# PUBLIC HEALTH SERVICE

### PATENT LICENSE-NON-EXCLUSIVE

This **Agreement** is based on the model Patent License Non-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 National Institute of Allergy and Infectious Diseases

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

NIH

and

ModernaTX, Inc.,
hereinafter referred to as the "Licensee",
having offices at 200 Technology Square, Cambridge, MA 02139
created and operating under the laws of Delaware

Tax ID No.: 27-0226313

for the NIAID internal use only:
License Number: L-049-2023-0
License Application Number: A-286-2020
Serial Number(s) of Licensed Patent(s) or Patent Application(s): See Appendix A.
Licensee: ModernaTX, Inc.
Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):
N/A
Additional Remarks:
N/A
Public Benefit(s): Development of a vaccine to prevent SARS-CoV-2 infection and/or COVID-19 disease

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), Appendix G (Royalty Payment Options), and Appendix H (Example Royalty Calculation).

### The NIAID and the Licensee agree as follows:

### 1. <u>BACKGROUND</u>

- 1.1 In the course of conducting biomedical and behavioral research, the **NIAID** investigators, together with investigators at Dartmouth College and The Scripps Research Institute (each, a "**Partner**"), made inventions that may have commercial applicability.
- By assignment of rights from the NIAID employees and other inventors, HHS, on behalf of the Government, owns or co-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 NIAID. Pursuant to agreements with each of the Partners, the NIAID has the exclusive right to grant licenses to the Partners' rights in the Licensed Patent Rights together with those of the Government, including the licenses and other rights set forth herein, in accordance with the terms set forth herein. The Partners continue to maintain an undivided ownership interest in such patent rights.
- 1.3 The Secretary of **HHS** has delegated to the **NIAID** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.
- 1.4 The **NIAID** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development including commercialization of products and processes for public use and benefit.
- 1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in light of marketed products it has and continues to develop for public use and benefit.

## 2. <u>DEFINITIONS</u>

Capitalized terms not otherwise defined herein will have the meanings set forth below:

- 2.1 "Additional License" means an exclusive or nonexclusive license that includes the Licensed Patent Rights and is granted to a Third Party who is responsible for paying a share of patent expenses, and wherein the exclusive or nonexclusive license has a field of use directed to clinical use. Additional License specifically excludes licenses directed solely to evaluation, internal use or commercialization of research reagents.
- 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 "Antigen" means any active ingredient or group of active ingredients that induces an adaptive immune response specific to itself.
- 2.4 "Benchmarks" mean the performance milestones that are set forth in Appendix D.
- 2.5 "BLA" means a Biologics License Application or similar application or submission for marketing approval filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

2.6	"Clinical Trial" means a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial and/o	or
	post-approval clinical trial.	

2.7	(b)(4)

- 2.8 "Commercial Development Plan" means the written commercialization plan attached as Appendix E.
- 2.9 "Effective Date" means November 1, 2022.
- 2.10 "First Commercial Sale" means the initial transfer by or on behalf of the Licensee (including its Affiliates) of Licensed Products to a Third Party or the initial practice of a Licensed Process by or on behalf of the Licensee or its Affiliates for a Third Party, in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.
- 2.11 "FDA" means the Food and Drug Administration.
- 2.12 "Government" means the Government of the United States of America.
- 2.13 "IND" means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a **Regulatory Authority** or in conformance of such a **Regulatory Authority**.
- 2.14 "Licensed Fields of Use" means the fields of use identified in Appendix B.
- 2.15 "Licensed Patent Rights" means:
  - (a) patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisionals and continuations of these applications (including subsequent divisionals and continuations of such divisionals and continuations), all patents issuing from these applications, divisionals, and continuations, and any reissues, reexaminations, and extensions of all these patents;
  - (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in Paragraph 2.15(a):
    - (i) continuations-in-part of Paragraph 2.15(a);
    - (ii) all divisionals and continuations of these continuations-in-part;
    - (iii) all patents issuing from these continuations-in-part, divisionals, and continuations;
    - (iv) priority patent application(s) of Paragraph 2.15(a); and
    - (v) any reissues, reexaminations, and extensions of all these patents;
  - (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in Paragraph 2.15(a): all counterpart foreign and U.S. patent applications and patents to Paragraphs 2.15(a) and 2.15(b), including those listed in Appendix A; and

- (d) **Licensed Patent Rights** shall *not* include claims of any patents or patent applications in Paragraphs 2.15(b) or 2.15(c) to the extent that such claims are solely directed to new matter that is not the subject matter disclosed by any patent application covered by Paragraph 2.15(a).
- 2.16 "Licensed Processes" means processes, that in the course of being practiced, are, or would be if the applicable patent application were to issue with the scope of claims as when filed, within the scope of one or more claims of the Licensed Patent Rights.
- 2.17 "Licensed Products" means tangible materials, the manufacture, use, sale, importation or other exploitation of which are, or would be if the applicable patent application were to issue with the scope of claims as when filed, within the scope of one or more claims of the Licensed Patent Rights, including all products developed through the practice of Licensed Processes, or the manufacture, use, sale or exploitation of which practices a Licensed Process. For clarity, Licensed Products that are intended to, or actually, require separate pivotal clinical trials will be deemed different Licensed Products for the purposes of this Agreement.
- 2.18 "Licensed Territory" means the geographical area identified in Appendix B.

