EX-10.2 3 regn-ex102x09302020x10q.htm PROJECT AGREEMENT BY AND BETWEEN THE REGISTRANT AND ATI

Exhibit 10.2

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT, MARKED BY BRACKETS, WERE OMITTED BECAUSE THOSE PORTIONS ARE NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL TO THE COMPANY IF PUBLICLY DISCLOSED.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

PROJECT AGREEMENT NO.: 1

MCDC BASE AGREEMENT NO.: 2020-504

PROJECT TITLE: MCDC2008-005; Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

PARTIES: Advanced Technology International ("MCDC CMF") and Regeneron Pharmaceuticals, Inc. ("Project Agreement Holder")

This Project Agreement is awarded under the authority of MCDC Base Agreement No. 2020-504, and herein incorporates all the terms and conditions thereof, as such terms and conditions are modified by the terms of the Statement Of Work attached hereto as Exhibit A (the "Statement of Work" or "SOW"). The parties agree that, to the extent any terms or conditions of the Statement of Work conflict with the terms and conditions of MCDC Base Agreement No. 2020-504, the terms and conditions of the Statement of Work shall apply and take precedence.

1. PAYMENT METHOD

The Payment Method for this Project Agreement is Firm Fixed Price with a not to exceed ceiling.

2. TERM OF THE PROJECT AGREEMENT

The period of performance for this Project Agreement is from the effective date, which is the date of the last signature through June 30, 2021.

3. OBLIGATION

The MCDC CMF's liability to make payments to the Project Agreement Holder is limited to only those funds obligated under this Project Agreement or by modification to the Project Agreement. MCDC CMF may incrementally fund this Project Agreement.

4. TOTAL FIRM FIXED PRICE

The total firm fixed price for the services to be provided by the Project Agreement Holder is as follows:

Total Firm Fixed Price $450,262,000

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5. TOTAL FUNDING

The total amount of funding currently available for payment and allotted to this Project Agreement is **$450,262,000**.

6. MILESTONE PAYMENT SCHEDULE

The Project Agreement Holder shall document the accomplishments of each Project Payable Milestone under each Project Agreement. Acceptance of Milestones shall be contingent upon approval from the Government Agreements Officer Representative (AOR) detailed in Clause No. 9, Technical and Administrative Representatives. Milestone payments will be paid in the amount indicated in the attached Milestone Payment Schedule (Attachment A).

7. APPROACH TO MEETING THE OTHER TRANSACTION AUTHORITY

In accordance with provision contained in 10 USC 2371b governing the use Other Transaction Agreements each MCDC Member Organization must meet at least one of the following conditions: have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the performance of an awarded Project Agreement; all significant participants in the Project Agreement other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors; or provide a cost share of no less than one third of the value of the Project Agreement awarded to the Member Organization. The Project Agreement Holder's approach to meeting the Other Transaction Authority requirement is identified below. Throughout the period of performance of any Project Agreement, the CMF and the Government will actively monitor the award to ensure compliance with this provision in accordance with implementation guidance from Headquarters – Department of the Army (HQDA) and/or Office of the Secretary of Defense (OSD). The Project Agreement Holder will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

The warranties and representations submitted as part of the proposal are hereby incorporated into this Project Agreement. The Project Agreement Holder was proposed as a nontraditional defense contractor and determined to be providing a significant contribution.

8. STATEMENT OF WORK

The Statement of Work, Attachment A, provides a detailed description of the work to be accomplished and reports and deliverables required by this Project Agreement. All changes to Attachment A must be incorporated via written modification to this Project Agreement. Additional guidance on report requirements is in Attachment B, Report Requirements.

9. TECHNICAL AND ADMINISTRATIVE REPRESENTATIVES

The following technical and contractual representatives of the Parties are hereby designated for this Project Agreement. Either party may change their designated representatives by written notification to the other.

MCDC CMF Contractual Representative:
Contracts Administrator
Advanced Technology International
315 Sigma Drive
Summerville, SC 29486
Email:
Phone:

Government Technical Representatives:
Agreements Officer Representative (AOR):

Email:
Phone:

Project Agreement Holder's Representatives:

Technical Representative:	Contractual Representative:
777 Old Saw Mill River Rd	777 Old Saw Mill River Rd
Tarrytown, NY 10591	Tarrytown, NY 10591
Email:	Email:
Phone:	Phone:

10. MARKING OF DELIVERABLES
Any Data delivered under this Project Agreement, by the Project Agreement Holder, shall be marked with a suitable notice or legend.

11. SECURITY ADMINISTRATION
The security level for this project is UNCLASSIFIED.

12. ATTACHMENTS
Attachments listed herein are hereby incorporated by reference into this Project Agreement.
A. Statement of Work, "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2"
B. Report Requirements
C. Technical Direction Letter (TDL) RPP-20-08 Regeneron

13. GOVERNMENT FURNISHED PROPERTY
At this time, Government Furnished Property is not provided for use under this Project Agreement.

14. PATENT RIGHTS AND DATA RIGHTS

Please reference Section 7 of Attachment A, Statement of Work.

15. FOLLOW-ON PRODUCTION PROVISION

Please reference Section 1 of Attachment A, Statement of Work.

16. SECURITY & OPSEC

The below language shall be used as Paragraph 6 of Article XVII in Regeneron's Base Agreement:

Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

17. ENTIRE AGREEMENT

This Project Agreement and the MCDC Base Agreement under which it is issued constitute the entire understanding and agreement between the parties with respect to the subject matter hereof.

