10 USC 2373 AGREEMENT

BETWEEN

Ology Bioservices, Inc. (Awardee or Contractor)
13200 NW Nano Court
Alachua, FL 32615
And
NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date: 21 Feb 2020

Agreement No.: W911QY-20-9-0003

Total Amount of the Agreement: (b) (4)

Ology Bioservices, Inc.	**Government** (b) (6)
(b) (6)	
Signature	**Signature**
(b) (6)	(b) (6)
Printed Name	**Printed Name**
(b) (6)	Agreements Officer
Title	**Title**
21 February 2020	21 Feb 2020
Date	**Date**

ARTICLE 1. Scope.

A. This 10 U.S.C. § 2373 Agreement (the "Agreement") is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10 U.S.C. § 2373 and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, cooperative agreement, or 10 U.S.C. § 2371(b) other transaction agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

B. The 2018 National Defense Authorization Act (NDAA) amended 10 U.S.C. § 2358 to add 10 U.S.C. § 2373 as "authorized means" of Defense contracting for research and development projects (Pub. L. 115–91, div. A, title VIII, § 862, Dec. 12, 2017, 131 Stat. 1495) and expressed a preference for use of 10 U.S.C. § 2373 for certain contracting actions: "In the execution of science and technology and prototyping programs" (Pub. L. 115–91, div. A, title VIII, § 867, Dec. 12, 2017, codified at 10 U.S.C. § 2371 note).

C. This Agreement meets all criteria necessary for 10 U.S.C. § 2373 contracting actions. Consistent with the stated purpose of the statute, the Parties agree that scope and the ultimate purpose of this Agreement is to acquire chemical activity and medical supplies and designs thereof necessary for experimental or test purposes in the development of the best supplies needed for national defense. Examples of supplies for purposes of this Agreement include manufacturing platforms, compounds, drug product, drug substance, conformance lots, optimized products, shakedown/engineering/ development runs, equipment, and materials. All supplies purchased for testing and experimental purposes under this Agreement are necessary to develop the best supplies for national defense, such as Food and Drug Administration (FDA) licensed vaccines and therapeutics.

D. This Agreement will facilitate multiple projects for development of specific supplies required by the Government within the scope of the Agreement as described herein, each of which will be described in a Statement of Work (SOW).

E. Each project facilitated by this Agreement, will produce quantities of supplies that are necessary for experimentation and technical evaluation of those supplies only. Any project with multiple SOWs shall not, in the aggregate, exceed the quantity necessary for experimentation and technical evaluation. All SOWs executed under this Agreement shall be within the scope of the Agreement as described herein. The Parties agree that this Agreement is not intended to, and does not authorize purchase of chemical activity and medical supplies and designs thereof in quantities greater than those necessary for experimental or test purposes in the development of the best supplies needed for national defense. Accordingly, the requirements of 10 USC Chapter 137 are not applicable to this Agreement or any SOW issued hereunder.

F. The Advanced Development Manufacturing Facility means the facility located at 13200 NW Nano Court Alachua, FL 32615 (ADMF). (b) (4) [redacted]

G. In consideration of the guaranteed minimum amount established under this Agreement, the Awardee will provide research and development to complete the deliverables described in each order's Statements of Work up to the stated maximum. The minimum amount of this Agreement shall be (b) (4) for the Term and the maximum amount of this Agreement shall be (b) (4) for the Term.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends for a period of (b) (4) (the Term). SOWs may be incorporated at any time during the Term and the delivery date of any such SOW may extend beyond the end of the Term.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least one hundred eighty (180) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this Agreement. Termination of this Agreement will not impact ongoing projects which were awarded prior to the notice of termination under this Agreement.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Agreement Officer (AO), after issuance of a cure notice and failure of the Awardee to cure the defect within thirty (b) (4) or the time allowed by the AO after Awardee's receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

(i) temporarily withhold payments pending correction of the deficiency,
(ii) disallow all or part of the cost of the activity or action not in compliance,
(iii) wholly or partly suspend or terminate this Agreement, including the termination of one or more SOWs issued under this Agreement,
(iv) withhold further funding,
(v) require Awardee to pay repurchase costs as defined in Article 2C1, Repurchase Against Contractors Account, or
(vi) take any other legally available remedies.

1. Repurchase Against Contractors Account.
   a. (b) (4) [redacted]

(b) (4) [redacted]

b. If repurchase is made at a price over the price of the supplies terminated, the AO shall, after completion and final payment of the repurchase contract or agreement, make written demand on the Contractor for the total amount of the excess, giving consideration to any increases or decreases in other costs such as transportation, discounts, etc. If the Contractor fails to make payment, the AO shall follow the procedures in FAR subpart 32.6 for collecting contract debts due the Government.

2. Termination for Cause Procedures.

If this Agreement is terminated for Cause in whole or in part, Awardee will grant the Government a non-exclusive, paid up, perpetual license to the patents and documentation necessary for the purpose of continuing development of all deliverables that were subject to the termination. Additionally, the Awardee shall provide the U.S. Government or its designee with a non-exclusive, paid up, license to any patent, copyright, technical data or regulatory information directly related to those terminated deliverables to permit the U.S. Government to pursue commercialization of the technology with a third party, on terms to be agreed between the Parties and subject to rights granted or held by third parties. The terms of this section and the obligations herein will be included in any exclusive license given by the Awardee to a third party for any intellectual property covered by this Agreement, on terms to be agreed between Awardee and such third party. This clause will survive the acquisition or merger of the Awardee by or with a third party.

Notwithstanding this Article 2.C, the Government's rights and Awardee 's obligations under this paragraph will cease to exist if the Government terminates this Agreement for any reason other than for Awardee 's failure to materially comply with the terms of this Agreement.

D. Survival: Except as noted in Article 2.C., in the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

ARTICLE 3. Project Management.

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related program decisions. The Government will have continuous involvement with the Awardee concerning SOW's directly associated with this Agreement. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix A.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:

Awardee Project Managers:

(b) (6) [redacted]	[redacted]

Government Project Managers (GPM):

Primary Project Manager:	Alternate Project Manager:
(b) (6) [redacted]	[redacted]

C. Key Personnel: The Contactor's organization shall be established with authority to effectively complete the deliverables. This organization shall become effective upon execution of this Agreement and its integrity shall be maintained until the deliverable(s) is/are accepted by the Government. The key personnel listed in the applicable SOW are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall provide written notification to the AO. The Awardee shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

D. Subcontract Approval: Modifications to subcontracts and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the AO prior to being executed.

ARTICLE 4. Agreement Administration.

In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this agreement between the Awardee and a person other than the Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper written contractual document executed by the Agreement Officer and Awardee Representative.

Government Representatives:

Agreements Officer (AO)

(b) (6)

Agreement Specialists (AS)

Primary	Alternate
(b) (6)	

Awardee Representatives:

(b) (6)

Ology Bioservices, Inc.

(b) (6)

(b) (6)

ARTICLE 5. Performance Objectives and Changes.

A. Statement of Work (SOW): The SOW, Appendix A, describes the scope of activities that will be undertaken by the Awardee pursuant to separately issued orders issued for specific requirements within the Scope of the Agreement (the "Orders"). Orders shall be issued as modifications to this Agreement. Each Order shall incorporate additional SOWs. In consideration of Government funding under this Agreement, the Awardee will provide research and development to complete the deliverables described in each SOW, which are incorporated herein and attached hereto as Appendix A. The first SOW shall be Appendix A-1, the next Appendix A-2, the next Appendix A-3, etc.

B. Recommendations for Modifications: At any time during the term of this Agreement, progress or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the AO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this

Agreement is formally revised by the AO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

C. Review of Recommendations: The AO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, or other proposed changes to the terms and conditions of this Agreement.

D. Government Changes. The Government may issue unilateral, within scope changes to the work called for under this Agreement, which the Awardee shall perform pending finalization of the Agreement's modification reflecting the change and associated costs. The Awardee will be reimbursed for costs incurred that are reasonable, allowable and allocable to the work performed as required by the Government's mandated change. In addition, the Government may unilaterally make minor or administrative no-cost agreement modifications (e.g., changes in the paying office or appropriation data, changes to Contractor personnel proposed by Contractor, etc.).

E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to the AO.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix C.

H. Disputes: For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the AO. The AO will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within (60) calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute.

