EX-10.1 2 ex_208661.htm EXHIBIT 10.1

EXHIBIT 10.1

Patent and Biological Materials License Agreement with the National Institute of Allergy and Infectious Diseases, dated October 22, 2020

Certain information as identified herein has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT NONEXCLUSIVE

and

BIOLOGICAL MATERIALS LICENSE AGREEMENT

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

National Institute of Allergy and Infectious Diseases an Institute or Center (hereinafter referred to as the "**IC**") of the

NIH

and

GeoVax, Inc.,

hereinafter referred to as the "**Licensee**",

having offices at

1900 Lake Park Dr., Ste. 380

Smyrna, Georgia 30080

created and operating under the laws of Georgia, United States.

Tax ID No.: 58-2646816

For the **IC's** internal use only:

License Number: L-257-2020-0

License Application Number: A-409-2020

Serial Number(s) of Licensed Patent(s) or Patent Application(s): see Appendix A

Licensee: GeoVax, Inc.

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

Additional Remarks: n/a

Public Benefit(s): Preventive Modified Vaccinia Ankara Virus-Virus Like Particle (MVA-VLP) vaccine primes and/or boosters against -"SARS-CoV-2.".

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 (tangible materials, Licensed Fields of Use and Licensed Territory), Appendix C (Royalties), Appendix D ((Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Royalty Reporting), 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, including intellectual properties and tangible materials, that may have commercial applicability.

1.2 By assignment of rights from the **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**, regardless of whether patents or patent applications claiming the **Materials** exist.

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 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 CFR Part 404.

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 any corporation or other business entity in which **Licensee** owns or controls, directly or indirectly, at least fifty percent (50%) of the voting rights or other ownership interest or is entitled to elect more than fifty percent (50%) of directors. In any country where the local law does not permit foreign equity participation of at least fifty percent (50%), then "**Affiliate**" means any company in which **Licensee** owns or controls, directly or indirectly, the maximum percentage of outstanding stock or voting rights that is permitted by local law.

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

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

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

2.7 "**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 all these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.7(a):

(i) continuations-in-part of 2.7(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 2.7(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 2.7(a): all counterpart foreign and U.S. patent applications and patents to 2.7(a) and 2.7(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.7(b) or 2.7(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.7(a).

2.8 "**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.

2.9 "**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. For the sake of clarity, vaccine primes and/or boosters incorporating **Materials** (or functional components of such) described in Appendix B are considered **Licensed Products**.

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

2.11 "**Materials**" means

(a) tangible materials, identified in Appendix B, including progeny, subclones, unmodified derivatives, fractions, or components isolated therefrom, whether or not within the scope of the claims of the **Licensed Patent Rights**;

(b) other 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;

(c) modifications created by **Licensee** that contain or incorporate any of the tangible materials identified in Paragraph 2.11(a) and 2.11(b) above.

2.12 "**Net Sales**" means the total gross amounts invoiced or otherwise charged (whether consisting of cash or any other form of consideration) for the **Final Sale** of **Licensed Products** to **Customers** by or on behalf of the **Licensee** or any **Affiliate**, less the following deductions (to the extent included in and not already deducted from the gross amount invoiced or otherwise charged) to the extent reasonable and customary and if separately invoiced: (a) wholesaler or trade quantity discounts actually granted to **Customers**; and (b) credits to **Customers** because of rejections or returns (specifically excluding any allowances for bad debt). Without prior approval of **IC**, total deductions for the calculation of **Net Sales** shall not exceed four (4) percent of the total gross amounts invoiced or otherwise charged. Where **Licensee** or any **Affiliate** is the **Customer**, the **Net Sales** shall be based on the gross amount normally invoiced or otherwise charged to other **Customers** in an arms-length transaction for such **Licensed Products**. For the avoidance of doubt, if **Licensee** or any **Affiliate** supplies (directly or indirectly) a product that constitutes of **Licensed Product** to any **Affiliate**, and such **Affiliate** includes such product in another product, then **Net Sales** shall be based on the total gross amount invoiced or otherwise charged for such other product in its entirety. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or any **Affiliate** and on its payroll, or for the cost of collections.