Except as provided herein (including in the SOW), all Terms and Conditions of the MCDC Base Agreement and its modifications remain unchanged and in full force and effect.

Applied Technologies Center
315 Sigma Drive
Summerville, SC 29486
www.ati.org

The Project Agreement Holder is required to sign this document and return to Advanced Technology International to finalize this action.

Regeneron Pharmaceuticals, Inc.	**Advanced Technology International**
By: /s/ Robert Landry	By: /s/
Name: Robert Landry	Name:
Title: Executive Vice President- Finance and Chief Financial Officer	Title:
Date: Jul 6, 2020	Date: 6 July 2020

Attachment A
Statement of Work

This page intentionally left blank. See separate document for Attachment A.

Statement of Work
For
Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

RPP #: RPP-20-08
Project Identifier: MCDC OTA 2008-005, W15QKN-16-9-1002
Consortium Member: Regeneron Pharmaceuticals, Inc.
Title of Proposal: Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

A. Preamble

Regeneron Pharmaceuticals, Inc. (referred to herein as "Regeneron", "Offeror", "Contractor" or "Recipient") has demonstrated experience with rapid scale-up of biopharmaceutical programs. Our excellent history of receiving development scale processes from Research and Development (R&D) laboratories, and then expanding to clinical or commercial Good Manufacturing Practice (GMP) scale production, is well documented. [* * *] We have consistently demonstrated our ability to expedite the delivery of high quality, safe and efficacious products (Ebola therapeutic) in partnership with the Government (anti-MERS, anti-Ebola).
Fully human monoclonal antibodies (mAbs) are molecules with high potency, predictable Pharmacokinetics (PK), and limited off-target toxicity, and thus provide attractive types of therapeutics for emerging diseases. Importantly, we have repeatedly demonstrated that candidate mAb-based drugs to prevent and/or treat emerging infections, can be rapidly obtained from Regeneron's proprietary VelocImmune® mice. Further, our ability to concurrently generate isogenic cell lines that are optimized for rapid antibody scale up and manufacturing using our proprietary Chemistry, Manufacturing, and Controls (CMC) platform technologies, have facilitated both testing of our mAbs in preclinical models and subsequent development of these mAbs into drugs suitable for human testing. In the process of completing many of these activities we have collaborated with other entities (including BARDA, Research Institutes, Government Laboratories and Universities). Our manufacturing has been designed to be paired with our proprietary VelocImmune® R&D technology, that is a proven process to rapidly take a research concept from the bench, into large scale production, with the ability to delivery medicines to patients.

The Government has advised Regeneron that it is appropriate for the project described in this Project Agreement to be performed through the Medical CBRN Defense Consortium (MCDC), under the authority of the MCDC Other Transaction Agreement No. W15QKN-16-9-1002. Regeneron is amenable to performing the project pursuant to such authority, based on the advice of the Government, and due to the unprecedented circumstances of the Coronavirus Disease 2019 (COVID-19) pandemic and, accordingly, the parties have entered into this Project Agreement.

[* * *]

B. Overall Objectives and Scope

This project is defined by discrete work segments for the continuous manufacture of drug substance, formulated drug substance and filled, packaged and labeled drug product, in accordance with a mutually agreed schedule.

Pursuant to this project, Regeneron will manufacture and sell drug product to the applicable United States (U.S.) Federal Government agency, for distribution in the U.S. All manufacturing described herein will be compliant with Food and Drug Administration (FDA) current Good Manufacturing Oractices (cGMP), as 21 CFR 210 and 211.

1.1 Introduction

The objective is to conduct the manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.

1.2 Scope

These manufacturing production activities will include manufacturing at-scale, filling and finishing, and storage and shipping of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)-specific monoclonal antibodies (referred to herein as the “prototype”, the “prototype product”, the “product” or “drug product”) for treatment and/or prophylaxis against COVID-19.

1.3 Definition of the Prototype Project

Consistent with USG objectives, Regeneron will employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act, to manufacture the prototype product. This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of manufacturing the prototype product during the ongoing COVID-19 pandemic. In addition, this is a prototype project because Regeneron will demonstrate, and prove-out the at-scale, multi-lot proprietary manufacturing activities of Regeneron in order to assess the feasibility of these activities to support the necessary quantity of the prototype product to treat the U.S. population. Successful completion of the prototype project will demonstrate Regeneron’s capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with little advance notification and (ii) facilitate the Government’s ability to stockpile and distribute large quantities of the drug product to respond when needed, including for use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. FDA. For clarity, any manufacturing and supply of drug product in excess of the

[* * *]

specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutual agreement between Regeneron and the Government.

The scope of effort supported by this agreement is further clarified in Section 1.4. It is important to note that nonclinical and clinical studies for the prototype are being conducted by Regeneron outside of this agreement. The results of those studies may be used to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement; however, such results (including the degree to which the data are "positive" or "negative") shall not be a factor in this prototype project.