I. Quality Agreement. A Quality Agreement will be developed separately for each Order exercised under this Agreement.

ARTICLE 6. INSPECTION/ACCEPTANCE

A. Inspection: The Government has the right to inspect and test all work called for by the applicable SOW during the period of performance. The Government or its designee, including

employees and contractors of the FDA, may inspect the areas of premises of the Awardee or any subawardee that are specifically designated to the performance of the work under the applicable SOW. Inspections and testing will be requested and scheduled between the Government Project Manager (or its designee) and Awardee Project Manager. The Government shall perform inspections and tests in a manner that will not unduly delay the work, and during an agreeable time and date for both the Government and Awardee (subawardee). If the Government performs any required inspection or test on the premises of the Awardee or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's or subawardee's premises.

B. The Government shall inspect/accept or reject the work after completion/delivery, unless otherwise specified in the Agreement. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the deliverable(s) performed at Awardee's facility shall not exceed 120 days after completion The Government waives the right to reject nonconforming work should it fail to notify the Awardee within the 120 days of delivery, unless otherwise specified in the applicable SOW. Acceptance of the work shall be conclusive. The Government shall notify the Awardee, and separately negotiate storage of a deliverable, if storage of the work is anticipated to exceed 120 days.

ARTICLE 7. Financial Matters

This is an expenditure-based agreement. The payments provided under this Agreement are intended to compensate the Awardee on a cost basis for performance under this Agreement. The Awardee shall provide its best efforts to complete a project based on the estimated cost.

A. Payment. Payments are based on amounts generated from the Awardee's financial or cost records. The Awardee shall be reimbursed for each element identified in the awarded cost proposal as set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each calendar year, and ends on September 30 of the subsequent calendar year.

B. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The Government may incrementally fund this agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth in the Line of Accounting and Appropriation, or subsequent amendments providing incremental funding.

C. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

D. The Government shall pay the Awardee, upon submission of proper invoices, the prices stipulated in this Agreement for work delivered or rendered and accepted, less any

deductions provided in this Agreement. Unless otherwise specified, payment shall be made upon acceptance of any portion of the work delivered or rendered for which a price is separately stated in the Agreement. Payments processed in WAWF and should be made within thirty (30) calendar days of receipt of a request for payment.

E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS

(a) Definitions.

Department of Defense Activity Address Code (DoDAAC) is a six-position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

(b) Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Awardee shall (i) have a designated electronic business point of contact in the System for Award Management at https://www.acquisition.gov; and (ii) be registered to use WAWF at https://wawf.eb.mil/ following the step-by-step procedures for self-registration available at this website.

(d) WAWF training. The Awardee should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb.mil/.

(e) WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Awardee shall use the following document type: Invoice and Receiving Report (Combo)

(2) Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

(3) Document routing. The Awardee shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	**HQ0490**
Issue By DoDAAC	**W911QY**
Admin DoDAAC	**W911QY**
Inspect By DoDAAC	**W56XNH**
Ship To Code	**W56XNH**

(4) Payment request and supporting documentation. The Awardee shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation in support of each payment request.

(5) WAWF email notifications. The Awardee shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

(b) (6) [redacted]

(b) (6) [redacted]

(g) WAWF point of contact.

(1) The Awardee may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

(2) For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

F. Comptroller General Access to Records. To the extent that the total Government payments under this Agreement exceed $5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that

provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

ARTICLE 8. Reserved

ARTICLE 9. Intellectual Property Rights

The Parties agree that the terms in this Article apply generally to this Agreement, and that the terms may be modified in any SOW issued under this Agreement by mutual agreement of the Parties. If a SOW does not address intellectual property rights, the terms of this Article will govern intellectual property rights related to that SOW. To the extent there is any conflict between this Article and the intellectual property rights provision contained in a SOW, the terms of the SOW shall control.

A. Background Intellectual Property and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement ("Background IP"). Additionally, no party to this Agreement will enter into an agreement with any manufacturer or other third party whereby the third party will obtain rights in Agreement Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the parties to the awarded contract.

B. Definitions. For purposes of this agreement, an "Agreement Invention" is any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement.
C. Awardee's Background IP. Prior to the issuance of any SOW, Awardee shall disclose Background IP which contain claims that are related to research contemplated under the SOW, and shall provide identifying information to the Government. No license(s) to any patent applications, issued patents, or Background IP shall be granted under this Agreement, and are specifically excluded from the definitions of "Agreement Invention" contained in this Agreement.

D. Patent indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of this Agreement, provided the Awardee is notified of such claims and proceedings as soon as practicable by the Government of the suit or action alleging such infringement and shall have been given such opportunity as is

afforded by applicable laws, rules, or regulations to participate in its defense. Further, this indemnity shall not apply to-
An infringement resulting from compliance with specific written instructions of the AO directing a change in the supplies to be delivered or in the materials or equipment to be used, or directing a manner of performance of the contract not normally used by the Contractor; An infringement resulting from addition to or change in supplies or components furnished subsequent to delivery or performance; or a claimed infringement that is unreasonably settled without the consent of the Contractor, unless required by final decree of a court of competent jurisdiction.

E. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. Prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an Agreement Invention, which is defined below, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this Article 10 shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an Agreement Invention.

F. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an Agreement Invention owned jointly by the Parties or solely by Awardee, at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a joint Agreement Invention only with Awardee's prior written approval.

G. Ownership. Ownership of any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement (Agreement Invention) will follow inventorship in accordance with U.S. patent law. The Bayh-Dole Act, 35 U.S.C. §§ 200-212 does not apply to this Agreement and, as such, title to Agreement Inventions will accrue to the inventor or inventor-organization. The Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. If either an Awardee employee or a Government employee makes a sole Agreement Invention, the entire rights to that Agreement Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an Agreement Invention, it will be owned jointly by the Awardee and the Government. Ownership of Agreement Inventions made in whole or in part with subawardee employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable subawardee.

H. Patent Applications. The Parties will respectively have the option to file a patent application claiming any Agreement Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint Agreement Invention. Within thirty (30) calendar days of being notified of the discovery of an Agreement Invention or filing a patent application

covering an Agreement Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an Agreement Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

I. Licenses. For each Agreement Invention made solely by the Awardee, (b) (4)

(b) (4)

For any Agreement Invention made solely by the Government, the (b) (4)

J. Awardee shall report any Agreement Inventions to the Government within 60 days of the time it was conceived or first reduced to practice under this Agreement. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

ARTICLE 10. Data Rights.

The Parties agree that the terms in this Article 10 apply generally to this Agreement, and that the terms may be modified in any SOW issued under this Agreement by mutual agreement of the Parties. If a SOW does not address data rights, the terms of this Article 10 will govern data rights related to that SOW. To the extent there is any conflict between this Article 11 and the data rights provision contained in a SOW, the terms of the SOW shall control.

A. For purposes of this Agreement, "Study Data" is all data generated in connection with the performance of the studies under this Agreement. Study Data shall be owned by the Awardee. The U.S. Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement within the Government and otherwise for "Unlimited Rights," as this term is defined in DFARS 252.227-7013(a)(16). The Government may, under a separate agreement or by modification to this Agreement, obtain any rights to use or disclose the Awardee's

material or data to the extent that such material or data was produced outside the scope of this Agreement.

Notwithstanding the above, as a result of this Agreement, the Government shall obtain "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16) specific to any Study Data generated under, and as a result of this Agreement.

B. The Awardee agrees to retain and maintain in good condition until five (5) years after completion or termination of this Agreement, all Study Data generated under this Agreement. In the event of exercise of the Government's rights as potentially granted under paragraph 2.C, the Awardee agrees to deliver at no additional cost to the Government, all Study Data, in Awardee's possession and developed under this Agreement, necessary to deliver the supplies identified on the particular SOW within sixty (60) calendar days from the date of the written request.

C. Marking of Data: The Awardee will mark any Study Data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated (b) (4) between the Government and the Awardee."

Any rights that the Awardee or the Government may have in Study Data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

D. All Technical Data and Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this Agreement with less than unlimited rights shall be identified with reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)) in a data rights assertions list supplied to the Government, for review and evaluation, prior to entering into the agreement for the applicable SOW. All other Technical Data and Software developed under funding of this Agreement shall be delivered with unlimited rights as provided for within this Article.

ARTICLE 11. Regulatory Rights.