2.13 "**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.

2.14 "**Customer**" means any individual or entity that receives **Licensed Product(s)**, provided however, that **Licensee**, or any **Affiliate** shall be deemed a **Customer** only if it receives **Licensed Product(s)** for its own end-use and not resale.

2.15 "**Effective Date**" means the first date when both **IC** and **Licensee** have signed this **Agreement**.

2.16 "**Fair Value**" means the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; for the calculation of assignment royalty, the measurement date for **Fair Value** shall be the date when all parties to the assignment have signed the assignment.

2.17 "**Final Sale**" means any sale, transfer, lease, exchange or other disposition or provision of a **Licensed Product** to a **Customer**. A **Final Sale** shall be deemed to have occurred upon the earliest to occur of the following (as applicable): (a) the transfer of title to such **Licensed Product** to a **Customer**; (b) the shipment of such **Licensed Product** to a **Customer**; (c) the provision of an invoice for such **License Product** to a **Customer**; or (d) payment by the **Customer** for **Licensed Product(s)**.

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

2.19 "**Third Party**" or "**Third Parties**" means a party or parties other than **IC**, on the one hand, or **Licensee** or its **Affiliate(s)**, on the other hand.

2.20 "**Average Price**" means, on a **Licensed Product**-by-**Licensed Product** and country-by-country basis, the total gross sales of a particular **Licensed Product** in a particular country during a particular calendar year divided by the total doses of such **Licensed Product** sold in such country during such calendar year.

2.21 "**Valid Claim**" means a claim of an issued and unexpired patent that is in force included within the **Licensed Patent Rights** which has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction (which decision is not appealable or has not been appealed within the time allowed for appeal), and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

2.22 "**Pro Rata Share**" means one of the following:

(a) in instances where the **Additional Coronavirus-Spike License(s)** granted by **NIAID** recover a predetermined percentage of patent costs, **Pro Rata Share** will mean one hundred percent (100%) of patent prosecution costs minus the percentage of patent prosecution costs recovered by the **Additional Coronavirus-Spike License(s)** which recover a pre-determined percentage of patent costs. For example, if **NIAID** has granted an **Additional Coronavirus-Spike License** which 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 Coronavirus-Spike License(s)** granted by **NIAID** recover a full **Pro Rata Share** of patent prosecution costs, **Pro Rata Share** will mean one (1) minus the value derived from the number of **Additional Coronavirus-Spike License(s)** granted by **NIAID** which recover a full **Pro Rata Share** of patent prosecution costs divided by the total number of licenses granted by **NIAID** which recover a full **Pro Rata Share** of patent prosecution costs. For example, if **NIAID** has granted four (4) **Additional Coronavirus-Spike Licenses** which 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

(c) instances where the **Additional Coronavirus-Spike License(s)** are granted according to the definition of both 2.22a) and 2.22(b), the **Pro Rata Share** paid by **Licensee** will be the value derived from the **Pro Rata Share** as determined under paragraph 2.22(a) multiplied by the value derived from the **Pro Rata Share** as determined under paragraph 2.22(b). For example, if two (2) **Additional Coronavirus-Spike Licenses** are granted wherein one (1) **Additional Coronavirus-Spike License** recovers twenty percent (20%) of patent prosecution costs and one (1) **Additional Coronavirus-Spike 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%).

2.23 "**Additional Coronavirus-Spike License**" means an exclusive or nonexclusive license that includes the **Licensed Patent Rights** associated with the E-234-2016 and E-086-2020 technologies as described in Appendix A of this **Agreement (**the **"Coronavirus-Spike 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 **Licensed Field of Use** directed to therapeutic applications. **Additional Coronavirus-Spike License** specifically excludes license directed solely to evaluation, internal research use or commercialization of research agents.