1.4 Objective

- Conduct its proprietary manufacturing production activities described in this proposal for prototypes consisting of novel, proprietary mAb therapeutics and prophylactics, to reduce pathology of COVID-19 disease and/or prevent development of disease when administered prophylactically.
- The prototypes will include one or more of the following, as mutually agreed between Offeror and the Government:
    - the mAbs known as REGN10987 and REGN10933, as a cocktail;
    - Other mAbs (as monotherapies or a cocktail) as agreed to by bilateral modification between Offeror and the Government.
- The deliverables will be the products listed above (i.e., REGN10987 and REGN10933), in the form of bulk formulated drug substance and/or filled and finished product in vials, as mutually agreed between Offeror and the Government, packaged and labeled drug product, results, reports and records associated with generation of data demonstrating quality and control.
- The products will be delivered in the form and quantity to be agreed between Offeror and the Government. It is expected that the prototypes will be stored by Offeror until such time as (a) they can be used for pre-clinical or clinical development purposes under an Investigational New Drug application (IND), or (b) upon the FDA's grant of an EUA under Section 564 of the Food, Drug and Cosmetic Act (FD&C Act), or full marketing approval under a full Biologics License Application (BLA) under Section 351(a) of the Public Health Service Act (PHSA).

1.5 Follow-on Activity

In accordance with 10.U.S.C. 2371b(f), and upon successful demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results achieved outside of this Agreement that would justify transitioning to production (e.g., EUA or BLA), additional at-scale manufacturing of [* * *], supported by a mutually agreed upon follow-on production contract or Other Transaction Agreement, may be awarded to Regeneron, without further competition, to partially or completely meet the USG objective of supplying a safe and effective COVID-19 therapeutic or prophylactic treatment courses to ensure nationwide

access. For clarity, any manufacturing and supply of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work shall be subject to a mutually-agreed upon separate agreement between Regeneron and the Government. For further clarity, neither party shall be obligated to negotiate or enter into such a separate agreement for follow-on production.

During the performance of the prototype project, the Government and contractor may negotiate the scope and price of follow-on production.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Practices, 21 CFR 210, 211

[* * *]

4.0 DELIVERABLES

Offeror assumed [* * *]. Regeneron shall have the right to provide deliverables directly to the Government and not to the Consortium Management Firm (CMF).

Deliverable Table (June 2020 - June 2021)

Deliverable	Due Date	Total Program Funds	Data Rights
Project Kick-Off; Deliverable	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
DS/FDS Bulk GMP Lot [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Fill Product [* * *]	[* * *]	[* * *]	[* * *]
Package/Label Product	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
Storage of Drug Product [* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
[* * *]	[* * *]	[* * *]	[* * *]
		$450,262,000 (FFP)	

[* * *]

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*Upon payment, delivery and acceptance in accordance with the terms of this Project Agreement, the Government will have title to the product produced under this Statement of Work. The Government will have the rights described below in Section 7.3 to technical data disclosed under this Statement of Work.
** Packaging and labeling of product will be performed following the determination of the use of the applicable drug product (e.g., for clinical trials or for distribution under an EUA or BLA).

5.0 MILESTONE PAYMENT SCHEDULE; TERMINATION COSTS

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	[* * *]	[* * *]	[* * *]
5.2	[* * *]	[* * *]	[* * *]
5.3	[* * *]	[* * *]	[* * *]
5.4	[* * *]	[* * *]	[* * *]
5.5	[* * *]	[* * *]	[* * *]
5.6	[* * *]	[* * *]	[* * *]
5.7	[* * *]	[* * *]	[* * *]
5.8	[* * *]	[* * *]	[* * *]
5.9	[* * *]	[* * *]	[* * *]
5.10	[* * *]	[* * *]	[* * *]
5.11	[* * *]	[* * *]	[* * *]
Total (Include Payment Type; FFP):			**$450,262,000**
Period of Performance:			**June 2020 – June 2021**

The overall price is fixed price at $450,262,000. Milestone payments will be made quarterly as set forth in the table above, corresponding to the deliverables and any 3rd party commitments Regeneron needs to make. In the event the deliverables in a given quarter are less than or exceed the projected quantity, the milestone payment for such quarter will be equitably adjusted based on the shortfall or excess amount, as applicable, however the price will not exceed $450,262,000 Milestone payment terms will be net 30 days.

Total pricing is a firm fixed price per lot, [* * *]. Regeneron will deliver [* * *] of filled/finished drug product. Regeneron will be entitled to full payment for drug product upon delivery/acceptance (as described herein) of filled/finished drug product, prior to packaging and labeling. However, Regeneron shall be responsible for the packaging and labeling of product at no additional cost following the determination of the use of such drug product (e.g., for clinical trials or for distribution under an EUA or BLA). Drug product will comply with the Drug Supply Chain Security Act serialization and tracking requirements. Drug product will not be co-formulated, except as otherwise mutually agreed by the parties. Unless and until otherwise mutually agreed, the drug product produced under this Statement of Work will be filled for therapeutic use. [* * *] Regeneron will provide the Government with the timeline for fill/finish activities, including the dates by which the parties must determine

[* * *]

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the allocation of fill/finish activities. Notwithstanding the foregoing, as part of this Project Agreement, Regeneron will have the right to utilize material and capacity supported by this agreement to fill up to [* * *], as well as any additional drug product mutually agreed upon by Regeneron and the Government (with respect to which use the Government will not unreasonably withhold consent.

In the event this Statement of Work is terminated prior to completion, termination costs recoverable by Regeneron under Section 2.04 of the MCDC Base Agreement, shall include the following: the full contract price for any drug product manufactured and not yet paid for; a pro-rated portion of the contract price for drug substance or drug product that is in process, based on the stage of production; [* * *] and raw materials that Regeneron purchased (or is obligated to purchase) that cannot be allocated to other products.