The Parties agree that the terms in this Article 11 apply generally to this Agreement, and that the terms may be modified in any SOW issued under this Agreement by mutual agreement of the Parties. If a SOW does not address regulatory rights, the terms of this Article 11 will govern regulatory rights related to that SOW. To the extent there is any conflict between this Article 11 and the data rights provision contained in a SOW, the terms of the SOW shall control.

This Agreement may include research with one or more investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. Subject to further negotiation between the parties and set forth in the SOW, the Contractor may serve as the

Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) Pre-Market Notification Filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this agreement. The Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20) has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

With respect to any products regulated by the FDA, the Contractor agrees to the following:

a. The Contractor shall provide to the Government all data, including top-line summaries and key conclusions from all studies, supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded under this Agreement. In addition, the Contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded under this Agreement. The Government will review any such submissions promptly upon receipt. The Contractor shall reasonably consider any comments provided by the Government, and prior to submission shall provide notification to the Government of any additional edits or revisions. The Contractor shall keep the Government reasonably apprised of planned FDA meetings and post-meeting outcomes relating to activities funded under this Agreement.
b. Communications. The Contractor shall provide the Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the regulatory submissions subject to this Agreement and ensure that the Government representatives are invited to participate in any formal Sponsor meetings with the FDA. The Contractor shall use its best efforts to ensure that the Government representatives are invited to participate in any informal Sponsor meetings with the FDA so long as the Contractor has 48 hour advance notice of such Sponsor meeting from the FDA prior to the scheduled meeting time.
c. Non-compliance with section (b) may result in termination of the agreement.
d. Product Development Failure. Certain product development failures may trigger certain remedies in Section "e." below for the Government advanced developer funding the development of the work contemplated in the applicable SOW. This remedy is not available to the Government for any cause outside of the following:
   (i) if this agreement is terminated for nonperformance; or
   (ii) the Contractor gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate this product development effort pre-market or to file for Federal bankruptcy protection.
e. If any of the product development failures listed in section "d" occur, the Contractor, upon the request of the Government:
   (i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to the Government or its designee;

(ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (e)(i) above; and

(iii) shall negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any patent, copyright or other intellectual property owned or controlled by the Contractor, developed prior to or outside the scope of this agreement, or any technical data that is necessary for the Government to pursue commercialization of this technology with a third party for sale to the Government or otherwise.

f. This clause will survive the acquisition or merger of the Contractor by or with a third party. This clause will also be included in any subcontracts/sub agreements relating to the development of the Technology. This clause will survive the expiration of this agreement.

ARTICLE 12. Foreign Access to Data.

Export Compliance: The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.

ARTICLE 13. Scientific Publications and Press Releases.

A. The Parties shall jointly agree on a publication plan for the data derived from studies executed under this Agreement (such data to be considered New Data). This publication plan will identify key New Data to be disclosed or presented and the target date for finalizing any related scientific abstract or manuscript. As part of its Monthly Progress Reports, the Awardee will share the publication plan with the Government.

B. The Parties will jointly develop each abstract or manuscript and agree on the authorship and the content of the final draft to be submitted; provided that authorship for each abstract and manuscript will be determined based on whether a particular individual made a significant contribution to the conceptualization, design, execution, or interpretation of a research study, as authorship is defined in the fifth edition of the Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, available at: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research.pdf.

C. Prior to submission for publication, the Parties shall provide drafts of proposed publications to the authors of such publications for review and comment, and shall provide copies to non-authors for viewing purposes. Review periods are (b) (4) for abstracts, or (b) (4) days if agreed by Project Managers and in order to meet publication submission deadlines. Review periods are (b) (4) calendar days for manuscripts. Contributing parties shall be appropriately accredited in any publication.

D. The Parties will jointly agree on whether to issue one or more press releases related to the resulting New Data. If all Parties agree that one or both Parties will issue a press release, each Party will also have the right to review and agree on the content in advance of its publication. Other parties, if any, contributing to the studies, will have review rights and will be appropriately accredited in the press release. For data generated in studies

executed by Awardee outside the scope of this Agreement, the Awardee, at its sole discretion, may issue a press release related to such data.

ARTICLE 14. Miscellaneous Clauses.

A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

B. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

C. Limitation of Liability. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

D. Disclosure of Information. Subject to Articles 10 and 11, the Awardee shall not release to anyone outside the Awardee's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this Agreement or any program related to this Agreement, unless (i) the Agreements Officer has given prior written approval or (ii) the information is otherwise in the public domain before the date of release.

E. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

F. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

G. Priority Access.

1) Defense Priority and Allocations Requirements. This Agreement, and each Order placed under this Agreement may be a rated order certified for national defense and emergency

preparedness, and the Contractor shall follow all requirements of the Defense Priorities and Allocations System (DPAS) regulation (15 CFR 700).

2) Reserved.

H. Assignment. (b) (4) [redacted]

I. Foreign Investment. (b) (4) [redacted]

J. (b) (4) [redacted]

K. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

L. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving

precedence in descending order as follows: (i) each SOW as included in Appendix A, (ii) the Articles of this Agreement, and (iii) other Appendices to the Agreement.

Appendix A

Statement of Work

PREAMBLE
Natick Contracting Division (Government) and Ology Bioservices, Inc., (Awardee or Contractor) have executed a 2373 Agreement (the "2373 Agreement") dated 21 Feb 2020, under which the Parties may enter into separate SOWs or Orders, incorporating the provisions of the 2373 Agreement. Upon execution by both Government and Awardee, this SOW shall be subject to the terms of the 2373 Agreement.

I. Statement of Work, Project 20-01 Rapid Monoclonal Antibodies Manufacturing System

RPP Title: Proposal for Enabling Biotechnologies ADMC
Statement of Objectives: Rapid Monoclonal Antibodies Manufacturing System

1.0 INTRODUCTION, SCOPE AND OBJECTIVES

1.1 Introduction

Recent advances in synthetic biology tools and methods have led to a dynamically evolving landscape of chemical and biological threats. mAbs represent state-of-the-art MCMs that can provide a rapid onset of effective prophylaxis or treatment of infection or intoxication caused by altered, emerging or entirely novel threats; however, current development timelines are too slow to respond in an operationally relevant timeframe. Thus, the JPEO-CBRND-EB requires chemical and medical supplies for experimental or test purposes to develop the best supplies for national defense against chemical and biological threats, namely, safe and effective mAb-based MCMs that can be rapidly delivered to the Warfighter in sufficient quantities for threat neutralization.

1.2 Scope

The scope of the proposed project is to develop and deliver a manufacturing platform that optimizes productivity and reduces manufacturing timelines for therapeutic mAbs in rapid response scenarios. This solution will balance the goals of rapid manufacturing with maintaining the QMS, helping to ensure uncompromised process/product quality during an emergency response and full compliance with FDA regulations and guidance. The terms of this Agreement allow for the classification of a manufacturing platform to be considered a supply item and as such suitable for purchase under the 10 U.S.C. 2373 authority.

1.3 Objectives

The objective of the proposed project is to further optimize the mAb products development cycle from supply chain requirements to CGMP DS manufacturing at a scale (b) (4) [redacted] The motivation is developing a substantially improved mAb development and production timeline without compromising product quality, safety or efficacy for use in the development of MCMs against biological, toxin and/or chemical threats to the Warfighter.

Sub-objectives related to performance requirements include the following:

- In coordination with the DoD, define levels of urgency based on lessons learned from

(b) (4) development in a one-day workshop
- Formalize QMS processes and procedures adapted for rapid response capability
- Optimize mAb manufacturing to improve yields and/or reduce time to CGMP DP

2.0 APPLICABLE REFERENCES

2.1 FDA Points to Consider, Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997)

2.2 FDA Points to Consider, Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (1993)
2.3 FDA Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (2004)
2.4 21 U.S. Code of Federal Regulations parts 210 and 211 CGMP in Manufacturing, Processing, Packing, or Holding of Drugs and Finished Pharmaceuticals
2.5 21 CFR Part 600, Biological Products: General
2.6 21 CFR Part 610, General Biological Products Product Standards
2.7 21 CFR Part 11, Electronic Records; Electronic Signatures
2.8 21 CFR Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies
2.9 21 CFR Parts 50, 54 and 56, Good Clinical Practices
2.10 ICH Q1A (R2) Stability Testing of New Drug Substances and Products
2.11 ICH Q2 (R1) Validation of Analytical procedures
2.12 ICH Q3A Impurities in New Drug Substances
2.13 ICH Q3B Impurities in New Drug Products
2.14 ICH Q3C Impurities: Residual Solvents
2.15 ICH Q3D Elemental Impurities
2.16 ICH Q7 Good Manufacturing Practice for Active Pharmaceutical Ingredients
2.17 Use of Laboratory Animals and Use of Human Subjects requirements of Article XXI General Provisions of the MCDC Base Agreement
2.18 Ology Bioservices Facility Master File

3.0 REQUIREMENTS

3.1 Task 1: Project Management (Ology Bio)

Assumptions:

- Labor for project oversight (PMs, PI, contracts and finance) spans the lifecycle of the product through final report.
- Data requirements span the lifecycle of the product through final report.
- The kick-off and quarterly meetings will be held virtually (e.g., via teleconference or video conference).