2.19	"Net Sales"(b)(4)	
	"Net Sales"(b)(4) (b)(4)	

0)(4)

- 2.20 "Phase I Clinical Trial" means a human clinical trial (including Phase Ia and Ib) in any country that is not a Phase II Clinical Trial, Phase III Clinical Trial or post-approval clinical trial.
- 2.21 "Phase II Clinical Trial" means a human clinical trial (including Phase 2a and 2b) in any country in which the protocol is designed to include at least one endpoint measuring efficacy (qualitative or quantitative) for a new indication, but the design is not sufficiently controlled or sized to support regulatory approval of the Licensed Product for marketing.
- 2.22 "Phase III Clinical Trial" means, for the purposes of this Agreement, a human clinical trial in any country in which the protocol is designed to support regulatory approval of the Licensed Product for marketing.
- 2.23 "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. The Parties acknowledge and agree that, as of the Effective Date, the Licensee or its Affiliate has achieved Practical Application of the applicable invention.
- 2.24 "Pro Rata Share" means one of the following:
  - (a) in instances where the **Additional License(s)** granted by **NIAID** recover a predetermined percentage of patent costs, one hundred percent (100%) of patent prosecution costs minus the percentage of patent prosecution costs recovered by the **Additional License(s)** which recover a pre-determined percentage of patent costs. For example, if **NIAID** has granted an **Additional license** that recovers twenty percent (20%) of patent prosecution costs, then the **Pro Rata Share** would be one hundred percent (100%) minus twenty percent (20%), or eighty percent (80%);
  - (b) in instances where the Additional License(s) granted by NIAID recover a full Pro Rata Share of patent prosecution costs, one (1) minus the value derived from the number of Additional License(s) granted by NIAID that recover a full Pro Rata Share of patent prosecution costs divided by the total number of licenses granted by NIAID that recover a full Pro Rata Share of patent prosecution costs. For example, if NIAID has granted four (4) Additional Licenses that recover a full Pro Rata Share of patent prosecution costs, then the Pro Rata Share would be, one (1) minus [four (4) divided by five (5)], or one fifth (1/5); or
  - instances where the **Additional License(s)** are granted according to the definition of both Paragraphs 2.24(a) and 2.24(b), the **Pro Rata Share** paid by **Licensee** will be the value derived from the **Pro Rata Share** as determined under Paragraph 2.24(a) multiplied by the value derived from the **Pro Rata Share** as determined under Paragraph 2.24(b). For example, if two (2) **Additional Licenses** are granted wherein one (1) **Additional License** recovers twenty percent (20%) of patent prosecution costs and one (1) **Additional License** recovers a full **Pro Rata Share** of patent prosecution costs, the **Pro Rata Share** would be (one hundred percent (100%) minus twenty percent (20%)) multiplied by one (1) minus (one (1) divided by two (2)), or eighty percent (80%) multiplied by one-half (1/2), equaling forty percent (40%).
- 2.25 "Regulatory Authority" means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of Licensed Products in the Licensed Territory, including, in the United States, the United States Food and Drug Administration and any successor or foreign governmental authority having substantially the same function.

- 2.26 "Sublicensee" means a Third Party to whom Licensee (directly or via an Affiliate or Sublicensee) has granted a permitted sublicense under the Licensed Patent Rights licensed to Licensee hereunder; but, in each case, excluding any Third Party acting solely as a distributor.
- 2.27 "Third Party" means a person or entity other than (a) Licensee or any of its Affiliates and (b) the NIAID.