3. GRANT OF RIGHTS

3.1 The **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive 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 Processes** in the **Licensed Fields of Use**. For the sake of clarity, the **Licensee** has no right to sell, transfer or otherwise distribute **Materials** that are not incorporated as a component of a vaccine prime and/or booster **Licensed Product** in combination with **Licensee's** proprietary technology.

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**.

3.3 **Materials** have been previously provided to **Licensee** under transfers separate from this **Agreement**. Upon request, and upon 1) receipt by **IC** of the license issue royalty and the pro-rated first year minimum annual royalty, 2) verification of these royalty payments, and 3) confirmation of **Licensee's** shipping carrier and account number to be used for shipping purposes**, IC** agrees to replace these **Materials**, as available, at reasonable cost, in the event of the unintentional destruction of such **Materials**. **IC** shall provide any such **Materials** to **Licensee** at **Licensee's** expense.

4. SUBLICENSING

4.1 The **Licensee** has no right to sublicense.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **IC** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for the **IC's** research use.

5.2 The **Licensee** 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 **IC**.

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 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 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.

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

6.7 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 additional royalties, within sixty (60) calendar days of the **IC's** submission of a statement and request for payment to the **Licensee**, an amount of royalties as set forth in Appendix C of this **Agreement**.

6.8 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 Paragraph 6.7. 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.

6.9 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to the **IC** and owe no payment obligation under Paragraph 6.7 for patent-related expenses paid in that country after the effective date of the written notice.

6.10 NO ROYALTIES SHALL BE PAID WITH FUNDS STEMMING FROM ANY FEDERAL CONTRACT, GRANT, OR COOPERATIVE AGREEMENT.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 The **IC** 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

8.1 The **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due to the **IC**. These records shall be retained for the term of this **Agreement** and for at least five (5) years from the last day of the final 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.

8.2 If an inspection shows an underreporting or underpayment of royalties due to the **IC** 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 9.6. All royalty payments required under this Paragraph shall be due within sixty (60) calendar days of the date the **IC** provides notice to the **Licensee** of the payment due.

8.3 **Licensee** agrees to conduct, or to arrange and pay for the cost of, an independent self-audit of sales and royalties at least every two (2) years if annual sales of **Licensed Product** are over Five Million Dollars ($5,000,000). The audit will address, at a minimum, the amount of gross sales by or on behalf of **Licensee** or any **Affiliate** during the audit period, the amount of funds owed to **IC** under this **Agreement**, and whether the amount owed has been paid to **IC** and is reflected in the records of **Licensee**. **Licensee** will submit the auditor's report promptly to **IC** upon completion. **Licensee** will pay for the entire cost of the audit.

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

9.1 *Annual Reporting***.** 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** and **Materials** 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.

(a) The **Licensee** shall provide to **IC** written annual progress 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) calendar days after December 31 of each calendar year. These progress reports shall be signed by an officer of **Licensee** and shall include, but not be limited to, at least the following topics:

(i) summary of work completed;

(ii) key scientific discoveries;

(iii) summary of work in-progress on research and development, status of applications for regulatory approvals, manufacture;

(iv) current schedule of anticipated events or **Benchmarks**;

(v) market plans for introduction of **Licensed Product(s)**; and

(vi) status of marketing, importing, and total **Net Sales** during the preceding calendar year as well as, plans for the present calendar year.

(b) The **IC** also encourages **Licensee** to include in progress reports information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights** and **Licensed Products**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for such differences. **Licensee** agrees to provide any additional information reasonably required by the **IC** to evaluate **Licensee's** performance under this **Agreement**.

(c) *Commercial Development Plan Amendments.* In any annual report, the **Licensee** may propose amendments to the **Commercial Development Plan** and **Benchmarks**. The **IC** shall not unreasonably withhold approval of any request of the **Licensee** to amend the **Commercial Development Plan** or **Benchmarks** if **Licensee's** 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**. At **IC's** discretion, amendments to change the **Commercial Development Plan** or **Benchmarks** (or both) may include amendment royalties. In determining whether or not to impose an amendment royalty, **IC** shall consider in good faith any information provided by **Licensee** demonstrating that a performance delay is due to inaction or delayed action by a regulatory agency and not by inaction or intentional or avoidable action by **Licensee**.