3.1.1 Planning

3.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) , provide an agenda (b) (4) prior to the meeting, and provide a meeting report within seven business days.

3.1.1.2 The Awardee shall provide an IMS (b) (4) The Company shall provide an updated IMS (b) (4) identifying task progress, percent completion and schedule slippage.

3.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project Charter, Communication Plan, IMS, WBS, Cost Management/Spend Plan and List of Deliverables.

3.1.2 Execution

3.1.2.1 Meetings

3.1.2.1.1 The Awardee shall conduct Integrated Project Team (IPT) meetings [redacted] The Awardee shall provide agendas for each meeting [redacted] and shall provide finalized meeting minutes to the Client [redacted]

3.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or Client request, to discuss issues as they arise. Minutes from these meetings shall be provided to the Client [redacted]

3.1.2.2 Reports

3.1.2.2.1 The Awardee shall deliver Monthly Progress Reports documenting technical progress made in the previous month; any concerns the PM or PI might have that would impact the performance, schedule or cost planned for the effort; and updated IMS. The Awardee shall submit each Monthly Progress Report by [redacted] of each month of performance. The U.S. Government will [redacted] respond to the report with any comments, and the Awardee will have [redacted] days to revise the deliverable or respond to those comments.

3.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities. When submitted, the Quarterly and Annual Reports may take the place of the monthly report.

3.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 10 calendar days after the end of each quarter of performance. The USG will have thirty calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

3.1.2.2.4 The Awardee shall prepare a Final Report at the end of the effort.

3.1.2.2.4.1 The Final Report shall be provided regardless of whether any or all of the project stages are exercised. The Awardee shall submit a Draft Final Report by the 45th calendar day following the end of the project period of performance. The USG shall provide comments to the Awardee by the 30th calendar day following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the 30th calendar day after receipt.

3.1.2.2.4.2 The Final Report shall narrate a complete summary of the project execution and associated results obtained. The narration will include outstanding problems and their

potential solutions, problems solved during the course of the year, and the solutions to the solved problems.

3.1.2.2.4.3 The Final Report shall demonstrate how the manufacturing platform was developed and advanced.

3.1.2.2.5 The Awardee shall perform, record and report physical inventory results of all Contractor Acquired Property in the contractor's possession, if the Awardee purchases material or equipment using USG funds, as approved by the Government Project Manager (GPM) during performance of the project.

3.1.2.2.6 Incident Reporting

3.1.2.2.6.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the USG in an incident report.

3.1.2.2.6.2 The Awardee shall telephonically contact the program manager for the USG within one day of incident.

3.1.2.2.6.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place.

3.2 Task 2: Establishment of Rapid Response Communications Paradigm, Designating Defined Levels of Urgency, and Rapidly Initiating Work (Ology Bio)

Assumptions:

- The final deliverable will be a policy document outlining Urgency Levels and describing the risk, schedule and cost implications under all scenarios.

3.2.1 Based on lessons learned from previous projects, such as (b) (4) [redacted], the Awardee shall develop a protocol that correspond to levels of response urgency so that the USG and the Awardee have a clear and aligned understanding of impacts from each level of urgency to product delivery schedule, cost and ongoing DoD ADM Facility operations.

3.2.2 In collaboration with the USG, the Awardee shall define the Urgency Levels.

3.2.3 The Awardee shall host a one-day workshop at the DoD ADM in coordination with the DoD to define Urgency Levels with emphasis on risk tolerance (e.g., how much risk can be assumed with urgency level 1 vs. 2, 3) in each area of operations and what needs to be in place to respond to each of the different urgency levels (e.g., prepositioned supply chain, equipment, personnel, resources, operational efficiencies, novel technologies).

3.2.4 The Awardee shall prepare an Urgency Level Policy Document with definitions for each Urgency Level, modifications to the rapid response approach based on risk and high- level schedule and budget information for each Urgency Level.

3.3 Task 3: Quality Management Process and Procedure Adaptation for Rapid Response (Ology Bio)

Assumptions:

- (b) (4) will be documented in the (b) (4) and will be implemented as defined in the (b) (4)

3.3.1 Subtask 3a: Supply Chain Management

3.3.1.1 The Awardee shall review the supply chain management system in a risk-based manner to reduce timelines associated with the supply chain, including but not limited to prepositioning of inventory, foreign supply chain dependency, and long-lead item procurement strategy.

3.3.2 Subtask 3b: Documentation in Support of CGMP Manufacturing

3.3.2.1 The Awardee shall review process documentation procedures that support CGMP manufacturing in a risk-based manner to reduce document preparation time in a rapid response scenario, including procedures related to developing batch records, qualifying equipment and operating equipment.

3.3.2.2 The Awardee shall review and evaluate the proposed documentation and process changes in response to Urgency Levels for compliance with FDA regulations and guidance. An Urgency Level QMS Adaptation SOP with a Risk Management Report will be drafted for review and evaluation by the USG, including the ONE-RAQA government regulatory advisors.

3.3.3 Subtask 3c: QC Process Improvements

3.3.3.1 The Awardee shall evaluate QC procedures in a risk-based manner to reduce QC cycle time in a rapid response scenario, including procedures related to compendial testing of mAbs; qualification of equipment, testing laboratories, and the Milliflex® Quantum rapid bioburden test method; scheduling of development and testing activities; and protocol and report templates.

3.3.4 Subtask 3d: QA Process Improvements

3.3.4.1 The Awardee shall evaluate QA procedures in a risk-based manner to reduce QA review cycle time in a rapid response scenario, including procedures related to scheduling of batch record reviews, QA oversight of manufacturing activities, and triaging of QA compliance reviews.

3.3.5 Subtask 3e: Project and Facility Management Improvements

3.3.5.1 The Awardee shall evaluate Project Management procedures in a risk-based manner to support streamlined and accelerated operations in a rapid response scenario, including procedures related to project initiation, execution and close-out activities and optimizing communication with the USG and subcontractors.

3.3.6 The Awardee shall prepare:

3.3.6.1 Urgency Level QMS Adaptation SOP for proposed documentation and process changes.

3.3.6.2 Risk Management Report for QMS Adaption
3.3.6.3 Supplier Agreements
3.3.6.4 CGMP mAb unit operation-specific batch record templates
3.3.6.5 Standardized test methods for compendial mAb assays
3.3.6.6 Qualification Report for the Milliflex® Quantum bioburden system

3.4 Task 4: (b) (4) System Optimized Manufacturing for Rapid Response (Ology Bio)

Assumptions:

- Costs of equipment required for perfusion and continuous chromatography have been included in the budget, and installation and qualification are included in the project schedule.
- Materials costs provided are estimates based on previous work. Depending on the final selection of equipment, consumables costs may vary and need to be revised. The final column sizes required will not be known until further work on the continuous chromatography process is performed.