[* * *]

7.0 PATENT RIGHTS; DATA RIGHTS; PREP ACT AND TRANSPARENCY

Article X, ("PATENT RIGHTS") and Article XI. ("DATA RIGHTS") of Other Transaction Agreement number W15QKN-16-9-1002 shall not apply to this Project Agreement and are hereby replaced for the purpose of this Project Agreement, with this Section 7.0 (including Sections 7.1-7.4 and the Definitions Appendix).
Definitions:

Capitalized terms used in this Section 7.0 (including Sections 7.1-7.4) shall have the meanings ascribed to such terms in the Definitions Appendix to this Project Agreement.

For purposes of this Project Agreement, all rights of the Government in and to Data or Subject Inventions are granted solely to The United States of America, as represented by the Department of Health & Human Services, Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)) and to no other agency of the United States of America (including JPEO) or representative of any such other agency (including the CMF). The parties acknowledge that Regeneron is permitted to communicate solely with BARDA regarding the matters described in this Section 7.0 (including Sections 7.1-7.4) and is not obligated to communicate with any other Government agency or representative regarding such matters.

7.1 BACKGROUND INTELLECTUAL PROPERTY

Each party acknowledges that it has no rights to the other party's inventions, discoveries, know-how, Data, technology or intellectual property generated, discovered, conceived or reduced to practice prior to or otherwise outside of this Statement of Work (also referred to herein as, this "Project Agreement" or this "Agreement"), and any improvements or modifications thereto, including, without limitation, the background intellectual property

[* * *]

(and improvements/modifications) for the Government and Regeneron described below, as follows:

Government Background Intellectual Property. None.

Contractor Background Intellectual Property:[* * *]

63/004,312, filed April 2, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

63/014,687, filed April 23, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

63/025,949, filed May 15, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

63/034,865, filed June 4, 2020 “Anti-SARS-CoV-2-Spike Glycoprotein Antibodies and Antigen-Binding Fragments”

[* * *]

No party relinquishes rights in any of its background intellectual property to any other party under this contract.

Either Party may update its disclosure of background intellectual property under this Section 7.1 upon written notice to the other Party.

7.2 PATENT RIGHTS

a. Allocation of Principal Rights

The parties agree that the Bayh-Dole statute does not apply to this Project Agreement. Ownership of inventions Made in the performance of this Project Agreement shall follow inventorship, and inventorship shall be determined in accordance with United States patent laws. With respect to any Subject Invention Made (in whole or in part) by or on behalf of Regeneron, unless Regeneron shall have notified the Government (in accordance with Subparagraph b. below) that Regeneron does not intend to properly disclose and elect title to a Subject Invention, Regeneron shall retain the entire right, title, and interest throughout the world to such Subject Invention, and the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States the Subject Invention throughout the world. This license does not include the right to use or allow others to use the Subject Invention for commercial purposes. If Regeneron does not properly disclose and elect title to any such Subject Invention (in

[* * *]

accordance with Subparagraph b. below), then the Government may exercise its rights to seek ownership of such Subject Invention, pursuant to clause 7.2.c. below.

b. Invention Disclosure, Election of Title, and Filing of Patent Application

i. Regeneron shall disclose in writing each Subject Invention to the OTTR within 12 months after the inventor discloses it in writing to Regeneron personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this Project Agreement under which the Subject Invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the Subject Invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the Subject Invention, or whether a manuscript describing the Subject Invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the Government funding agency (HHS/BARDA), Regeneron shall promptly notify the OTTR of the acceptance of any manuscript describing the Subject Invention for publication and any on sale or public use.

ii. Regeneron shall elect in writing whether or not to retain ownership of any Subject Invention by notifying the OTTR within 2 years of disclosure to the Government funding agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than 60 calendar days prior to the end of the statutory period.

iii. Regeneron shall file either a provisional or a non-provisional patent application for an elected Subject Invention within 1 year after election of title. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, Regeneron shall file the application prior to the end of that statutory period. If Regeneron files an initial provisional application, it shall file a non-provisional application within 10 months of the filing of the initial provisional application. Regeneron shall include a Government Support Clause (GSC) within the specification of any United States patent applications and any patent issuing thereon covering a subject invention.

iv. Regeneron may request extensions of time for disclosure, election, or filing under subparagraphs (b)(i), (b)(ii) and (b)(iii) of this clause. An extension of time for each deadline, may be granted at the discretion of the Government funding agency.

v. If Regeneron determines that it does not intend to elect to retain title to any such Subject Invention, Regeneron shall notify the Government, in writing, within two (2) years of disclosure to the Government. However, in any case where publication, sale, or public use has initiated the one (1)-year statutory

[* * *]

period wherein valid patent protection can still be obtained in the United States, the period for such notice may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.

c. Conditions When the Government May Obtain Title

Upon the Government's written request, Regeneron shall convey title to any Subject Invention to the Government funding agency if Regeneron fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Subparagraph b of Section 7.2. The Government may request title after learning of the failure of Regeneron to disclose or elect within the specified times for an unlimited time. The Government funding agency may request title upon Regeneron's omission to timely file patent applications in any country. The Government funding agency may request title in any country in which Regeneron decides to discontinue prosecution.

