be considered by the other party.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **IC**. These 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 the **IC**, by an accountant or other designated auditor selected by the **IC** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the **IC** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **IC** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **IC** provides to the **Licensee** notice of the payment due.

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

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **IC** with the **Commercial Evaluation Plan** in Appendix E, under which the **Licensee** intends to advance the subject matter of the **Licensed Patent Rights** towards **Practical Application**. Based on this plan, performance **Benchmarks** were determined as specified in Appendix D.

9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercialization 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, manufacture and status of sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. Following execution of a **Term Extension Amendment**, the progress report shall also include information on the **Licensee**'s implementation of the **Access Plan**. The **IC** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercialization Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercialization Plan**, acceptance of which by the **IC** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **IC** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **IC**. The **IC** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercialization Plan** and toward bringing the **Licensed Products** to the point of **Practical Application** as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercialization Plan** and **Benchmarks** at the request of the **IC** to address any **Licensed Fields of Use** not specifically addressed in the plan originally submitted.

9.3 The **Licensee** shall report to the **IC** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 The **Licensee** shall submit to the **IC**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **IC** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.20 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

9.5 The **Licensee** agrees to forward semi-annually to the **IC** a copy of these reports received by the **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to the **IC** by the **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. 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**. The royalty report required by Paragraph 9.4 shall be mailed to the **IC** at its address for **Agreement** Notices indicated on the Signature Page or electronically mailed to the email address indicated on the Signature Page.

9.7 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay the tax and be responsible for all filings with appropriate agencies of foreign governments.

9.8 Additional royalties may be assessed by the **IC** 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 the **IC** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **IC** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **IC** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **IC** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and the **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include substantial adherence to the **Commercialization Plan** in Appendix E and achievement of the **Benchmarks** in Appendix D. The efforts of a sublicensee shall be considered the efforts of the **Licensee**.

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

10.3 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of the **Licensed Products** or materials produced through the use of the **Licensed Processes** available to patient assistance programs.

10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 The **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or the **Licensed Processes** or their packaging for educational and display purposes only.

10.6 Within three (3) months after the first marketing approval of a **Licensed Product** or **Licensed Process** by the **FDA** (or a foreign equivalent), the **Licensee** shall submit a current, non-confidential summary of any **Access Plan** (Appendix E- Section II) that **NIH** may publish or otherwise make available to third parties without further consultation or permission.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **IC** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.

11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **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**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Licensed Patent Rights** provided, however, that the **IC** and appropriate **Government** authorities shall have the first right to take such actions; and

(d) if the **Licensee** desires to initiate a suit for patent infringement, the **Licensee** shall notify the **IC** in writing. If the **IC** does not notify the **Licensee** of its intent to pursue legal action within ninety (90) days, the **Licensee** shall be free to initiate suit. The **IC** shall have a continuing right to intervene in the suit. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including all costs incurred by the **Government** in opposing the motion or other action. In all cases, the **Licensee** agrees to keep the **IC** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **IC** and give careful consideration to the views of the **IC** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity or non-infringement of any of the **Licensed Patent Rights** shall be brought against the **Licensee** or raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29 or other statutes, the **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**;

(b) in any suit, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment involving the **Licensed Patent Rights**-provided, however, that the **IC** and appropriate **Government** authorities shall have the first right to take these actions and shall have a continuing right to intervene in the suit; and

(d) if the **IC** does not notify the **Licensee** of its intent to respond to the legal action within a reasonable time, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **IC**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **IC** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **IC** and give careful consideration to the views of the **IC** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 In any action under Paragraphs 11.2 or 11.3 the expenses including costs, fees, attorney fees, and disbursements, shall be paid by the **Licensee**. The value of any recovery made by the **Licensee** through court judgment or settlement shall be treated as **Net Sales** and subject to earned royalties.

11.5 The **IC** shall cooperate fully with the **Licensee** in connection with any action under Paragraphs 11.2 or 11.3. The **IC** agrees promptly to provide access to all necessary documents and to render reasonable assistance in response to a request by the **Licensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **IC** offers no warranties other than those specified in Article 1.

12.2 The **IC** 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** or **Materials** may be exploited without infringing other patents or other intellectual property rights of third parties.

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

12.4 The **IC** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **IC**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, 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 the **Licensee**, its sublicensees, directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or **Materials** by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective on the **Effective Date**, unless the provisions of Paragraph 14.16 are not fulfilled, and shall expire two (2) years later, unless sooner terminated as provided in this Article 13. The Parties acknowledge that the initial **Agreement** term may be extended by a **Term Extension Amendment.** If the **Licensee** desires to execute a **Term Extension Amendment**, it shall provide the **IC** with written notice to this effect no later than eighteen (18) months following the **Effective Date**. Such notice shall contain at least i) a **Commercial Development Plan**, ii) an **Access Plan**, iii) a proposed field of use no broader than the **Licensed Fields of Use**, and iv) desired performance milestones corresponding to the **Commercial Development Plan**. Thereafter, the Parties agree to negotiate in good faith and shall use reasonable efforts to execute a **Term Extension Amendment** prior to the expiration date of the **Agreement**.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **IC** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **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, the **Licensee** shall immediately notify the **IC** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** or any licenses in any country or territory by giving the **IC** sixty (60) days written notice to that effect.