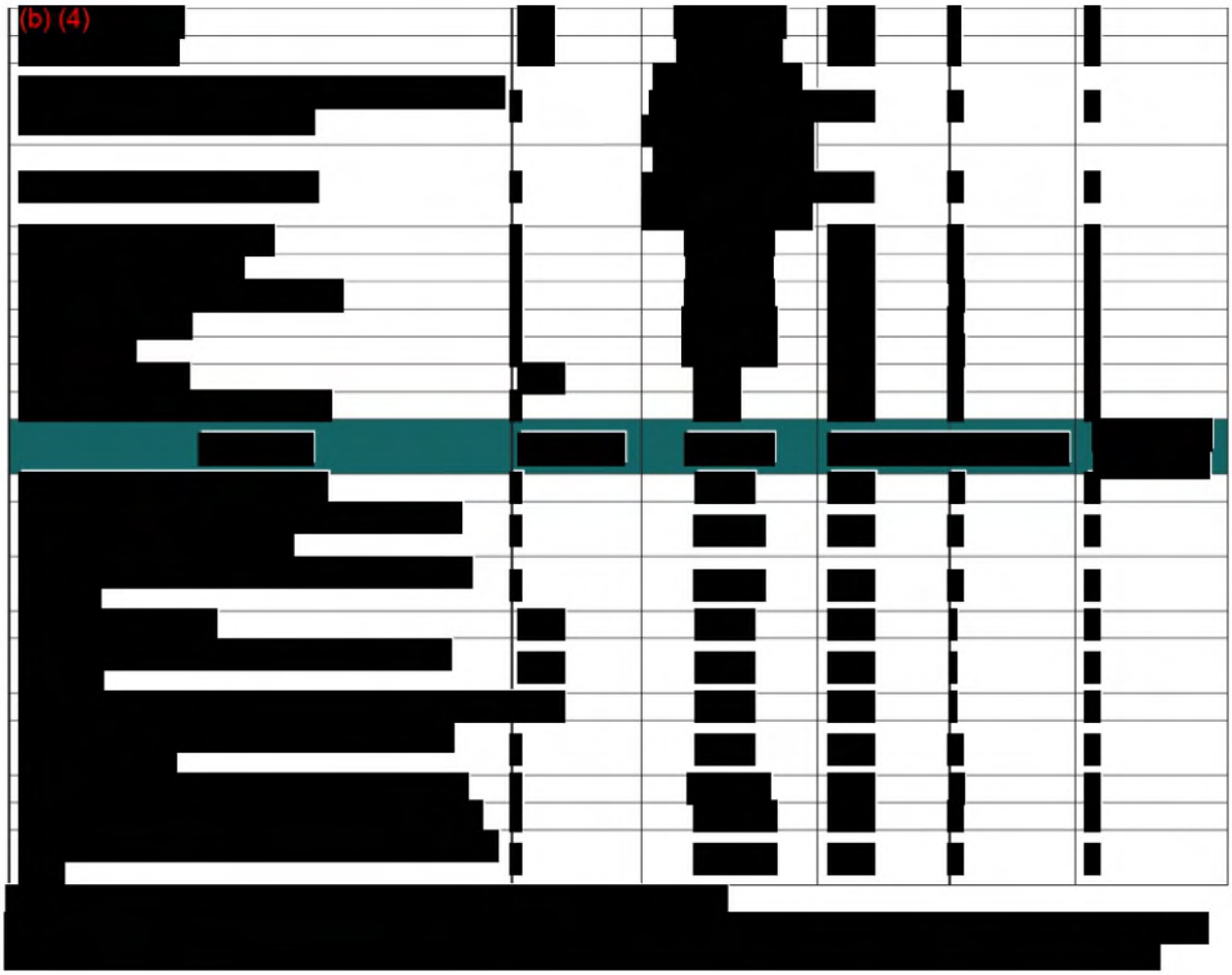
3.4.1 The Awardee shall develop a continuous upstream process using the (b) (4)

3.4.1.1 The Awardee shall install and qualify the (b) (4) .
3.4.1.2 The Awardee shall perform (b) (4) [redacted]
3.4.1.3 In collaboration with the USG, the Awardee shall establish success criteria for (b) (4) [redacted]
3.4.1.4 The Awardee shall perform (b) (4) [redacted]
3.4.1.5 The Awardee shall prepare Development Reports for:
3.4.1.5.1 (b) (4) [redacted]
3.4.1.5.2 (b) (4) [redacted]
3.4.1.6 The Awardee shall develop a continuous chromatography-based downstream process using the (b) (4) [redacted]
3.4.1.6.1 The Awardee shall install and qualify the continuous chromatography system.
3.4.1.6.2 The Awardee shall use materials generated during the perfusion runs to (b) (4) [redacted]
3.4.1.6.3 The Awardee shall prepare Development Reports for: 3.4.1.6.3.1 Continuous Chromatography Runs

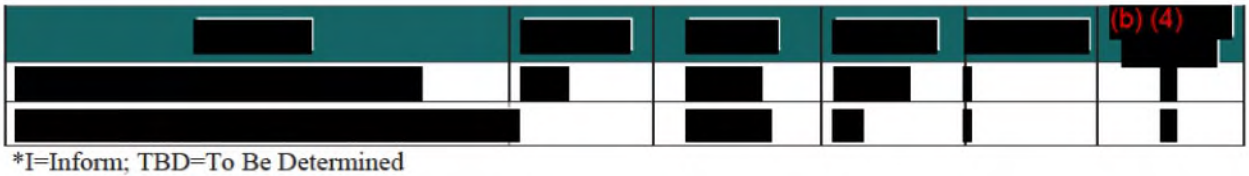
4.0 DELIVERABLES

4.1 Data Deliverables

[redacted]	[redacted]	[redacted]	[redacted]	(b) (4)
[redacted]		[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]



4.2 Deliverables



*I=Inform; TBD=To Be Determined

4.3 Acceptance of Deliverables

The USG will provide acceptance of all data deliverables within thirty days of delivery. The USG will provide acceptance of all deliverables within sixty days of delivery.

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

The following are Ology Bio's Background Intellectual Property (IP) and Materials, as defined in (b) (4)

Ology Bio's Background IP and Materials shall remain the property of Ology Bio. No license(s) to Ology Bio's Background IP and Materials shall be granted under this SOW or Agreement, and the Background IP above are specifically excluded from the definition of "Agreement Invention" contained in Article 9 Section B of the 2373 Agreement.

6.0 SHIPPING PROVISIONS

Controlled, temperature-monitored domestic shipments shall be conducted with World Courier or Federal Express. The manufacturing platform will be delivered to the USG per instructions provided by the project Agreement's Officer Representative (AOR) identified in CLIN 0001 of the Agreement. Data deliverables will be provided in electronic format and coordinated with the project AOR, as required.

7.0 Reporting and Data Requirements

7.1 Progress Reports

7.1.1 Monthly. A Monthly Progress Report (MPR) shall be submitted by the 15th of each month. The MPR will contain the technical progress made during the previous. The schedule update will include the explanation for any changes in the schedule, drivers for the change, as applicable. The report will also address any concerns that would impact the performance, schedule, or cost planned for the effort. Updated project risks and mitigation activities will also be included.

7.1.2 Final. A Final Report shall be submitted at the end of this project's performance inclusive of the base period activities as well as any exercised options. The report will narrate a complete summary of the project execution and results obtained. The narration will include outstanding problems and their potential solutions, problems solved during the project, the solutions to the solved problems, and how the product was advanced.

7.2 Regulatory and Technical Data Package

The Contractor shall be responsible for submitting all documentation required to support regulatory filings with the FDA related to deliverables under this project, as specified in this SOW. The Contractor shall provide the Government with copies of all technical data generated by the Contractor during performance of contract necessary to pursue FDA approval and notify the Government of FDA decisions as these take place. All written communications to and/or from the FDA generated during the performance of this SOW and received from the FDA by the Contractor will be provided to the Government. All documentation shall be prepared for the submission to the FDA and provided to the Government in the format required by the sponsor. Any pre-existing technical data that is required to support government funded activities will be on terms mutually agreed to via negotiation prior to award through an assertion process that identifies such pre-existing technical data and its potential relationship to this SOW hereunder.

7.3 Meetings

7.3.1 Kick-Off Meeting. The Awardee will schedule a post-award kick-off meeting (b) (4) [redacted] following the award date of this SOW with all key SOW stakeholders. This one-day meeting is conducted to establish a common purpose among stakeholders and to provide for a clear understanding of the scope of the project, the schedule for key activities/milestones, the team roster and individual responsibilities, appropriate

communication pathways and the general administration of the project. To support the post award contract kick-off meeting, Awardee will provide read-ahead materials, presentations, relevant documents, and an agenda. This meeting will be attended by Awardee key personnel, designated SMEs and investigator representatives. The Project Manager will work with the Government to determine timing and location for this meeting. Awardee will provide a meeting report to the USG within (b) (4) calendar days after conduct of the meeting. This report will include action items and due dates, any presentation materials as well as summaries of the discussions held.