9.2 The **Licensee** shall report to the **IC** the date of achievement of each **Benchmark** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) calendar days of such occurrence.

9.3 *Semi-annual Sales Reports*. Following the date of the **First Commercial Sale**, **Licensee** must submit to the **IC**, within sixty (60) calendar days after each calendar half-year ending June 30 and December 31, a written sales report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold 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 sales report, the **Licensee** shall submit payment of earned royalties due for that reporting period. If no earned royalties are due to the **IC** for any reporting period, the written report shall so state. The sales report shall be certified as correct by an authorized officer of the **Licensee** and shall include the information identified in Appendix F and shall make clear the following information:

(a) gross receipts from **Final Sales** of **Licensed Products** for which an earned royalty is payable under Paragraph 6.3;

(b) any deductions from gross receipts used to arrive at **Net Sales**; and

(c) **Licensee's** computation of the aggregate earned royalties payable to **IC**. **Licensee** agrees to provide a copy of sales report information in electronic spreadsheet format (e.g., Microsoft Excel) when submitting sales reports by electronic mail.

9.4 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. **Licensee** shall pay any loss of exchange, value, taxes, bank charge, or other expense incurred in the transfer of or conversion to U.S. dollars. The royalty reports required by Paragraph 9.3 shall be mailed to the **IC** at its address for **Agreement** Notices indicated on the Signature Page.

9.5 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall promptly pay this tax and be responsible for all filings with appropriate agencies of foreign governments. **Licensee** will use its best efforts to furnish **IC** with proof of payment of any tax. **IC** shall cooperate in good faith with **Licensee** for the purposes of tax obligations and filing of exemption and credit recovery paperwork.

9.6 For each royalty payment not received by **IC** when due, **Licensee** must pay to **IC** as an additional royalty, if assessed by the **IC**, a compound interest charge of one percent (1%) per month, to be calculated from the date payment was due until the date payment is actually received by **IC**. The payment of any additional royalties incurred under this Paragraph 9.6 shall not prevent the **IC** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.7 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 CFR §5.65(d).

9.8 With each report submitted to **IC** under this Article 9, **Licensee** shall provide the name, mailing address, telephone number and email address of **Licensee's** current Official for financial notices and for **Agreement** notices, if such individual is not the person listed on the Signature Page.

10. PERFORMANCE AND DILIGENCE OBLIGATIONS

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **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.

10.2 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of **Licensed Products** available to patient assistance programs in the **Licensed Territory**, to the extent commercially reasonable and without otherwise harming the business interests or viability of **Licensee**.

10.3 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**.

10.4 The **Licensee** agrees to supply, to the Office of Technology Transfer, **NIH** and Technology Transfer and Intellectual Property Office (TTIPO), **NIAID** with inert samples of the **Licensed Products** or **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 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against the **IC**, the **IC** agrees to notify the **Licensee** that an action alleging invalidity has been brought. The **IC** agrees to discuss in good faith with the **Licensee** regarding defending any such declaratory judgement action, and the cost of such defense, but for the sake of clarity the **IC** does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity nor shall any discussion bind the **IC** to commence legal action. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. 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. Upon the **Licensee's** payment of all costs incurred by the **Government** as a result of the **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**.

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** or **Materials** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** or **Materials** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **IC** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY **MATERIALS** OR 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**, any **Affiliate(s)**, its directors, employees, or third parties of any **Licensed Patent Rights**, **Licensed Products** or **Materials**; 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 14.14 are not fulfilled, and shall extend on a country-by-country basis to the later of (a) twenty (20) years from the **First Commercial Sale** where no **Licensed Patent Rights** exist or have ceased to exist, or (b) 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** (or its **Affiliate(s)**) 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) calendar 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** completely or in any country of the **Licensed Territory** by giving the **IC** sixty (60) days written notice to that effect.