2.28	"Valid Claim" means (b)(4)
	(b)(4)

### 3. GRANT OF RIGHTS

- 3.1 The NIAID hereby grants, effective as of the Effective Date, and the Licensee accepts on behalf of itself and its Affiliates, subject to the terms and conditions of this Agreement, a nonexclusive license under the Licensed Patent Rights in the Licensed Territory for Licensee and its Affiliates to make and have made, to use and have used, to distribute and have distributed, to sell and have sold, to offer to sell, and to import and export any Licensed Products in the Licensed Fields of Use and to practice and have practiced any Licensed Processes 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 **NIAID** or any other person or entity (including the **Partners**), other than the **Licensed Patent Rights** regardless of whether these patent applications or patents are dominant or subordinate to the **Licensed Patent Rights**. Except as permitted under 35 U.S.C. § 271(e)(1), neither the **Licensee** nor any of its **Affiliates** will use or practice any **Licensed Patent Rights** outside the scope of or otherwise not in compliance with the rights and licenses granted to the **Licensee** and its **Affiliates** under this **Agreement**.
- 3.3 If the Licensee wishes to amend the Licensed Fields of Use to include additional fields or indications for (b)(4) then the Licensee will prepare and submit to the NIAID a Commercial Development Plan and Benchmarks that (a) includes the development activities for the Licensed Products that the Licensee or its Affiliate proposes to conduct in such proposed additional fields or indications and (b) is reasonably acceptable to the NIAID. Upon receipt by the NIAID of such a Commercial Development Plan and Benchmarks that are reasonably acceptable to the NIAID, the Parties will enter into an amendment to this Agreement that includes an update to the Licensed Fields of Use commensurate with the scope of the additional fields or indications that are the subject of such Commercial Development Plan, and an update to Appendices D (Benchmarks and Performance) and E (Commercial Development Plan) to reflect the additions to the Licensed Fields of Use.

.4	(b)(4)

### 4. <u>SUBLICENSING</u>

- 4.1 Solely with respect to any sublicense agreement with any Third Party, upon written approval by the NIAID, which shall include prior review of any such sublicense agreement by the NIAID for a period of fifteen (15) business days, and which approval shall not be unreasonably conditioned, withheld or delayed by the NIAID, the Licensee or its Affiliates may enter into sublicensing agreements under the Licensed Patent Rights only when it concurrently licenses proprietary or in-licensed intellectual property rights with respect to a Licensed Product. For the avoidance of doubt, neither the Licensee nor any of its Affiliates have the right to solely sublicense the Licensed Patent Rights on a standalone basis. In reviewing any proposed sublicense agreement, the NIAID will keep the terms of such proposed sublicense agreement confidential, to the extent provided for by law.
- 4.2 The **Licensee** and any of its **Affiliates** agree that any sublicenses granted by the **Licensee** or any such **Affiliate** shall include confidentiality and nonuse provisions at least as restrictive as those set forth in this **Agreement**, shall be consistent with and subordinate to the terms of this **Agreement**, and shall provide that the applicable terms and conditions of this **Agreement**, including the obligations to the **NIAID** set forth in Paragraphs 5.1-5.2, 8, 10.1, 10.2, 11.1, 12.6, 13.7-13.9 and 14.10 of this **Agreement**, shall be binding upon the **Sublicensee** as if it were a party to this **Agreement**. The **Licensee** and its **Affiliates** further agree to attach copies of these Paragraphs to all sublicense agreements.
- 4.3 Any sublicenses granted by the Licensee or and any of its Affiliates shall provide for the termination of the sublicense, or the conversion to a license directly between the Sublicensees and the NIAID, at the option of the Sublicensee, upon termination of this Agreement under Article 13. This conversion is subject to the NIAID approval (not to be unreasonably withheld, delayed or conditioned) and contingent upon acceptance by the Sublicensee of the remaining provisions of this Agreement.
- 4.4 The **Licensee** agrees, and will cause its applicable **Affiliate**, to forward to the **NIAID** a true and complete copy of each fully executed sublicense agreement postmarked within thirty (30) days after the execution of such sublicense agreement. To the extent permitted by law, the **NIAID** agrees to maintain each sublicense agreement in confidence, except that the **NIAID** may share each such sublicense agreement with its **Partners**, *provided* the Partners are bound by non-use and non-disclosure obligations that are no less restrictive than those set forth herein.
- 4.5 Notwithstanding any sublicense to any Third Party, ModernaTX, Inc. will remain responsible to the NIAID for the performance of all of the Licensee's and its Affiliates' obligations under, and compliance with, all applicable terms and conditions of, this Agreement, including any obligations delegated to its Sublicensees or with respect to any rights exercised or obligations performed by any Affiliate of ModernaTX, Inc.