d. Rights to Regeneron and Protection of Regeneron's Right to File

Regeneron shall retain a fully paid up, sub-licensable, nonexclusive, royalty-free license throughout the world in each Subject Invention to which the Government obtains title. Regeneron license extends to Regeneron's subsidiaries and other affiliates (outside this Agreement), if any, within the corporate structure of which Regeneron is a party and includes the right to grant licenses of the same scope to the extent that Regeneron was legally obligated or permitted to do so at the time the Project Agreement was executed. The license is otherwise transferable only with the approval of the Government, except when transferred to an Affiliate or successor of that part of Regeneron's business to which the Subject Invention pertains. The Government approval for license transfer shall be provided on a timely basis (and in no event later than 90 calendar days following Regeneron's request) and shall not be unreasonably withheld.

i. The Regeneron license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or nonexclusive license submitted consistent with appropriate provisions at 37 CFR Part 404. Regeneron's license shall not be revoked in that field of use or the geographical areas in which Regeneron has achieved Practical Application of the Subject Invention and continues to make the benefits of the Subject Invention accessible to the public.

ii. Before revocation or modification of Regeneron's license, the Government shall furnish Regeneron with a written notice of its intention to revoke or modify the license, which notice shall include a detailed explanation of the reasons for such revocation or modification, and Regeneron shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be revoked or modified.

[* * *]

e. Action to Protect the Government's Interest

Regeneron agrees to execute or to have executed and promptly deliver to the Government all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those Subject Inventions to which Regeneron elects to retain title, and (ii) convey title to the Government when requested under Subparagraph c of this Section 7.2 and to enable the Government to obtain patent protection throughout the world in that Subject Invention.

i. Regeneron agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by Regeneron, each Subject Invention made under this Agreement so Regeneron can comply with the disclosure provisions of this Section 7.2. Regeneron shall use reasonable efforts to instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

ii. Regeneron shall notify the Government of any decisions not to continue the prosecution of a patent application for a Subject Invention, pay maintenance fees, or defend in a reexamination or opposition proceedings on a patent of a Subject Invention, in any country, not less than thirty (30) calendar days before the expiration of the response period required by the relevant patent office.

Regeneron shall include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, the following statement: "This invention was made with Government support under Agreement **MCDC2020-504**, awarded by the U.S. Department of Health and Human Services. The Government has certain rights in the invention."

f. Lower Tier Agreements

Regeneron shall ensure that its Affiliate agreements and Sub-Recipient Agreements regardless of tier, for experimental, developmental, or research work entered into after the Effective Date and submitted for reimbursement under this Agreement, contain invention reporting and assignment requirements sufficient to permit Regeneron to comply with this Section 7.2.

g. Reporting on Utilization of Subject Inventions

i. Regeneron agrees to submit, during the term of this Project Agreement, an annual report on the utilization of a Subject Invention or on efforts at obtaining such utilization that is being made by Regeneron or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Regeneron also agrees to

[* * *]

provide additional reports as may be requested by the Government in connection with any march-in proceedings undertaken by the Government in accordance with Subparagraph h of this Section 7.2. Consistent with 35 U.S.C. § 202(c)(5), the Government agrees it shall not disclose such information to persons outside the Government without permission of Regeneron.

ii. All required reports shall be submitted to the e-room, OTAS, OTAO, and OTTR.

h. Compulsory Licensing Rights

Regeneron agrees that, with respect to any Subject Invention in which it has retained title, the Government has the right to require Regeneron, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if Regeneron, assignee, or exclusive licensee refuses such a request, the Government has the right to grant such a license within the Field itself *only* if the Government determines that:

i. Action is necessary to alleviate the following health or safety needs that may affect the United States and Regeneron (itself or through its assignee, subcontractor or licensee) is unwilling or unable to manufacture or supply the Subject Invention to address such needs:

a. Declaration for Public Health Emergency by the Secretary of HHS;

b. Determination that there is a significant potential for a public Health emergency that has a significant potential to affect a national or health security of U.S. citizens as determined by the Secretary of HHS; or

c. Declaration by WHO Director General of a public health emergency of international concern.

7.3 DATA RIGHTS

a. Allocation of Principal Rights

i. For Data produced under this SOW including Computer Software, to the extent developed with Government funds provided under this SOW, except as expressly provided elsewhere in this Project Agreement (including Section 7.3.b.), Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data (a) to exercise Government Purpose Rights for a period of ten (10) years following the production of such Data, (b) to exercise Unlimited Rights following the expiration of such ten (10)- year period. For Data produced under this Project Agreement, excluding Computer Software, to the extent developed with private funds and for other Data designated by

[* * *]

Regeneron as "Limited Rights Data", Regeneron grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in such Data to exercise Limited Rights. The Government will not obtain any rights in Computer Software produced under this Project Agreement to the extent developed with private funds. For certificates of analysis and batch records pertaining to drug product purchased under this Project Agreement, the Government shall have Unlimited Rights.

ii. Regeneron agrees to retain and maintain in good condition all Data produced under this Project Agreement and necessary to achieve Practical Application of any Subject Invention in accordance with Regeneron's established record retention practices. In the event of an exercise of the Government's compulsory licensing rights as set forth under Section 7.2.h., Regeneron agrees, upon written request from the Government, to deliver at no additional cost to the Government, all existing Data produced under this Project Agreement necessary to achieve Practical Application of the relevant Subject Invention within sixty (60) calendar days from the date of the written request.