7.3.2 Integrated Product Team Meetings. The Project Manager will facilitate Integrated Product Team (IPT) teleconferences for this SOW, which will suffice as Progress Review Meetings to be attended by the essential members of the Product Development Team, and Government staff to provide updates on Agreement performance. Awardee will provide agendas for these meetings to all IPT members in advance. Awardee will capture minutes from all IPT teleconferences and will provide minutes within five business days to the Government.

7.3.3 Ad Hoc Meetings. Ad hoc meetings will be held as necessary, upon team member or Government request, to discuss issues as they arise. Awardee will provide information and updates upon Government request. Awardee will provide minutes from these meetings within five business days to the Government.

8. WBS AND WBS DICTIONARY

9. INTEGRATED MASTER SCHEDULE

A rolled-up project IMS is provided below that aligns with the WBS and technical proposal and SOW. The tasks account for the entire project. The IMS is also provided electronically as an MS Project file.

Ology Bioservices, Inc.

BY: (b) (6) [redacted] 05 00

NAME: (b) (6) [redacted]

TITLE: [redacted]

DATE: 21 February 2020

NATICK CONTRACTING DIVISION

BY: (b) (6) [redacted]

NAME: (b) (6) [redacted]

TITLE: Agreements Officer

DATE: 21 Feb 2020

(b) (4)

Appendix B
Project Schedule Payment Schedule

The Government shall pay the Contractor, upon the submission of proper invoices or vouchers Expenditures shall be submitted based on the awarded budget. Federal funds are to be used only for costs that a reasonable and prudent person would incur in carrying out the work. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31). An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements. Final payment of the Agreement shall be determined upon mutual agreement and settlement of any outstanding indirect costs.

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the AO and be in writing, of which email is an acceptable form.

Appendix C
Government Property

Government Property: "Government Property" means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee at the Government's cost under fixed price terms of this Agreement (FP-GP) and specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the AO who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: [Mark N/A if none]:

Use	Description	Make/Model	Est. Cost
Project Specific Equipment Requirements			

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the AO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.

The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical

inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the AO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the AO, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

Awardee Liability for Government Property. "Loss of Government Property" means the loss, damage or destruction to Government Property reducing the Government's expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, normal wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE'S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES: (I) AO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED OR SHIPPED UNDER THE GOVERNMENT'S INSTRUCTIONS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT'S DIRECTIONS.

AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
	DO-N6	1 | 8

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
W911QY2090003	22 Feb 2020	0011438990

5. ISSUED BY	CODE	6. ADMINISTERED BY *(If other than Item 5)*	CODE
W6QK ACC-APG NATICK CONTRACT NG DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, city, county, state and zip code)*	8. DELIVERY	
OLOGY BIOSERVICES, NC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726	[ ] FOB ORIGIN [X] OTHER *(See below)*	
	9 DISCOUNT FOR PROMPT PAYMENT	
	10 SUBMIT INVOICES *(4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN:	ITEM
CODE 3GQS9	FACILITY CODE	

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
JPM MCS JPM CBRN MEDICAL FT. DETRICK, MD VA 21702	W56XNH	DEFENSE F NANCE AND ACCOUNT NG SERVICE DFAS- NDY VP GFEBS 8899 E 56TH STREET NDIANAPOLIS IN 46249-3800	HQ0490

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )	**See Schedule**

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				

15G. TOTAL AMOUNT OF CONTRACT **$3,275,778.21**

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				**PART II - CONTRACT CLAUSES**	
X	A	SOLICITATION/ CONTRACT FORM	1		I	CONTRACT CLAUSES	
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2 - 3			**PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.**	
	C	DESCRIPTION/ SPECS./ WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				**PART IV - REPRESENTATIONS AND INSTRUCTIONS**	
	E	INSPECTION AND ACCEPTANCE			K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	4				
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	H	SPECIAL CONTRACT REQUIREMENTS			M	EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17 [ ] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return copies to issuing office) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein (Attachments are listed herein)

18 [ ] SEALED-BID AWARD (Contractor is not required to sign this document)
Your bid on Solicitation Number _____
including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract No further contractual document is necessary (Block 18 should be checked only when awarding a sealed-bid contract)

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
	(b) (6)

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____ *(Signature of person authorized to sign)*		B (b) (6) *(Signature of Contracting Officer)*	22-Feb-2020

Section B - Supplies or Services and Prices

BUSINESS SIZE
ATTN (b) (4)
[redacted]

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			Job		(b) (4)

(b) (4)
[redacted] Rapid mAB Manufacturing labor, materials, equipment and associated allowable costs delineated the in Statment of Work entitled (b) (4) [redacted] hereby incorporated into the Agreement under Appendix A.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.

The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:
(b) (6)
[redacted]
FOB: Destination
PSC CD: AN14

ESTIMATED COST (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00

FUNDING TO CLIN 0001
FFP
PURCHASE REQUEST NUMBER: 0011438990

NET AMT $0.00

ACRN AA (b) (4)
CIN: GFEBS001143899000001

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	N/A

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	21-NOV-2020		JPM MCS JPM CBRN MEDICAL FT. DETRICK, MD VA 21702 FOB: Destination	W56XNH
000101	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

AGREEMENT ADMINISTRATION

A. In no event shall any understanding of agreement, modification, change order, or other matter in deviation from the terms and conditions of this agreement between the contractor and a person other than the Agreement Officer be effective or binding upon the Government. All Such actions must be formalized by a proper agreement document executed by the Agreement Officer.

B. The telephone number and email address of the Agreement Officer and Agreement Specialists are:

Agreement Officer
(b) (6)

Agreement Specialists
(b) (6)

Susan E. Ruzicka
(b) (6)

C. The telephone number and email address of the Agreement Officer's Representatives (AOR)* are as follows:

Primary Project Manager
(b) (6)

Alternate Program Manager
(b) (6)

*Project level AORs are specified in the Project CLIN description.

ACCOUNTING AND APPROPRIATION DATA

AA: 097202020210400000260100060602 55 A.0011316.3.1.1 6100.9000021001
COST CODE: A5XAH
AMOUNT (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001143899000001	(b) (4)

CLAUSES INCORPORATED BY REFERENCE

52.232-22 Limitation Of Funds APR 1984

CLAUSES INCORPORATED BY FULL TEXT

252.204-7006 BILLING INSTRUCTIONS (OCT 2005)

When submitting a request for payment, the Contractor shall--

(a) Identify the contract line item(s) on the payment request that reasonably reflect contract work performance; and

(b) Separately identify a payment amount for each contract line item included in the payment request.

(End of clause)

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

"Department of Defense Activity Address Code (DoDAAC)" is a six position code that uniquely identifies a unit, activity, or organization.

"Document type" means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

"Local processing office (LPO)" is the office responsible for payment certification when payment certification is done external to the entitlement system.

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and

(2) Be registered to use WAWF at https://wawf.eb mil/ following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at https://wawf.eb mil/.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

_____

(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

__2-in-1_____

(Contracting Officer: Insert either "Invoice 2in1" or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH
Other DoDAAC(s)	____

(*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(**Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Agreement Officer: (b) (6)
Agreement Specialists: (b) (6)
(b) (6)

CLIN 0001 Project 20-01 AOR: (b) (6)

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
S	1 | 6

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00002	18-Mar-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 22-Feb-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to incorporate Project 20-05 under CLIN 0002, correct CLIN 0001 and subCLINS 000101 and 000102 contract type, and incorporate incremental funding under CLIN 000201. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	(b) (6) TEL: EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	[redacted]	BY (b) (6) (Signature of Contracting Officer)	18 Mar 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00002

A. The purpose of this modification is as follows:

1. (b) (4) Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19, Attachment 1, is hereby incorporated into the agreement under CLIN 0002.

2. The total cost of this agreement is hereby increased by (b) (4), from (b) (4) to (b) (4)

3. CLIN 000201 is hereby added to the agreement to incorporate incremental funding in the amount of (b) (4) under ACRN (b) (4).

4. (b) (4)

B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any Article in this agreement resulting from the incorporation of project 20-05 identified in paragraph A.1.

C. Both parties hereby agree that the costs specific to subawards Battelle and IITRI are subject to Government review to determine reasonableness and definitization, which may result in a change to the final negotiated costs.

D. Defense Priority and Allocations Requirements. This is a rated order certified for national defense and emergency preparedness, and the Contractor shall follow all requirements of the Defense Priorities and Allocations System (DPAS) regulation (15 CFR 700). Rating DO C-9

E. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4).

SECTION B - SUPPLIES OR SERVICES AND PRICES

Global Changes

(b) (4)
(b) (4).