- 5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS
- 5.1 The **NIAID** acknowledges that the **Licensee** or its **Affiliate** has provided the **NIAID** with **Licensed Products** or materials made through the **Licensed Processes** for research use.
- 5.2 The **Licensee** (on behalf of itself and its **Affiliates**) agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States unless a written waiver is obtained in advance from the **NIAID**.
- 6. ROYALTIES AND REIMBURSEMENT
- 6.1 The **Licensee** agrees to pay the **NIAID** the noncreditable, nonrefundable Pre-Effective Date Royalties as set forth in Appendix C.
- 6.2 The **Licensee** agrees to pay the **NIAID** a minimum annual royalty as set forth in Appendix C.
- 6.3 The **Licensee** agrees to pay the **NIAID** earned royalties as set forth in Appendix C.
- 6.4 The **Licensee** agrees to pay the **NIAID** Benchmark royalties as set forth in Appendix C.
- No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are within the scope of more than one of the **Licensed Patent Rights**.
- On sales of **Licensed Products** by the **Licensee** or its **Affiliates** or **Sublicensees** 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 the **Licensee** or its **Affiliate** or **Sublicensee** (as applicable) would have received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.
- 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 **NIAID** prior to the date of the final signature to this **Agreement**, the **Licensee** shall pay the **NIAID**, as an additional royalty, within sixty (60) days after the **NIAID**'s submission of a reasonably detailed written statement and request for payment to the **Licensee**, an amount equivalent to a **Pro Rata Share** of the unreimbursed patent expenses previously paid by the **NIAID**. The **Licensee**'s obligation under this Paragraph 6.7 shall not exceed (b)(4) of said unreimbursed expenses previously paid by the **NIAID**.
- 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 **NIAID** on or after the date of the final signature to this **Agreement**, the **NIAID**, in its sole discretion, may require the **Licensee**:
  - (a) to pay the **NIAID** on an annual basis, within sixty (60) days after the **NIAID's** submission of a reasonably detailed written statement and request for payment, a royalty amount equivalent to the **Pro Rata Share** of these unreimbursed expenses paid during the previous calendar year(s);
  - (b) to pay the Pro Rata Share of these unreimbursed expenses directly to the law firm employed by the NIAID to handle these functions. However, in this event, the NIAID and not the Licensee shall be the client of the law firm; or

(c) under exceptional 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, provided that the Licensee shall not have any obligation to assume such responsibility. 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 NIAID with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

The **Licensee**'s obligation under this Paragraph 6.8 shall not exceed (b)(4) of said unreimbursed expenses paid by the **NIAID** on or after the date of the final signature to this **Agreement**.

6.9 The **NIAID** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIAID** has requested payment from the **Licensee** under Paragraphs 6.7 and 6.8. The **Licensee** agrees (on behalf of itself and its **Affiliates**) that all information provided by the **NIAID** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a **Third Party** (other than to the **Licensee's Sublicensee(s)** on a need-to-know basis and as confidential commercial information), except as required by law or a court of competent jurisdiction.

### 7. PATENT FILING, PROSECUTION, AND MAINTENANCE

The **NIAID** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

### 8. RECORD KEEPING

The **Licensee** agrees to keep (and to cause its **Affiliates** and **Sublicensees** to keep) accurate and correct records of **Licensed Products** made, used, sold, offered for sale, imported or exported and **Licensed Processes** practiced under this **Agreement** on or after the **Effective Date** appropriate to determine the amount of royalties due the **NIAID**. 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 **NIAID**, by an independent, certified accountant or other designated auditor selected by the **NIAID** for the sole purpose of verifying reports and royalty payments hereunder. As a condition to examining any records of the **Licensee**, such accountant or auditor must have executed and delivered to the **Licensee** a confidentiality agreement as reasonably requested by the **Licensee**. 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 **NIAID** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.7. All royalty payments required under this Paragraph 8 shall be due within sixty (60) days of the date the **NIAID** provides the **Licensee** notice of the payment due. All such underpayments shall be subject to the interest rate set forth in Paragraph 9.7.

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

- 9.1 Prior to signing this **Agreement**, the **Licensee** or its **Affiliate** has brought the **Licensed Patent Rights** to the point of **Practical Application**. In addition, the **Licensee** has provided the **NIAID** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** (itself or through its **Affiliates**) intends to use commercially reasonable efforts to bring the subject matter of the **Licensed Patent Rights** to additional **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, high-level summary 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, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. The NIAID also encourages these reports to include information on any of the Licensee's or its Affiliates' 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 such differences. In any annual report, the Licensee may propose amendments to the Commercial Development Plan, acceptance of which by the NIAID may not be denied unreasonably. The Licensee agrees, and will cause its Affiliates, to provide any additional information reasonably required by the NIAID to evaluate the Licensee's performance under this Agreement. The Licensee may amend the Benchmarks at any time upon written approval by the NIAID. The NIAID 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 point of Practical Application.

9.3 The **Licensee** shall report to the **NIAID** 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 after such occurrences.

9.4	(D)(4)

9.5 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*, or by another reputable, reliable, industry-recognized source of accurate conversion rates that are not materially different from the conversion rates quoted by *The Wall Street Journal*, on the day that the revenue is recognized by the **Licensee** or its **Affiliates** or **Sublicensees**, as applicable, and 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 **NIAID** at its address for **Agreement** notices indicated on the Signature Page.