iii. Regeneron's right to use Data is not restricted and includes the right under Regeneron's established business policies to make public research Data (especially human research Data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis.

b. Proprietary Manufacturing Data

Notwithstanding anything to the contrary in this Project Agreement, Regeneron retains all rights in and to Data relating to or comprising Regeneron's proprietary manufacturing technology and processes, including any trade secrets, Chemistry, Manufacturing and Controls information (CMC Data), and Data concerning or arising from test method development, device or delivery system development, assay development, formulation, quality assurance/quality control development, technology transfer, process development and scale-up and cell-line development, and the Government shall have no rights to use such Data independently from this Agreement or to disclose such Data to any third party. Regeneron may designate certain Data concerning its manufacturing activities as Limited Rights Data, in which case the Government shall have Limited Rights in and to such Data. Regeneron will use reasonable efforts to mark any Limited Rights Data delivered under this Project Agreement with appropriate Limited Rights markings.

c. Identification and Disposition of Data

Regeneron shall keep copies of all Data relevant to this Project Agreement as required by the Food and Drug Administration (FDA) for the time specified by the FDA. The Government reserves the right to review any other data determined by the Government to be

[* * *]

relevant to this Agreement. The Government further acknowledges that Regeneron holds the commercialization rights for all products developed under this Agreement in the U.S. and will be responsible for their registration with the FDA. This provision is subject to any applicable limitations on the Government's rights under Article VIII.B.a-b of the BARDA OTA.

7.4 REGULATORY RIGHTS

The Contractor agrees to the following:

a. Regulatory Data. Regeneron shall provide to the OTTR and OTAS copies of formal FDA submissions pertaining to the scope of the project, no later than 10 business days before submission to the FDA. For clarity, CMC Data included in such submissions shall be subject to Section 7.3.b.

b. Rights of Reference. Upon mutual agreement, Regeneron will grant to the Government a right of reference to any Regulatory Application submitted in support of this Project Agreement, solely for the purpose of the Government conducting a clinical trial with the drug product supplied under this Project Agreement under a protocol approved by Regeneron for performance by the Government. In such a case, Regeneron agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the Government's data rights as articulated in other provisions of this award.

c. Clause 7.4.b. will survive the acquisition or merger of the Contractor by or with a third party. This clause will survive the expiration of this contract.

7.5 PREP Act Coverage. It is the intent of the Parties that the drug product provided pursuant to this Agreement be covered by the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), or any amendments thereto that provides liability protection for such use. Based on an independent review by each of the Parties of the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties believe that Regeneron is a covered person eligible for immunity under the PREP Act for activities related to medical countermeasures against COVID-19. To the extent DoD or BARDA is authorized to do so as an Authority Having Jurisdiction, the Government designates Regeneron as a covered person eligible for immunity under the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), for activities related to medical countermeasures against COVID-19. The Government further warrants that the drug product provided pursuant to this Project Agreement will not be (a) sold to any entity nor will it be returned after acceptance under the terms of this contract or (b) distributed or used, or authorized for distribution or use, outside the United States or to the extent such activities are not protected from liability under an active PREP Act declaration.

[* * *]

7.6 Transparency. To the extent permitted under applicable laws, the Government will provide Regeneron in a timely manner copies of reports concerning this Project Agreement that are provided to other Government agencies or legislative or executive branches of the government.

8.0 SECURITY

The security classification level for this effort is UNCLASSIFIED.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

None

11.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Alternate AOR

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION:

Requiring Activity:

US Department of Health & Human Services (HHS), Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA)

[* * *]

Definitions Appendix

Computer Software:

To perform and further this Project Agreement:

Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

Does not include computer databases or computer software documentation.

Data: Means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and Computer Software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Field: The development of anti-pathogen assets to treat, diagnose or prevent emerging infectious diseases.

Government: The United States of America, as represented by the Department of Health & Human Services ("Government"), Office of the Assistant Secretary for Preparedness & Response ("ASPR"), Office of Biomedical Advanced Research and Development ("BARDA") (represented by Office of Acquisition Management, Contracts and Grants (AMCG)).

Government Purpose: Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations, or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose technical data for commercial purposes or authorize others to do so.

Government Purpose Rights: The rights by Government to—

1. Use, modify, reproduce, release, perform, display, or disclose technical data within the Government without restriction; and

2. Release or disclose technical data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that data for United States Government Purpose.

Invention: Any invention or discovery that is or may be patentable or otherwise protectable under Title 35 of the United States Code.

[* * *]

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for research purposes for the Field. Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Agreement. The Government may not, without the prior written permission of Recipient, release or disclose the Data outside the Government, use the Data for competitive procurement or manufacture, release or disclose the data for commercial purposes, or authorize the Data to be used by another party. The Parties shall maintain the confidentiality of all Data subject to or designated as falling within Limited Rights.

Limited Rights Data: Data, other than Computer Software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such Data pertain to items, components, or processes developed at private expense, including minor modifications.

Made: The conception or first actual reduction to practice of the invention as defined in this Agreement.

Option: An option, entered into by bilateral agreement pursuant to a Statement of Work and budget, by which, for a specified time, the Government may elect to purchase additional supplies or services called for by the Agreement.

**Other Transaction Agreement Officer ("OTAO"): ** Is the responsible Government official authorized to bind the Government by signing this Agreement and bilateral modifications.