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

(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 **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.1;

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

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

(d)

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

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

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

(h) has not provided timely annual progress or semi-annual royalty reports to **IC** under Article 9; or

(i) has not made timely royalty payments to **IC** under Article 6.

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 9.3. 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 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 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) calendar 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 CFR §404.11, appeal the decision by written submission to the designated the **IC** official. The decision of the designated **IC** 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) calendar 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 expense, due to the **IC** shall become immediately due and payable upon termination or expiration.

13.10 Unless otherwise specifically provided for under this **Agreement**, within thirty (30) calendar days of termination, cancellation or expiration of this **Agreement**, the **Licensee** shall return all **Materials**, **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **IC** or provide the **IC** with written certification of the destruction thereof. The **Licensee** may not be granted additional **HHS** 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 **Materials**, **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**, 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 or 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)** 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 within sixty calendar (60) days of the assignment execution, one percent (1%) of the **Fair Value** of any consideration received for any assignment of this **Agreement**. **Licensee** shall provide **IC** with a copy of any executed assignment agreement. The **Licensee** agrees in its use of any **IC**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including the **NIH** and the **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 CFR Part 50 and 45 CFR 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.

14.8 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 **IC** neither represents that a license is or is not required or that, if required, it shall be issued.

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

14.10 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**, **NIH**, **FDA** or **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **IC**.

14.11 **Licensee** and **IC** 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 the **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.

14.12 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 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.13 Paragraphs 6.5, 6.10, 8.1, 8.2, 9.5-9.7, 12.1-12.5, 13.2, 13.8, 13.9, 13.10, 14.11, 14.12, 14.13 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.

14.14 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) calendar days from the date of the **IC** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT NONEXCLUSIVE and BML

SIGNATURE PAGE

For the **IC**:

_____ _____ _____

Michael R. Mowatt, Ph.D. Date
Director
Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases
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:

_____ _____

Mr. David A. Dodd Date
Chairman and CEO
GeoVax, Inc.
1900 Lake Park Drive
Suite 380
Smyrna, GA 30080
ddodd@geovax.com

Mr. David A. Dodd

Chairman and CEO

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

Mr. David A. Dodd
Name

Chairman and CEO
Title

Mailing Address

1900 Lake Park Drive
Suite 380
Smyrna, GA 30080

Email Address: ddodd@geovax.com

Phone: 678-384-7222 (office); 864-290-9114 (mobile)

Fax: N/A

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

Mr. David A. Dodd
Name

Chairman and CEO
Title

Mailing Address

GeoVax, Inc.

1900 Lake Park Dr. Suite 380

Smyrna, Georgia 30080

Email Address: ddodd@geovax.com

Phone: 678-384-7222 (office); 864-290-9114 (mobile)

Fax: N/A

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):

I. E-552-1982 technology:

HHS Ref. No.	Territory	Application No.	Patent No.
E-552-1982-2-US-03	United States	07/987,546	7045313
E-552-1982-2-US-04	United States	08/470,357	7015024
E-552-1982-2-US-06	United States	08/470,360	6998252
E-552-1982-2-US-05	United States	08/470,359	7045136

II. E-018-2010 technology:

HHS Ref. No.	Territory	Application No.	Patent No.
E-018-2010-0-AU-03	Australia	2010306559	2010306559
E-018-2010-0-CA-04	Canada	2777744	2777744
E-018-2010-0-EP-05	European Patent	10771611	2488649, validated in DE, DK, FR, GB, NL
E-018-2010-0-IN-06	India	4311/DELNP/2012	**presently pending*
E-018-2010-0-JP-07	Japan	2012-534414	5789263
E-018-2010-0-US-08	United States	13/502,205	9,133,480
E-018-2010-0-ZA-09	South Africa	2012/03551	2012/03551
E-018-2010-0-US-10	United States	14/837,382	9,879,231
E-018-2010-0-PCT-02	PCT	PCT/US2010/052929	*expired*
E-018-2010-0-US-01	United States	61/252,326	*converted*