- 9.6 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments. The **Licensee** may not deduct or withhold from any amounts payable under this **Agreement** any taxes that it is required by applicable law to deduct or withhold, including from subsequent payments made pursuant to this **Agreement**. In the event that the **Licensee** is required to make any filings with any foreign jurisdiction to avoid being subject to withholding tax in any jurisdiction outside the United States regarding amounts payable based on this **Agreement**, then the **Licensee** shall be directly responsible for the payment of any reasonable and documented expenses of such filings, and shall make payment of such amounts within sixty (60) days following receipt of an invoice and related supporting documentation.
- 9.7 Additional royalties may be assessed by the **NIAID** on any payment payable hereunder that is more than (b)(4) overdue at an annual rate of (b)(4) or the maximum rate allowable by applicable law, whichever is less. This interest rate may be applied retroactively from the original due date until the date of receipt by the **NIAID** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIAID** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.8 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 **NIAID** as commercial and financial information obtained from a person and as privileged and confidential; *provided* that the **NIAID** may share all such plans and reports with its **Partners** on a confidential basis with non-disclosure and non-use obligations at least as restrictive as those set forth herein, and any proposed disclosure of these records by the **NIAID** 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	(b)(4)

- 10.2 The Parties acknowledge and agree that the Licensee has achieved First Commercial Sale, and until the expiration or termination of this Agreement, the Licensee shall use its reasonable commercial efforts to continue to make Licensed Products and Licensed Processes reasonably accessible to the United States public.
- 10.3 The Licensee agrees, to the extent commercially reasonable, to make reasonable quantities of Licensed Products or materials produced through the use of Licensed Processes available to patient assistance programs.
- 10.4 The **Licensee** agrees, 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 extent not already supplied), to the Technology Transfer and Intellectual Property Office, **NIAID**, at the mailing address 5601 Fishers Lane, Suite 6D, Rockville, MD 20852-3804 U.S.A., with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

### 11. <u>INFRINGEMENT AND PATENT ENFORCEMENT</u>

- The **NIAID** 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 that may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either party becomes aware.
- In the event that a declaratory judgment action alleging invalidity of any of the Licensed Patent Rights shall be brought against the NIAID, the NIAID agrees to notify the Licensee that an action alleging invalidity has been brought. The NIAID does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity. Neither the Licensee nor any of its Affiliates shall take any action to compel the Government or the Partners either to initiate or to join in any declaratory judgment action. Should the Government or the Partners be made a party to any declaratory judgment action alleging invalidity of any of the Licensed Patent Rights by motion or any other action of the Licensee or its Affiliate, the Licensee shall reimburse the Government and the Partners for any costs, expenses, or fees, which the Government or the Partners incur as a result of the motion or other action. Upon the Licensee's payment of all costs incurred by the Government and the Partners as a result of Licensee's joinder motion or other action, these actions by the Licensee shall not be considered a default in the performance of any material obligation under this Agreement.

11.3	(b)(4)

- 12. NEGATION OF WARRANTIES AND INDEMNIFICATION
- 12.1 The **NIAID** offers no warranties other than those specified in Article 1.
- 12.2 The **NIAID** does not warrant the validity or enforceability of the **Licensed Patent Rights** and, except as set forth in Article 1, makes no representations or warranties whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be practiced without infringing other patents or other intellectual property rights of **Third Parties**.
- 12.3 EXCEPT AS EXPRESSLY SET FORTH IN ARTICLE 1, THE **NIAID** MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING OF MERCHANTABILITY, NON-INFRINGEMENT 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 LICENSEE ACCEPTS THE LICENSED PATENT RIGHTS AND THE LICENSED PRODUCTS "AS IS", AND THE NIAID DOES NOT OFFER ANY GUARANTEE OF ANY KIND.
- 12.5 The **NIAID** does not represent that it shall commence legal actions against **Third Parties** infringing the **Licensed Patent Rights**.