Other Transaction Agreement Specialist ("OTAS"): Is a supporting official that assists and represents the OTAO. The OTAO is the only official who can bind the Government.

**Other Transaction Agreement Technical Representative ("OTTR"): ** Is the primary Government official for all technical matters on the Agreement.

Practical Application: With respect to a Subject Invention, 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 such conditions as to establish that the Subject Invention is capable of being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public for a regulatory approved product.

Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent.

Sub-Recipient: Akin to a subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for the Recipient, an Affiliate, or a Sub-Recipient. A Sub-Recipient differs from an Affiliate in that Sub-Recipients are not listed as an Affiliate in Attachment 3 and may be used to execute tasks under the SOW by Recipient or Affiliate.

Sub-Recipient Agreement: Any contract entered into by a Sub-Recipient to furnish supplies or services for performance of this Agreement. This term describes an agreement with a 1st-Tier Sub-Recipient, except as expressly noted in this Agreement.

[* * *]

Attachment B
Report Requirements

This page intentionally left blank. See separate document for Attachment B.

REPORT REQUIREMENTS

If classified information is required to be submitted under this Agreement, it must be submitted to the addresses specified in the SOW or DD254. No classified information should be submitted directly to ATI.

Any applicable Contract Data Requirements Lists (CDRLs), Data Item Descriptions (DIDs) or other report guidance for this Project may be included at the end of this attachment.

ATI, in addition to the AOR, must receive a copy of the Quarterly Status Reports and the Final Status Report. Quarterly Status Reports, Annual Status Reports, and Final Status Reports should be submitted to . All other deliverables shall be submitted to the AOR only, but ATI must be notified that the deliverable has been submitted to the AOR. The AOR will provide ATI a completed Sign- off Memorandum as evidence the milestone deliverable was received and deemed acceptable.

If you would like a copy of the Report Requirements template in MS Word, please email

A. QUARTERLY STATUS REPORT

The Recipient shall submit or otherwise provide a Quarterly Status Report in the format as shown in this attachment on the last day of the month of the calendar quarter (i.e., **March 31, June 30, and December 31**). A sample template is provided.

I. The Recipient's Technical Status Report will, at a minimum, address the following: Comments on Technical/Cost/Schedule Performance, Project Quad Chart, Milestone Status, Non-Traditional Defense Contractor Participation and Plans for the Next Quarter.

B. PAYABLE MILESTONES/DELIVERABLES

The Recipient shall submit to the Agreements Officer Representative and MCDC CMF Representative documentation describing the extent of accomplishment of Payable Milestones and Deliverables.

I. **Submission of Payable Milestones/Deliverables**. The Recipient is required to submit all deliverables identified as Payable Milestones, as shown in the Payable Milestone Schedule, as well as any other deliverables/reports listed in the Statement of Work.

II. **Sign-off Memorandum.** The Sign-off Memorandum as shown in this attachment shall accompany all submissions indicated in section B.I. The Agreements Officer Representative shall provide written approval using the Sign-off Memorandum to the MCDC Consortium Management Firm. The Sign-off Memorandum will be used to verify that all submissions are technically acceptable. It will also be used to substantiate invoice payment for firm fixed price agreements.

C. ANNUAL STATUS REPORTING

I. The Project Agreement Holder shall submit an Annual Status Report on **September 30** each year (same format as Quarterly Status Report for one year period) for all projects whose periods of performances are greater than

one year in accordance with the terms and conditions of the MCDC Base Agreement. The Annual Status Report must also include the following:

i. A comparison of actual accomplishments with the goals and objectives of the project established for the period.
ii. Reasons why established goals and objectives were not met, if appropriate.
iii. A cumulative chronological list of written publications in technical journals. Include those in press as well as manuscripts in preparation and planned for later submission. Indicate likely journals, authors and titles.
iv. Papers presented at meetings, conferences, seminars, etc.
v. New discoveries, inventions or patent disclosures and specific applications stemming from the individual project provided that such disclosure shall not compromise the rights of the inventor.
vi. Reporting on Utilization of Subject Inventions should be included in the Annual Status Report per Section 10.08 of the Base Agreement.

Quarterly Status Report

for

<Project Agreement Holder Name>

Project No. MCDC-XX-XX-XXX

Reporting Period: DATE - DATE

Project Agreement Holder

<Project Lead>

<Other Project Team Member(s)>

Project Team Technical POC

Name Company Street Address
City, State Zip Code Phone Number Email address

Submitted: <date>

---

1. Comments on Technical/Cost/Schedule Performance

The purpose of this section is to bring project stakeholders up to speed on current project status. It is not intended to be a line-by-line account of the quarter's activities; details of that nature are reserved for the latter section of this report. Rather, this section should highlight technical, cost, and schedule performance for the quarter, and report overall progress towards successful technology transition and implementation – an executive summary-like synopsis. This section should also be used to cite project-related concerns.

Properly crafted, this section is typically about one-half page in length.

2. Project Quad Chart

Quad charts are used for many purposes, including high level briefings. Therefore, it is imperative that information be current and accurate, especially in regards to the lower quadrants. The text - where populated - in the quad chart below is for sample purposes only.