(b) (4)

[redacted]

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			Job		$3,275,778.21

PROJECT 20-01: Rapid mAB Manufacturing
CPFF
Project 20-01: Rapid mAB Manufacturing labor, materials, equipment and associated allowable costs delineated the in Statement of Work entitled, "Project 20-01 Rapid Monoclonal Antibodies Manufacturing System, hereby incorporated into the Agreement under Appendix A.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.

The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:
(b) (6)
[redacted]

FOB: Destination
PSC CD: AN14

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	(b) (4)

SUBCLIN 000101

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00
	FUNDING TO CLIN 0001 CPFF PURCHASE REQUEST NUMBER: 0011438990				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AA CIN: GFEBS001143899000001				(b) (4)

SUBCLIN 000102

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102					$0.00
	Funding to CLN 0001 CPFF ACRN AA PURCHASE REQUEST NUMBER: 0011438990-0006				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AA CIN: GFEBS001143899000002				(b) (4)

CLIN 0002 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002			Job		(b) (4)

PROJECT 20-05: (b) (4)
CPFF
(b) (4) labor, materials, equipment and associated costs delineated the in Statement of Work entitled, "Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19", hereby incorporated into the Agreement under Appendix A.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.

The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:
(b) (6)

FOB: Destination
PSC CD: AN14

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	(b) (4)

SUBCLIN 000201 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000201					$0.00

GFY 2020 Funding
CPFF
PURCHASE REQUEST NUMBER: 0011474203

ESTIMATED COST	$0.00
FIXED FEE	$0.00
TOTAL EST COST + FEE	$0.00

ACRN AB (b) (4)
CIN: GFEBS001147420300001

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0002:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000201:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0002 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
28-MAR-2022		JPM MCS JPM CBRN MEDICAL FT. DETRICK, MD VA 21702 FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000201:
Funding on SUBCLIN 000201 is initiated as follows:

ACRN: AB

CIN: GFEBS001147420300001

Acctng Data: 097202020210130000181704464632 52 S.0025760.7.5.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPII

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
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2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00003	19-Mar-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to incorporate Project 20-03 under CLN 0003 and incorporate incremental funding under CLN 000301. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
		(b) (6) TEL: (b) (6)
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA
(Signature of person authorized to sign)		(b) (6)
		16C. DATE SIGNED 19-Mar-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00003

A. The purpose of this amendment is as follows:
   a. The SOW for Project 20-03, Procurement, Commissioning and Qualification of (b) (4) (b) (4) at the DoD ADM Facility, Appendix A-3, is hereby incorporated into the agreement under CLIN 0003.
   b. The total cost of the agreement is hereby increased by (b) (4), from (b) (4) to (b) (4).
   c. CLIN 000301 is hereby added to the agreement into incorporate incremental funding in the amount of (b) (4) under ACRN (b) (4)
B. The parties hereby agree that changes effected by this amendment constitute both the consideration and the equitable adjustment due under any Article in this agreement resulting from the incorporation of Project 20-03.
C. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003			Job		(b) (4)

PROJECT 20-03: (b) (4)
CPFF
Project 20-03: Procurement, Commissioning and Qualification of (b) (4) (b) (4) at the DoD ADM Facility labor, materials, equipment and associated allowable costs delineated the in Statment of Work entitled, "Procurement, Commissioning and Qualification of (b) (4) (b) (4) at the DoD ADM Facility," hereby incorporated into the Agreement under Appendix A.

The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.

The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:
(b) (6)
FOB: Destination
PSC CD: AN14

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	(b) (4)

SUBCLIN 000301 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301					$0.00

GFY 2020 Funding
CPFF
Project 20-03
PURCHASE REQUEST NUMBER: 0011473355

ESTIMATED COST	$0.00
FIXED FEE	$0.00
TOTAL EST COST + FEE	$0.00

ACRN AC (b) (4)
CIN: GFEBS001147335500001

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0003:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000301:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0003 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
30-SEP-2020		MCS JPL EB 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000301:
Funding on SUBCLIN 000301 is initiated as follows:

ACRN: AC

CIN: GFEBS001147335500001

Acctng Data: 097202020210400000260100060602 55 A.0011316.3.1.2 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: A5XAH

(End of Summary of Changes)

1. STATEMENT OF WORK

Title: Procurement, Commissioning and Qualification of (b) (4) (b) (4) at the DoD ADM Facility

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated 21 February 2020 shall govern performance of work under this SOW. The SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The purpose of this SOW is to procure, commission, and qualify (b) (4) (b) (4) (the supplies) at the DoD ADM facility. These fermenters will be utilized in future developmental work at the ADM facility, including production of MCMs under cGMPs leading to the development of FDA approved medical countermeasures (the best supplies). Current equipment does not provide sufficient volume for the full scale production runs necessary on advanced development projects.

2.0 REQUIREMENTS

2.1 Task 1: Purchase, Installation and (b) (4) Fermenters

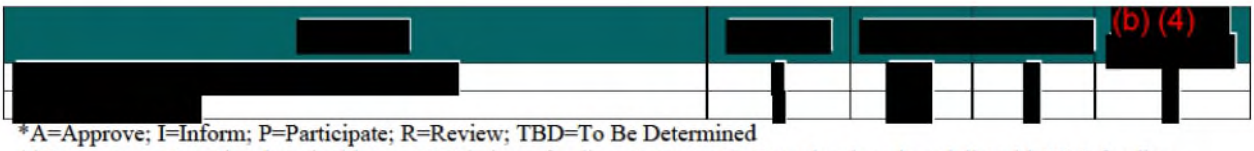
Assumptions:

- (b) (4) (b) (4) from (b) (4) (current identified vendor) will be purchased along with any other necessary components, systems, documentation or services to achieve the project's goal of commissioning and qualifying the fermenters at the DoD ADM Facility.

2.1.1 The Awardee shall conduct an Engineering review, including generating a User Requirements Specification, Component Criticality Assessment and System Level Impact Assessment.
2.1.2 The Awardee shall purchase (b) (4) (b) (4) .
2.1.3 The Awardee shall perform a FAT prior to (b) (4) shipment.
2.1.4 The Awardee shall install (b) (4) fermenters at the DoD ADM Facility and perform SAT.
2.1.5 The Awardee shall perform IQ of the (b) (4) (b) (4) .
2.1.6 The Awardee shall perform OQ of the (b) (4) (b) (4)
2.1.7 The Awardee shall prepare a Qualification Report for the (b) (4) (b) (4) .
2.1.8 The Awardee shall procure a stock-pile of (b) (4) (b) (4) to ensure on-going use is possible following qualification.

3.0 DELIVERABLES

3.1 Data Deliverables



*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined
**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

3.2 Supply Deliverables

*I=Inform; P=Participate; R=Review; TBD=To Be Determined

3.1 Acceptance of Deliverables

The U.S. Government (USG) will provide review of all data deliverables within 30 days of delivery. The USG will acknowledge receipt of all supply deliverables within 60 days of delivery. Equipment delivered under this SOW will be transferred to the facility Government Property List and maintained in accordance with applicable regulations.

4.0 SHIPPING PROVISIONS

The final product will be delivered to the DoD ADM Facility in coordination with the project Agreement's Officer Representative (AOR) identified in CLIN 0003 of the Agreement. Data deliverables will be provided in electronic format and coordinated with the project AOR as required.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00004	21-Mar-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the agreement.

E. IMPORTANT: Contractor [X] is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: (b) (6)

The purpose of this modification is to incorporate additional funding under CLIN 0003. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	21-Mar-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00004

The purpose of this amendment is to incorporate additional funding under CLIN 0003. All other terms and conditions remain the same and in full force and effect.