13.5 The **IC** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **IC** determines that the **Licensee**:

(a) is not executing the **Commercialization Plan** and the **Licensee** cannot otherwise demonstrate to the **IC's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping the **Licensed Products** or the **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs;

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived; or

(h) has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under this **Agreement.**

13.6 In making the determination referenced in Paragraph 13.5, the **IC** 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 the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **IC** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **IC's** concerns as to the items referenced in 13.5(a)-13.5(h). If the **Licensee** fails to alleviate the **IC's** concerns as to the items referenced in 13.5(a)-13.5(h) or fails to initiate corrective action to the **IC's** satisfaction, the **IC** may terminate this **Agreement**.

13.7 When the public health and safety so require, and after written notice to the **Licensee** providing the **Licensee** a sixty (60) day opportunity to respond, the **IC** shall have the right to require the **Licensee** to grant sublicenses to responsible applicants, on reasonable terms, in any **Licensed Fields of Use** under the **Licensed Patent Rights**, unless the **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**. The **IC** shall not require the granting of a sublicense unless the responsible applicant has first negotiated in good faith with the **Licensee**.

13.8 The **IC** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that this action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.9 Within thirty (30) days of receipt of written notice of the **IC's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **IC** official or designee. The decision of the designated **IC** official or designee shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be accessible.

13.10 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expenses, due to the **IC** 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 the **IC** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return or cause to be returned all **Materials** and **Licensed Products** to the **IC,** including those in the possession of its **Third Party Collaborator(s)** and **Third Party Contractor(s)**, or provide the **IC** with written certification of their destruction. The **Licensee** may not be granted additional **IC** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 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 that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by the **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Licensed Patent Rights**, the **Licensed Products** and the **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 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, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 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 the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 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.

14.6 All **Agreement** 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 another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the 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.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **IC**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **IC** approves a proposed assignment, other than an assignment commensurate with a **Change of Control** event, the **Licensee** shall pay the **IC**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment.

14.8 The **Licensee** agrees in its use of any **Materials** to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the **Materials** 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. The **Licensee** agrees not to use the **Materials** for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **IC** 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 the research or trials.

14.9 The **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 these items may require a license from the appropriate agency of the U.S. **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of this agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **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 the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **IC's** patent rights in those countries.

14.11 By entering into this **Agreement**, the **IC** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **IC**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **IC**, the **FDA** or the **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **IC**.

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. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **IC** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **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 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **IC**.

14.15 Article 2 (Definitions) and Paragraphs 4.3, 8.1, 9.5-9.8, 12.1-12.5, 13.9, 13.10, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.

14.16 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's** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *START-UP EXCLUSIVE*

SIGNATURE PAGE

For the **IC**:

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

Address for Agreement notices and reports:

E-mail: LicenseNotices_Reports@mail.nih.gov (preferred)

Mail: License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6701 Rockledge Drive, Suite 700, MS 7788
Bethesda, Maryland 20892 U.S.A.

(For courier deliveries please check https://www.ott.nih.gov/licensing/license-noticesreports)

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

_____

_____

_____

_____

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: _____

III. Official and Mailing Address for the Shipment of **Materials**

_____
Name

_____
Title

Mailing Address:

_____

_____

_____

_____

Email Address: _____

Phone: _____

Licensee's Shipping Carrier and Account Number: _____

_____

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) or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S) AND MATERIALS

Patent(s) or Patent Application(s):

I.

Materials:

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

(a)

II. **Licensed Territory:**

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to the **IC** a non-creditable, nonrefundable license issue royalty in the amount of five thousand dollars ($5,000.00) within sixty (60) days from the **Effective Date** of this **Agreement.**

II. The **Licensee** agrees to pay to the **IC** a nonrefundable minimum annual royalty in the amount of _____ dollars ($X) as follows:

(a) The first minimum annual royalty is due on the third anniversary of the **Effective Date** of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the third anniversary date of this **Agreement** and the next subsequent January 1; and

(b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. The **Licensee** agrees to pay the **IC** earned royalties of _____ percent (X%) on **Net Sales** by or on behalf of the **Licensee** and its sublicensees.

IV. The **Licensee** agrees to pay the **IC** a **Change of Control** royalty of _____ percent (X%) on the fair market value of any consideration received in connection with a **Change of Control** within sixty (60) days of such **Change of Control** event.

V. The **Licensee** agrees to pay the **IC Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:

(a) Prior to execution of the **Term Extension Amendment**, this Appendix C-Section V is intentionally left blank.

(b)

(c)

(d)

(e)

VI. The **Licensee** agrees to pay the **IC** additional sublicensing royalties of ____ percent (X%) on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense.

APPENDIX D – BENCHMARKS AND PERFORMANCE

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

I.