<table>
<tr><th colspan="2">< Project Agreement Title></th></tr>
<tr><td colspan="2"></td></tr>
<tr><th>Goals & Objectives</th><th>Project Information</th></tr>
<tr><td>Briefly describe the goals of the project; include the technical objectives and the implementation targets.</td><td>Project Lead:
Team Members:
Period of Performance:
Funding:
Cumulative Amt Invoiced:
Total Cost Share Reported:</td></tr>
<tr><th>Milestones & Technical Achievements</th><th>Implementation & Payoff</th></tr>
<tr><td>Apr 16: Kickoff Meeting
Jun 16: Design Analysis complete
Jul 16: Materials/Equipment Rec'd
Oct 16: Prototype construction complete
May 17: Initial testing complete
Oct 17: Production units implemented in shipyard processes</td><td>Schedule: Target date for implementation.
Status: Current status towards implementation event.

Briefly describe what benefits will accrue from this project's successful completion and implementation. Be quantitative to the greatest extent possible.</td></tr>
<tr><td colspan="2"><u>Current Status:</u> Technical = Green/Yellow/Red (delta) Schedule = Green/Yellow/Red (delta) Cost = Green/Yellow/Red (delta)</td></tr>
</table>

Current Status Legend: Green = Good/On Budget Yellow = Minor Weakness/Known Risk Red = Major Weakness/Critical Delta:
⇧ = upgrade from last assessment; ⇩ = downgrade from last assessment; ⇨ = no change

3. Supplemental Information

In order to improve the usefulness of the quad charts and provide sufficient project information, the Quarterly Status Report must be supplemented with data described below.

3.1 Milestone Status:

No.	Milestone	Due Date	Percent Complete This Period	Cumulative Percent Complete
1				
2				
3				

3.2 Non-Traditional Defense Contractor Participation

Name of Nontraditional*	Planned Start Date	Actual Start Date	Reason for Deviation from Plan

3.3 Plans for Next Quarter

- Major achievements planned for the next quarter

MEMORANDUM: Agreements Officer Representative Sign-Off

To: Agreements Officer Representative (AOR) From: ___
Date: ___
Reference: (a) MCDC Base Agreement between ATI and
_____ Agreement No. __
(b) Project Agreement No. ___
Subject: Milestone Approval

The following deliverable(s) associated with the Milestone(s) listed below have been completed:

MS#	Deliverable
XX	___

It is requested that verification of these accomplishments be provided to the MCDC Consortium Management Firm.

To: MCDC Consortium Management Firm

CERTIFICATION BY AGREEMENTS OFFICER REPRESENTATIVE:

The Project Agreement Holder has made satisfactory progress and provided the required deliverables associated with this milestone. I certify the work performed is in accordance with the approved Statement of Work (SOW) included in the agreement.

Other comments or concerns regarding this or future milestones:

[Note: For any non-satisfactory areas include a discussion of what was not acceptable, references to previous correspondence on the issue, and what corrective actions are needed to effect payment.]

_____ _____
Agreements Officer Representative Date:

Attachment C
Technical Direction Letter (TDL) RPP-20-08 Regeneron

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DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

06 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-08, Objective TRE-PRE-20-08 for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" (Regeneron Pharmaceuticals, Inc.)

REF: Regeneron Request for Technical Direction Letter, RPP 20-08 under OTA W15QKN-16-9- 1002 for Objective TRE-PRE-20-08, dated 30 June 2020

Advanced Technology International
ATTN: Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear ,

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-08 on 17 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Regeneron as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Regeneron to award this proposal under Other Transaction Agreement W15QKN-16-9- 1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Regeneron's proposal for "Large-Scale Manufacturing of Antibodies Directed to SARS-CoV-2" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The cost proposal that has been analyzed and negotiated by the Government, you are hereby directed to issue a Project Agreement to Regeneron for the subject project. The total project value has been determined fair and reasonable and Regeneron's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed [* * *]. The break-out of the costs is as follows: $450,262,000.00 to perform project efforts included in the SOW and [* * *] for the Consortium Management Firm (CMF) Administrative Cost. [* * *] The effort currently has
[* * *] of available funding, comprised of $450,262,000.00 for the Project Agreement and [* * *] for the CMF. PAH COVID-19 work shall be tracked separately using the funding obligated via modification P00074. [* * *]

The PAH is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

The Government and Advanced Technology International (“ATI”) hereby agree and confirm that (a) ATI, in its capacity as the Consortium Management Firm under the Medical CBRN Defense Consortium (MCDC) Other Transaction Agreement No. W15QKN-16-9-1002 (the MCDC Agreement), has the authorization to enter into the Medical CBRN Defense Consortium Base Agreement No. 2020-504 and the Statement of Work (collectively, the “Regeneron Agreement”) with Regeneron on behalf of the Government, (b) the Government is and shall be bound by its obligations set forth in the Regeneron Agreement, and the MCDC Agreement is hereby amended to incorporate these obligations in the MCDC Agreement, as that Agreement relates to Regeneron, and (c) Regeneron is an intended third-party beneficiary of such obligations that can enforce them directly against the Government, and (d) in the event of any conflict between the Regeneron Agreement, on the one hand, and the MCDC Agreement, on the other hand, the Regeneron Agreement shall control and take precedence.

Points of Contact:

Agreements Specialist:
E-mail:
Phone:

Agreements Officer:
E-mail:
Phone:

Regards,

Agreements Officer
Signed by:

Attachments:
Attachment 1: MCDC2008-005 - Regeneron - 7-3-2020
Attachment 2: OPSEC Language Addendum
[***]

_____
ATI Signatory