- 12.6 The **Licensee** shall indemnify and hold the **NIAID**, the **Partners**, and their respective employees, officers, directors, students, fellows, agents, and consultants (collectively, "**Indemnitees**") harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage, in each case to the extent arising out of **Third Party** claims asserted against **Indemnitees** in connection with or arising out of:
  - (a) the use by or on behalf of the Licensee or its Affiliates or Sublicensees, or its and their respective directors, employees or agents, of any Licensed Patent Rights or Licensed Processes;
  - (b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes or materials by or on behalf of the Licensee or its Affiliates or Sublicensees, or its and their respective directors, employees or agents, or other products or processes developed in connection with or arising out of the Licensed Patent Rights; or
  - (c) the Licensee's or its Affiliates' or Sublicensees' gross negligence, or willful misconduct, breach of applicable law, or breach of this Agreement.
    - This Paragraph 12.6 shall not apply if it changes or negatively impacts in any way Licensee's protections under the Public Readiness and Emergency Preparedness Act (Public Law 109–148, Division C, § 2), including any declarations and/or amendments related thereto, or to the extent any such indemnifiable claims result from **NIAID**'s gross negligence.
- 12.7 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice including products liability insurance, with reputable and financially secure insurance carriers (or pursuant to a program of self-insurance reasonably satisfactory to the **NIAID**) to cover its and its **Affiliates**' indemnification obligations.
- 13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS
- When signed by all parties, this **Agreement** will be effective as of the **Effective Date**, 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.
- In the event that the **Licensee** or its **Affiliate** commits a material breach of a covenant or provision under this **Agreement**, and if the breach has not been remedied within ninety (90) days after the date of notice in writing of the default, then the **NIAID** 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 **NIAID** in writing.
- The **Licensee** shall have a unilateral right to terminate this **Agreement** in its entirety by giving the **NIAID** sixty (60) days' written notice to that effect.
- 13.5 The NIAID shall specifically have the right to terminate or modify, at its option, this Agreement, if Licensee:
  - (a) is not executing the Commercial Development Plan set forth on Appendix D and the Licensee cannot otherwise demonstrate to the NIAID's satisfaction that the Licensee has taken, or can be expected to take within a reasonable time, effective steps to achieve Practical Application of the Licensed Products or 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 provision under this **Agreement**, which termination will be pursuant to Section 13.2;
- (e) is not using reasonable commercial efforts to keep Licensed Products or Licensed Processes reasonably available to the public after First Commercial Sale;
- (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 U.S. Federal antitrust laws in connection with its performance under this **Agreement**.

Notwithstanding any provision to the contrary set forth in this Agreement, in consideration for Licensee's activities with respect to the exploitation of **Licensed Products** in the **Licensed Fields of Use** as of the **Effective Date**, the **NIAID** will not have the right to terminate or modify this **Agreement** solely with respect to the **Licensed Fields of Use** as of the **Effective Date** pursuant to the following Paragraphs: 13.5(a), 13.5(b), 13.5(e), or 13.5(f), and NIAID hereby affirms that the **Licensee's** activities with respect to the exploitation of **Licensed Products** in the **Licensed Fields of Use** as of the **Effective Date**, satisfies each of them. Accordingly, **NIAID** will not have the right to terminate or modify this **Agreement** pursuant to those Paragraphs.

- In making the determination whether to terminate or modify this **Agreement** under Paragraph 13.5, the **NIAID** 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 **NIAID** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to cure, the breach of other circumstances referenced in Paragraphs 13.5(a)-13.5(h). If the **Licensee** fails to effect such cure as to the items referenced in Paragraphs 13.5(a)-13.5(h) or fails to initiate corrective action to the **NIAID**'s reasonable satisfaction, then the **NIAID** may terminate this **Agreement**.
- 13.7 The **NIAID** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that the 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**.
- 13.8 Within thirty (30) days after receipt of written notice of the **NIAID**'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 the **NIAID** official. The decision of the designated **NIAID** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within ninety (90) days after 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 expense, due to the NIAID shall become immediately due and payable upon termination or expiration, and the Licensee shall pay all such amounts no later than sixty (60) days after submission of such final report. Unless otherwise specifically provided for under this Agreement, upon termination of this Agreement, (a) all rights and licenses granted to the Licensee and its Affiliates hereunder shall cease and the Licensee and its Affiliates will no longer have a license to sell, offer for sale, distribute, import, export, or manufacture the Licensed Products, except that following the effective date of termination of this Agreement, the Licensee and its Affiliates shall be licensed to continue to sell, offer for sale, distribute, import, and export its existing inventory of the Licensed Products for so long as such product remains in compliance with its specifications, including its expiration date, during which time all sales of the Licensed Product will be included as Net Sales and all payment and reporting terms under this **Agreement** shall continue to apply in full force and effect during such period; and (b) following the expiration of all Licensed Product remaining, as of the effective date of termination of this Agreement, in the Licensee's or its Affiliates' inventory, the Licensee and its Affiliates shall not have any license under this Agreement to sell, offer for sale, distribute, import, and export such expired Licensed Product. The Licensee may not be granted additional NIAID 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 **Licensee** and the **Government** relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **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, then 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.
- 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 Signature Page, or to any other address as may be designated in writing by such other **Party**. **Agreement** notices shall be considered timely if such 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) or to a successor of all or substantially all of Licensee's business to which this Agreement relates, without the prior written consent of the NIAID, not to be unreasonably withheld, delayed or conditioned and any assignment in violation of this Paragraph 14.7 shall be null and void. Any successor or assignee of rights or obligations permitted under this Agreement will, in writing to the other party, expressly assume performance of such rights or obligations. Any permitted assignment of this Agreement will be binding on the successors of the assigning party. Any assignment or attempted assignment by either party in violation of the terms of this Paragraph 14.7 will be null, void, and of no legal effect. 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 except as provided in Article 4 and this Paragraph 14.7. In the event that the NIAID approves a proposed assignment, the Licensee shall pay the NIAID, as an additional royalty, one percent (1%) of the fair market value of any consideration received for such assignment of this Agreement within sixty (60) days after the assignment.
- 14.8 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 materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. The **NIAID** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.9 Neither Party will make any press release or other public statement regarding the terms of this Agreement or the subject matter hereof without the prior written approval of the other **Party**; provided that nothing will restrict either Party from disclosing the existence of this Agreement. After the issuance of any such press release or any other permitted public disclosure by a Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior approval so long as the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein. For clarity, either Party may disclose, and nothing set forth herein will limit either Party from so disclosing, the terms of this Agreement, or the subject matter hereof, (a) to the extent required to comply with the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process; provided that such Party will first provide a copy of the proposed disclosure to the other Party as far in advance of such disclosure as is reasonably practicable under the circumstances and reasonably and in good-faith consider the other Party's comments and requests to limit such disclosure, (b) in connection with any tax filing or grant application, subject to reasonable expectations of confidentiality where practicable, and (c) in connection with any litigation, or congressional request or to comply with any other applicable law or requirement of the Government.
- 14.10 The **Licensee** agrees, and will cause its **Affiliates**, 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 **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **Licensed Patent Rights** in those countries.
- 14.11 By entering into this **Agreement**, the **NIAID** 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, and shall cause its **Affiliates** not to, state or imply that this **Agreement** is an endorsement by the **Government**, the **NIAID**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall, and shall cause its **Affiliates** not to, not use the names of the **NIAID**, the **FDA**, **HHS**, or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIAID**.