III. E-248-2006 technology:

HHS Ref. No.	Territory	Application No.	Patent No.
E-248-2006-0-EP-03	European Patent	07874019.8	07874019.8, validated in BE, CH, DE, DK, ES, FR, GB, IE, IT, NL
E-248-2006-0-IN-04	India	1535/DELNP/2009	281791
E-248-2006-0-US-05	United States	12/377,847	9,133,478
E-248-2006-0-CN-06	China	200780035385.3	200780035385.3
E-248-2006-0-EP-07	European Patent	11183527.8	11183527.8, validated in DE, DK, ES, FR, GB, NL
E-248-2006-0-CN-18	China	2013100549071	2013100549071
E-248-2006-0-US-19	United States	14/833,913	10,421,978
E-248-2006-0-CN-20	China	201610183481.3	**presently pending*
E-248-2006-0-US-26	United States	16/579,276	**presently pending*
E-248-2006-1-PCT-02	PCT	PCT/US2007/076829	*expired*
E-248-2006-0-PCT-02	PCT	PCT/IB2007/004575	*expired*
E-248-2006-1-US-01	United States	60/840,755	*converted*
E-248-2006-0-US-01	United States	60/840,093	*converted*

IV. E-234-2016 technology:

HHS Ref. No.	Territory	Application No.	Patent No.
E-234-2016-1-EP-02	European Patent	17800655.7	*presently pending
E-234-2016-1-US-03	United States	16/344,774	*presently pending
E-234-2016-1-PCT-01	PCT	17800655.7	expired
E-234-2016-0-US-01	United States	62/412,703	converted

V. E-086-2020 technology:

HHS Ref. No.	Territory	Application No.	Patent No.
E-086-2020-0-US-01	United States	62/972,886	*presently pending

APPENDIX B – TANGIBLE MATERIALS, LICENSED FIELDS OF USE AND TERRITORY

I. **Tangible Materials:**

(a) plasmid shuttle vector pLW-76 (as described by **HHS** reference number E-018-2010/0).

(b) plasmid shuttle vector pLW-73 (as described by **HHS** reference number E-248-2006/0).

II. **Licensed Fields of Use:**

(a) development and use of **Licensed Patent Rights** and **Materials** in combination with **Licensee's** proprietary technology for the creation of a preventive Modified Vaccinia Ankara Virus-Virus Like Particle (MVA-VLP) vaccine primes and/or boosters against -"SARS-CoV-2."

III. **Licensed Territory:**

(a) Worldwide.

APPENDIX C – ROYALTIES

[This appendix has been redacted in its entirety]

APPENDIX D – BENCHMARKS AND PERFORMANCE

[This appendix has been redacted in its entirety]

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

Commercial Market and Commercialization Plans

The anticipated relevant commercial market consists primarily of government agencies and health organizations purchasing for at risk worldwide populations of contracting COVID-19, which at this time is nearly universal due to the fluid epidemiological nature of this virus.

GeoVax anticipates that there will be multiple COVID-19 vaccines successfully developed and licensed for use. Depending on the eventual epidemiology of COVID-19, there may be need for ongoing Product supply and support or the dynamics may dictate more of a public health stockpile/replenishment business model. Regardless, GeoVax management is highly experienced in successful management of Product acceptance and supply in either situation.

Eventual market acceptance, penetration and competitive market share will be a function of the attributes of the Product (e.g., single-dose; durability; efficacy; stability; cost, etc.) that is demonstrated via the product development process. In addition, order of market entry will be a factor in market use and market share attained. GeoVax is focused on rapidly developing the Product, advancing into animal testing as soon as possible, then into clinical development, advancing to regulatory licensure. Upon regulatory licensure, GeoVax anticipates Product commercialization within three months, having minimized the interim commercial-planning period between regulatory submission decision and licensure.

