PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT – 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

[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.:____________________
For the IC internal use only:

License Number:

License Application 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)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D (Benchmarks and Performance), Appendix E (Commercial Development 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.

2. **DEFINITIONS**

   2.1 “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.

   2.2 “Benchmarks” mean the performance milestones that are set forth in Appendix D.

   2.3 “Commercial Development Plan” means the written commercialization plan attached as Appendix E.

   2.4 “CRADA” means a Cooperative Research and Development Agreement.

   2.5 “FDA” means the Food and Drug Administration.

   2.6 “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.

   2.7 “Government” means the Government of the United States of America.

   2.8 “Licensed Fields of Use” means the fields of use identified in Appendix B.

   2.9 “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 2.9(a):

(i) continuations-in-part of 2.9(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 2.9(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 2.9(a): all counterpart foreign and U.S. patent applications and patents to 2.9(a) and 2.9(b), including those listed in Appendix A; and

(d) Licensed Patent Rights shall not include 2.9(b) or 2.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.9(a).

2.10 “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.

2.11 “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.

2.12 “Licensed Territory” means the geographical area identified in Appendix B.

2.13 “Net Sales” means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of the Licensee or its sublicensees, and from leasing, renting, or otherwise making the Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the Licensee, or sublicensees, and on its payroll, or for the cost of collections.
2.14 “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.

2.15 “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.

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 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. §3710(a)(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. §3710(a)(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 noncreditable, 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** sublicensing royalties as set forth in Appendix C.

6.6 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.

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

6.8 On sales of the **Licensed Products** by the **Licensee** to sublicensees or on sales made in other than an arms-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 arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.
6.9 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 prior to the effective date of this Agreement, the Licensee shall pay the IC, as an additional royalty, within sixty (60) days of the IC’s submission of a statement and request for payment to the Licensee, an amount equivalent to these unreimbursed expenses previously paid by the IC.

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 IC, at its sole option, may require the Licensee:

(a) to pay the IC on an annual basis, within sixty (60) days of the IC’s submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);

(b) to handle these functions. However, in this event, the IC and not the Licensee shall be the client of the law firm; or

(c) in limited circumstances, the Licensee may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the Licensed Patent Rights. In that event, the Licensee shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the IC with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 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 6.9 and 6.10. 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.

6.12 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 Paragraph 6.10 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 Except as otherwise provided in this Article 7, 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.
7.2 Upon the IC’s written request, the Licensee shall assume the responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and shall, on an ongoing basis, promptly furnish copies of all patent-related documents to the IC. In this event, the Licensee shall, subject to the prior approval of the IC, select registered patent attorneys or patent agents to provide these services on behalf of the Licensee and the IC. The IC shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The Licensee and its attorneys or agents shall consult with the IC in all aspects of the preparation, filing, prosecution and maintenance of patent applications and patents included within the Licensed Patent Rights and shall provide the IC sufficient opportunity to comment on any document that the Licensee intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.3 At any time, the IC may provide the Licensee with written notice that the IC wishes to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights. If the IC elects to reassume these responsibilities, the Licensee agrees to cooperate fully with the IC, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and to provide the IC with complete copies of any and all documents or other materials that the IC deems necessary to undertake such responsibilities. The Licensee shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the IC’s choice.

7.4 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 Development Plan in Appendix E, under which the Licensee intends to bring the subject matter of the Licensed Patent Rights to the point of Practical Application. This Commercial Development Plan is hereby incorporated by reference into this Agreement. Based on this plan, performance Benchmarks are determined as specified in Appendix D.
9.2 The *Licensee* shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacture and status of sublicensing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. 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 **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for these differences. In the annual report, the **Licensee** may propose amendments to the **Commercial Development 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 **Commercial Development Plan** and toward bringing the **Licensed Products** to the **Practical Application** as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercial Development 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 2.13 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.

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 adherence to the Commercial Development Plan in Appendix E and performance 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.

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 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 OR 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 when signed by all parties, 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.

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 Commercial Development Plan submitted with its request for a license 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; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2 unless waived.
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(g). If the Licensee fails to alleviate the IC’s concerns as to the items referenced in 13.5(a)-13.5(g) 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 all Licensed Products or other materials included within the Licensed Patent Rights to the IC or provide the IC with certification of the destruction thereof. 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, 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 IC-supplied 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 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 – EXCLUSIVE

SIGNATURE PAGE

For the IC:

________________________  _______________
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.nih.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:

________________________  _______________
Signature of Authorized Official Date

Printed Name

________________________________________________________________________
Title

I. Official and Mailing Address for Agreement notices:

Name

Title

Mailing Address
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) or imprisonment).
APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

I.

II.

III.

IV.

V.
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 noncreditable, nonrefundable license issue royalty in the amount of _______ dollars ($X) 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 within sixty (60) days of the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1; 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 Benchmark royalties within sixty (60) days of achieving each Benchmark:

(a)

(b)

(c)

(d)

(e)

V. 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.

II.

III.

IV.

V.

VI.

VII.
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

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

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

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:

<table>
<thead>
<tr>
<th>Beneficiary Account:</th>
<th>Federal Reserve Bank of New York or TREAS NYC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bank:</td>
<td>Federal Reserve Bank of New York</td>
</tr>
<tr>
<td>ABA#:</td>
<td>021030004</td>
</tr>
<tr>
<td>Account Number:</td>
<td>75080031</td>
</tr>
<tr>
<td>Bank Address:</td>
<td>33 Liberty Street, New York, NY 10045</td>
</tr>
<tr>
<td>Payment Details:</td>
<td>License Number (L-XXX-XXXX)</td>
</tr>
<tr>
<td></td>
<td>Name of the Licensee</td>
</tr>
</tbody>
</table>

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:

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

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:

A-XXX-201X
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