- 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.
- 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.
- Paragraphs 2, 3.4, 4.5, 8, 9.4-9.5 (solely with respect to payments due prior to the effective date of termination of this **Agreement** or during any sell-off), 9.6-9.8, 11.2 (except the first sentence thereof), 12.1-12.6, 13.8, 13.9, 14.2, 14.5, 14.6, 14.12 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.
- 14.15 The terms and conditions of this **Agreement** shall, at the **NIAID**'s sole option, be considered by the **NIAID** to be withdrawn from the **Licensee**'s consideration and the terms and conditions of this **Agreement**, and this **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIAID** within sixty (60) days from the date of the **NIAID** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

# NIH PATENT LICENSE AGREEMENT – NONEXCLUSIVE

### SIGNATURE PAGE

For the **NIAID**:

Michael R. Mowatt -S Digitally signed by Michael R. Mowatt -S Date: 2022.12.14 16:51:57 -05'00'

Michael R, Mowatt, PhD

Date

Director

Technology Transfer and Intellectual Property Office, NIAID 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 6701 Rockledge Dr., Ste 700 Bethesda, Maryland 20892-7788 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: (b)(6)	14 December 2022
Signature of Authorized Official	Date
Shannon Klinger	
Printed Name	
Chief Legal Officer	
Title	

Official and Mailing Address for Agreement notices:

Shannon Klinger
Chief Legal Officer
200 Technology Square
Cambridge, MA 02141
P: (b)(6)
E-mail: (b)(6)

Official and Mailing Address for Financial notices:

Christoph Brackmann
Senior Vice President, Finance
200 Technology Square
Cambridge, MA 02141
Email: (b)(6)

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

### APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

### Patent(s) or Patent Application(s):

US Provisional Patent Application 62/412,703 filed 25 October 2016 entitled "Prefusion coronavirus spike proteins and their use" [HHS Ref. No. E-234-2016-0-US-01]

PCT Patent Application PCT/US2017/058370 filed 25 October 2017 entitled "Prefusion coronavirus spike proteins and their use" [HHS Ref. No. E-234-2016-1-PCT-01]

EP Patent Application 17800655.7 filed 13 May 2019, entitled "Prefusion coronavirus spike proteins and their use" [HHS Ref. No. E-234-2016-1-EP-02]

US Patent Number 10,960,070 issued 30 March 2021 entitled "Prefusion coronavirus spike proteins and their use" [HHS Ref. No. E-234-2016-1-US-03]

US Patent Application 17/194,834 filed 8 March 2021 entitled "Prefusion coronavirus spike proteins and their use" [HHS Ref. No. E-234-2016-1-US-04]

### APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

1.	Licensed Fields of Use:
(b)(4)	
II.	Licensed Territory:
(b)(4)	
III.	<b>Least Developed Countries:</b>

Africa (34): Angola, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Rwanda, São Tomé and Príncipe, Senegal, Sierra Leone, Somalia, South Sudan, Togo, Uganda, United Republic of Tanzania, Zambia

**Asia (14):** Afghanistan, Bangladesh, Bhutan, Cambodia, Kiribati, Lao People's Democratic Republic, Myanmar, Nepal, Samoa, Solomon Islands, Timor-Leste, Tuvalu, Vanuatu, Yemen

Latin America and the Caribbean (1): Haiti

(Source: United Nations Office of the High Representative (UN-OHRLLS) as of October 23, 2013.)