Following successful completion of Phase 2 clinical development, GeoVax will establish secure commercial distribution and supply chain agreements/relationships to enable eventual commercialization and Product supply across global territories. GeoVax management has extensive experience in establishing and successfully managing a combination of internal and such external commercial/distribution relations throughout Europe, Africa, South America and the Asia/Pacific region.

Eventual sales derived from the Product commercialization will result from several factors, including those previously noted: Product differentiation/performance attributes; order of market entry; COVID-19 epidemiology and dynamics; manufacturing costs; and, Product pricing. All such commercial-related factors will be evaluated, along with other factors that may be specific to differing governmental territories, healthcare systems, etc., during the Product development process. Current information suggests that a COVID-19 vaccine will be utilized throughout the world, but critical epidemiologic dynamics remain uncertain.

GeoVax will focus priority effort on ensuring broad access to the COVID-19 vaccine, following a model of achieving marginal profit, recognizing the critical need to ensure widespread access and benefit from the anticipated COVID-19 vaccine. Further commercial and market-related information will continue to evolve, providing an ongoing basis to refine the specific market parameters such as (a) number of relevant patients (US and worldwide), (b) utilization of Product (ongoing or episodic), (c) differentiation of Product versus competitive products (re market acceptance and penetration) and other critical commercial parameters.

Clinical Development and Regulatory Plans

Toxicology:

Toxicology testing is absent from our project plan. We had an Initial Targeted Engagement for Regulatory Advice on CBER products (INTERACT) meeting on May 15, 2020 with the FDA in which we discussed our overall development plan and our proposal to omit animal toxicity testing in light of the proven safety profile of MVA as a vaccine platform. Acknowledging the previous safety experience available for MVA-based vaccine platforms, the FDA concurred that no additional non-clinical and toxicology studies will be required, provided that the immune response to the ultimately chosen GeoVax vaccine construct is adequately assessed in appropriate animal models.

Clinical:

As described below under Regulatory Path, our development program is geared toward Emergency Use Authorization (EUA) readiness. To generate the human safety and immunogenicity data required for an EUA, we will propose a Phase 1a/1b trial to FDA. The final design of the clinical trial will be determined in discussions with FDA, most importantly the Pre-IND meeting. Our draft design for this study, which can be completed in approximately four months (excluding follow-up phase), calls for a Phase 1a dose-ranging study in approximately 40 volunteers (three vaccine groups and one placebo group; 10 participants per group). Assuming that safety endpoints are met, we will choose a single dose from the dose-ranging study and test it in Phase 1b in approximately 150 volunteers (100 in vaccine group, 50 in placebo group). With this Phase 1a/1b trial, we expect to obtain adequate data to enable use of the vaccine under an EUA.

In the Phase 1a/1b Clinical Trial, we will obtain safety and immunogenicity data in healthy normal volunteers. An abbreviated synopsis for this clinical trial is provided in the table below. Our trial is designed to provide initial data on safety, tolerability, and immunogenicity and to identify an optimal regimen in Phase 1a and then to obtain additional data in a larger, more diverse population in Phase 1b to enable use of our vaccine under an EUA.

Abbreviated Clinical Trial Synopsis				
Group	**N**	**Vaccine (target virus)**	**Dose (TCID50)**	**Regimen**
Phase 1a (Single Site, Healthy Normal Volunteers)				
1	15	GEO-SARS-CoV2	1×10^7	Single dose (day 0)
2	15	GEO-SARS-CoV2	3×10^7	Single dose (day 0)
3	15	GEO-SARS-CoV2	1×10^8	Single dose (day 0)
4	15	GEO-SARS-CoV2	1×10^8	Prime-boost (days 0 & 28)
6	15	Placebo	-	Prime-boost (days 0 & 28)
Phase 1b (Multiple Sites, Healthy Normal Volunteers)				
7	150	GEO-SARS-CoV2	Determined based on results of Phase 1a	
8	50	Placebo	Determined based on results of Phase 1a	
Measurements				
Standard safety and tolerability assessments, binding antibody, neutralizing antibody, T-cell responses				