APPENDIX E – COMMERCIALIZATION PLAN

I. Research, Development and Marketing Plan:

II. **Access Plan**: (Prior to execution of the **Term Extension Amendment**, responses to the following prompts are intentially omitted.)

a. Brief description of the **Licensed Products** and **Licensed Processes** contemplated under this **Agreement:**

b. Brief description of the anticipated patient population(s):

c. Brief description of other products, tools, facilities, or unique resources that would be necessary for use of the **Licensed Products** and **Licensed Processes:**

d. Strategies to promote patient access, across criteria of affordability, availability, acceptability, and sustainability, to the extent such access can be advanced on terms that are commercially reasonable:

e. Brief description of plans to monitor the efficacy of the proposed access plan over the term of the license and steps to remedy any detected shortcomings:

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- License reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

Checks are no longer accepted.
New Payment Options Effective September 2024

The License Number (L-xxx-xxxx-x) MUST appear on payments, reports, and correspondence.

Agency Contacts: Office of Technology Transfer (OTT) OTT-Royalties@mail.nih.gov

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to $24,999. Submit your payment through the U.S. Treasury web site located at: **https://www.pay.gov/public/form/start/28680443**.

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:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the **NIH ROYALTY FUND**.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	***CTR (or CTP)***
{4200}	Beneficiary Identifier (account number)	*(enter 12-digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS/NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY NAME**
{6000}	Originator to Beneficiary Information - Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information - Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER (L-xxx-xxxx-x)**
{6000}	Originator to Beneficiary Information - Line 3	*(enter information to identify the purpose of the payment)* **INVOICE NUMBER**
{6000}	Originator to Beneficiary Information - Line 4	*(enter information to identify the purpose of the payment)*

Notes:
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.

**Anything other than the 12-digit gateway account # will cause the Fedwire to be returned.

Drawn on a **non-US bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in US Dollars (USD).

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3100}	Sender Bank ABA routing number	*(enter the US correspondent bank's ABA routing number)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	***CTR (or CTP)***
{4200}	Beneficiary Identifier (account number)**	*(enter 12-digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY'S NAME**
{6000}	Originator to Beneficiary Information - Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information - Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER (L-xxx-xxxx-x)**
{6000}	Originator to Beneficiary Information - Line 3	*(enter information to identify the purpose of the payment)* **INVOICE NUMBER**
{6000}	Originator to Beneficiary Information - Line 4	*(enter information to identify the purpose of the payment)*

Notes:
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.
**Anything other than the 12-digit gateway account # will cause the Fedwire to be returned.

SWIFT CODE: FRNYUS33

Automated Clearing House (ACH)

The IC encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). ACH payments can be submitted by two methods: Pay.gov (for US banks only) or standard ACH payment (US and non-US banks accepted).

Pay.gov: ACH payments can be submitted for US banks only. Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443.

Standard ACH: credits can be submitted for payments up to $99,999,999 for US and International banks. Please provide the following instructions to your Financial Institution for the remittance of Automated Clearing House (ACH) credits to the United States Department of Health of Human Services - National Institutes of Health (NIH):

Drawn on a **US** or **non-US bank account** via standard ACH:

NACHA Record Type Code	NACHA Field	NACHA Data Element Name	Required Information
5	3	Company Name	*(enter the name of the payor)*
5	6	Standard Entry Class Code	**CTX**
5	9	Effective Entry Date	*(enter intended settlement date)*
6	2	Transaction Code*	**22**
6	3 & 4	Receiving DFI Identification (ABA routing #)	**051036706**
6	5	DFI Account Number	**875080031006**
6	6	Amount	*(enter payment amount)*
6	8	Receiving Company Name	*(enter the identifying information)*
7	3	Payment Related Information	*(see format instructions below)*

Additional Payment Related Information should be included in NACHA Record 7 Field 3 and must conform to the ANSI ASC X12 standards using the EDI 820 Transaction Set Data Segments. A sample format follows.

Segment Contents	Element Descriptions
RMR*AR*License number**Amount being paid\N1*8R*Licensee Name**RMR*AR*license number 2**Amount being Paid 2\N1*8R*Licensee Name2**	DATA SEGMENT - Remittance Advice Accounts Receivable **RMR** * *(delimiter)* Reference Identification Qualifier: **AR** Accounts Receivable Number * *(delimiter)* **License number** (L-xxx-xxxx-x) * *(delimiter)* * *(delimiter)* Monetary Amount: Amount being paid \ *(segment terminator)* DATA SEGMENT – Name: **N1** * *(delimiter)* Entity Identifier Code: **8R** Identifies customer * *(delimiter)* Name: **Licensee name** \ *(segment terminator)*
Example: Licensee LLC with Licensee number L-xxx-20xx-x pays $1,000.00 *RMR*AR*L-xxx-20xx-x**1000.00\N1*8R*Licensee LLC *	

ACH debits are not permitted to this ABA routing number. All debits received will be automatically rejected/returned.

Agency Contacts: Office of Technology Transfer (OTT) OTT-Royalties@mail.nih.gov