# APPENDIX C - ROYALTIES

yalı	ties:
.)	
	(b)(4)
	(b)(4) the <b>Licensee</b> agrees to pay to the <b>NIAID</b> a noncreditable, nonrefundable royalty in the amount of Four Hundred Million dollars (\$400,000,000) (b)(4)
	(b)(4)
	The Licensee agrees to pay to the NIAID a nonrefundable minimum annual royalty as follows:
	(b)(4)
	The <b>Licensee</b> agrees to pay the <b>NIAID</b> earned royalties on <b>Net Sales</b> of <b>Licensed Products</b> in the <b>Licensed Territory</b> by or on behalf of the <b>Licensee</b> or its <b>Affiliates</b> and any of its or their <b>Sublicensees</b> a follows:
	(b)(4)

(b)(4)	

	(b)(4)
	(b)(4)
	(b)(4) the <b>Licensee</b> agrees to pay the <b>NIAID</b> the <b>Benchmark</b> royalties set forth below (b)(4)
	(b)(4)
	Control to the second will be described in inter (CO) does from binding on both and Providence of
	Such royalty payment will be due within sixty (60) days after achieving each such <b>Benchmark</b> .
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(b)(4)		

# <u>APPENDIX D – BENCHMARKS AND PERFORMANCE</u>

The **Licensee** agrees to use commercially reasonable efforts to achieve the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days after achieving a **Benchmark**, shall notify the **NIAID** that the **Benchmark** has been achieved:

(b)(4); (b)(3):35 U.S.C. § 209(f)		

# APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

4); (b)(3):35 U.S.C. § 209(f)

### 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 on a Licensed Product by Licensed Product and country by country basis
- 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	В	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

New Payment Options Effective March 2018

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 \$24,999. 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 **NIAID** 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 **NIAID** "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:

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
Tield Tag		
{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 #) <b>875080031006</b>
{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
{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 financi	al institution address for Treasury's routing number	r is 33 Liberty Street, New York, NY 10045.

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a foreign 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}	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
{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:

<sup>\*</sup>The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.

<sup>\*\*</sup>Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: FRNYUS33** 

### **Agency Contacts**:

Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

### Checks

All checks should be made payable to "NIH Patent Licensing"

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

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 6701 Rockledge Drive Suite 700, MSC 7788 Bethesda, Maryland 20892

# APPENDIX H – EXAMPLE ROYALTY CALCULATION

### **Certificate Of Completion** Envelope Id: 93D994299BD84E55A14B60F3635F42C1 Status: Completed Subject: Complete with DocuSign: NIH License Agreement for Countersignature\_A-286-2020.pdf Source Envelope: Document Pages: 33 Signatures: 1 Envelope Originator: Certificate Pages: 1 Initials: 0 Melanie Barber AutoNav: Enabled 200 Technology Square Cambridge, MA 02141 Envelopeld Stamping: Enabled (b)(6)Time Zone: (UTC-05:00) Eastern Time (US & Canada) IP Address: (b)(6) **Record Tracking** Status: Original Holder: Melanie Barber Location: DocuSign 12/14/2022 5:24:40 PM (b)(6)Signer Events Signature **Timestamp** DocuSigned by Shannon Klinger Sent: 12/14/2022 5:27:46 PM (b)(6) Viewed: 12/14/2022 6:52:28 PM Chief Legal Officer Signed: 12/14/2022 6:52:42 PM Security Level: Email, Account Authentication Signature Adoption: Pre-selected Style (None) Using IP Address: (b)(6) Signed using mobile Electronic Record and Signature Disclosure: Not Offered via DocuSign In Person Signer Events Signature **Timestamp Editor Delivery Events Status** Timestamp **Agent Delivery Events Status Timestamp Intermediary Delivery Events Status Timestamp Certified Delivery Events Status Timestamp Carbon Copy Events Status Timestamp** Sent: 12/14/2022 6:52:52 PM Jimmy Cao COPIED (b)(6) Viewed: 12/14/2022 6:56:51 PM Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign Witness Events Signature **Timestamp Notary Events** Signature **Timestamp Envelope Summary Events Status Timestamps**

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Security Checked

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Security Checked

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12/14/2022 5:27:46 PM

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12/14/2022 6:52:42 PM

12/14/2022 6:52:52 PM

**Timestamps** 

**Envelope Sent** 

Completed

Certified Delivered

Signing Complete

**Payment Events**