The Phase 1a/1b strategy is our preferred strategy, but we will present plans for Phase 1 and Phase 2 studies to be implemented if FDA does not accept Phase 1a/1b as adequate to enable an EUA. Planning for the Phase 1 study will commence during Q4 2020, working in conjunction with clinical advisors and seeking input from the FDA. Management of the clinical development program and requisite regulatory support will be performed by TRI (Technical Resources International), a highly experienced Contract Research Organization with experience supporting ~800 vaccine studies, extensive knowledge of clinical trial management and regulatory relative to vaccine development and registration.

The Phase 1 study is anticipated to include between 30-50 patients across 3-5 sites within the U.S. The Phase 2 and Phase 3 clinical programs will be designed in conjunction with input from the FDA, assistance from TRI and input from internal clinical advisors and staff. Planning for the Phase 2 program is anticipated to begin during Q4 2021, although informal planning and design of the study will begin earlier. The Phase 2 study is anticipated to include approximately 100-200 patients utilizing 10-20 sites in the U.S., however, depending on which of the GeoVax COVID-19 vaccines advances to clinical development, the protocol will be appropriately modified and designed to support the Phase 2 study relative to that respective vaccine.

Upon successful completion of the Phase 2 program, FDA will be consulted relative to clinical protocol design requirement for the Phase 3 program. Typically, a Phase 3 study for an infectious disease vaccine includes a minimum of ~5,000 participants, but can include as high as 30,000+. Should the Phase 3 COVID-19 candidate vaccine be the design relative to very high-risk, immunocompromised populations, the study design would include fewer patients, using a stratified cohort design. The first dosing of a patient in the Phase 3 program is expected to occur by December 1, 2023 with submission of the BLA targeted by June 1, 2025. Regulatory approval is anticipated to occur by June 1, 2026, with anticipated commercialization and market entry scheduled to occur within three months of regulatory approval. Throughout the clinical development program, including the design and planning periods, interaction and input from FDA will be sought, as well as ongoing involvement of highly recognized clinical experts within the infectious disease vaccine industry.

Regulatory Path:

It is unclear whether 2019-nCoV will persist as a pathogen, like influenza, or will be contained, like SARS. Anticipating the former, our focus is on bringing the vaccine to the point of readiness for use under an EUA, the regulatory process by which the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

To minimize the time required to obtain an EUA, we will engage with FDA early and often in the development process for our vaccine. We had an Initial Targeted Engagement for Regulatory Advice on CBER products (INTERACT) meeting on May 15, 2020 with the FDA in which discussed our overall development plan and our proposal to omit animal toxicity testing in light of the proven safety profile of MVA as a vaccine platform. Acknowledging the previous safety experience available for MVA-based vaccine platforms, the FDA concurred that no additional non-clinical and toxicology studies will be required, provided that the immune response to the ultimately chosen GeoVax vaccine construct is adequately assessed in appropriate animal models.

As soon as process development and animal studies have generated clear data on the performance of the vaccine, we will present our plans for first-in-human clinical testing to FDA in a Pre-IND meeting. When our Phase 1 clinical trial material has been produced and all IND-enabling studies have been completed, we will file an IND to enable initiation of clinical trials. During our clinical trials and in consultation with FDA, we will produce vaccine suitable for use under an EUA. Upon completion of the initial clinical trial and production of the EUA lots (which will occur almost simultaneously, assuming that a Phase 1a/1b trial is adequate), we will achieve EUA readiness in approximately 14 months.

APPENDIX F –ROYALTY REPORTING

Required royalty report information includes:

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

Example

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

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

APPENDIX G – ROYALTY PAYMENT OPTIONS

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 **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/startJ28680443. 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:

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

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)	*(enter 12 digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*
Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.		

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:
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.
Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: FRNYUS33

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.S. bank account** 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
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852