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000302 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000302					$0.00
	Funding FY 20 CPFF PURCHASE REQUEST NUMBER: 0011476080				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AB				(b) (4)
	CIN: GFEBS001147608000001				

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000302:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000302:
Funding on SUBCLIN 000302 is initiated as follows:

ACRN: AB

CIN: GFEBS001147608000001

Acctng Data: 097202020210130000181704464632525 S.0025760.7.5.1 6100.9000021001

Increase: $715,265.00

Total (b) (4)

Cost Code: AHPII

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
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2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00005	22-Mar-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 22-Feb-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to incorporate Project 20-04 under CLIN 0004, incorporate incremental funding, and revise Article 14.G. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	22-Mar-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
P00005

A. The purpose of this amendment is as follows:

a. Paragraph A.1 of modification P00002 is hereby changed from:

1. (b) (4) [redacted]

To:
1. (b) (4) [redacted]

b. (b) (4)

c. The total cost of the agreement is hereby increased by (b) (4) [redacted] from (b) (4) [redacted] to (b) (4) [redacted].

d. (b) (4)

e. Article 14.G is hereby replace in its entirety with "Any project order incorporated into this agreement may be DO C-9 rated order certified for national defense, emergency preparedness, and energy program use under the Defense Priorities and Allocations System (DPAS) (15 CFR700), and the Awardee will be required to follow all of the requirements of this regulation.

f. (b) (4)

B. (b) (4)

C. All other terms and conditions remain the same and in full force and effect.

The following have been modified:
P00004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301					$0.00
	GFY 2020 Funding CPFF Project 20-03 PURCHASE REQUEST NUMBER: 0011473355				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AC CIN: GFEBS001147335500001				(b) (4)

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0004 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004			Job		(b) (4)
	(b) (4), (b) (6)				

SUBCLIN 000401 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000401					$0.00
	FY 20 Funding CPFF PURCHASE REQUEST NUMBER: 0011474201				
				ESTIMATED COST	$0.00
				FIXED FEE	$0.00
				TOTAL EST COST + FEE	$0.00
	ACRN AB CIN: GFEBS001147420100001				(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0004:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000401:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0004 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-MAR-2022		N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000401:
Funding on SUBCLIN 000401 is initiated as follows:

ACRN: AB

CIN: GFEBS001147420100001

Acctng Data: 097202020210130000181704464632525 S.0025760.7.5.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPII

(End of Summary of Changes)

1. STATEMENT OF WORK

Title: Rapid COVID-19 Plasmid Manufacturing for Phase 1 Clinical Programs

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated *21 February 2020* shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The purpose of this project is to manufacture vials of CGMP plasmid DNA DP suitable for use in a clinical trial (the supply), to support Department of Defense requirements for an FDA-approved COVID-19 vaccine (the best supplies). Based on information provided (b) (4) an be manufactured per lot.

(b) (4)

2.0 REQUIREMENTS

2.1 Task 1: Project Initiation and Oversight

Notes:

- Labor for project oversight (Project Manager [PM], Principal Investigator [PI], contracts and finance) spans the lifecycle of the project.
- Data requirements span the lifecycle of the project through delivery of doses.
- If a due date for a deliverable is on a weekend or holiday, then the deliverable will be due on the next business day.

2.1.1 Planning

2.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) business days following the (b) (4) contract award, provide an agenda (b) (4) business days prior to the meeting, and provide a meeting report (b) (4) business days. The kickoff meeting will be held virtually.

2.1.1.2 The Awardee shall provide an Integrated Master Schedule (IMS) (b) (4) . The Awardee shall provide an updated IMS identifying task progress, percent completion and schedule slippage.

2.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project

Charter, Communication Plan, IMS, Work Breakdown Structure (WBS), Cost Management/Spend Plan and List of Deliverables.

2.1.2 Execution

2.1.2.1 Meetings

2.1.2.1.1 The Awardee shall conduct IPT meetings no less than twice per month. The Awardee shall provide the agendas and IPT slide decks within 24 hours in advance of the IPT. Finalized meeting minutes shall be submitted to the USG within five business days following each teleconference.

2.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or USG request, to discuss issues as they arise. Minutes from these meetings shall be provided to the USG within five business days following the meeting.

2.1.2.2 Reports

2.1.2.2.1 The Awardee shall deliver a Monthly IMS and spend plan for the life cycle of the project. The Awardee shall submit each Monthly IMS and spend plan within 20 calendar days after the end of each month of performance. The USG will have 10 calendar days to respond to the report with any comments, and the Awardee will have an additional five calendar days to revise the deliverable or respond to those comments.

2.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities. Delivery dates for Quarterly and Annual Progress reports will be based on award date and not the calendar year.

2.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 20 calendar days after the end of each quarter of performance. The USG will have 30 calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

2.1.2.2.4 The Awardee shall perform, record and report physical inventory results of all Contractor Acquired Property in the contractor's possession, if the Awardee purchases material or equipment using USG funds, as approved by the Agreement Officer's Representative (AOR) during performance of the project.

2.1.2.2.5 Incident Reporting

2.1.2.2.5.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the USG in an incident report. In addition, the Awardee shall provide advance notice of critical path schedule changes resulting in more than a 15 calendar-day shift that are not

handled as Incident Reports. The (b) (4) PM shall provide written notification (via email) to the AOR.

2.1.2.2.5.2 The Awardee shall telephonically contact the program manager for the USG no later than 24 hours after the incident is identified.

2.1.2.2.5.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place. If additional time is required for the Root Cause Analysis, the (b) (4) PM will work with the AOR to agree on timing of the written summary report.

2.1.2.2.6 The Project Agreement Holder (PAH) shall establish a Quality Agreement with the USG. The PAH shall provide the draft Quality Agreement within ten calendar days of project award. The draft Quality Agreement will be submitted via e-mail to the USG technical representatives. The USG shall respond with comments or acceptance ten calendar days following receipt of the draft Quality Agreement. The final agreement with incorporated changes shall be submitted five calendar days after receipt of USG comments. The USG will provide written acceptance.

2.1.2.2.7 The PAH shall also develop a Quality Agreement with (b) (4) that defines the roles and responsibilities of both parties. The Quality Agreement with (b) (4) will be provided to the USG for informational purposes rather than review and approval.

2.1.2.2.8 The Awardee shall support USG quality audits of the Awardee's systems and procedures, insofar as they relate to the service and control of the USG's product. These audits may be performed at times mutually agreed upon by the Awardee and the USG. The Awardee shall provide the USG with monthly follow-ups on the status of audit observation commitments found in the USG annual audit or regulatory inspection, as they apply to the USG's product.

2.1.3 Regulatory/CMC Support

2.1.3.1 The Awardee shall provide support to the product sponsor to enabling updating of their CMC sections with manufacturing data and technical information.

2.2 Task 2: Technology Transfer

Note:

- Process Establishment Runs will be performed with COVID-19 plasmid and upstream parameters (b) (4)

2.2.1 (b) (4) Information Transfer, Gap Analysis and Risk Assessment

2.2.1.1 The awardee will perform technology transfer (b) (4) . In accordance with a Consulting Agreement and Quality Agreement that will be finalized and signed after execution of this agreement, the awardee will manage the following support from Inovio:

2.2.1.1.1 Review of all required documentation including analytical assay protocols and specifications, development records, batch records, list of equipment and any other documentation to support this project

2.2.1.1.2 Receipt of the necessary cell lines to support the technology transfer and WCB development

2.2.1.1.3 (b) (4) support the technology transfer of the upstream and downstream processing for manufacture of their DNA plasmid vaccine candidate

2.2.1.1.4 (b) (4)

2.2.1.1.5 Test plan for analytical comparability and assistance in demonstration comparability

2.2.1.1.6 Under the terms of Quality Agreement (b) (4) 1) upon confirmation of comparability, (b) (4) add (b) (4) as a manufacturer in their IND; 2) (b) (4) shall provide all correspondence to and from the FDA related to the addition of (b) (4) manufacturing facility. Awardee shall provide all FDA correspondence to the USG within 3 days of receipt (b) (4) ; and 3) (b) (4) shall provide a Letter of Authorization to their Master File as needed by the USG.

2.2.1.2 The Awardee shall complete an initial Risk Assessment and Mitigation Strategy including all tasks and supply chain management.

2.2.1.3 The Awardee shall conduct a Gap Analysis of the transferred information to identify any potential gaps or weaknesses associated with any of the tasks.

2.2.2 Review of (b) (4) Documentation

2.2.2.1 The Awardee shall review all project-related documents provided (b) (4) .

2.2.2.2 The Awardee shall draft a Development Plan, including relevant information from the documents provided (b) (4) , that will outline the relevant scope of work and revise it based on the client's feedback.

2.2.3 Transfer of Product-Specific Materials from (b) (4) and Procurement of Materials and Components

2.2.3.1 The Awardee shall develop a preliminary BOM using approved suppliers.

2.2.3.2 Upon completion of risk assessments and required permits, the Awardee shall coordinate with (b) (4) for the shipment of materials to the DoD ADM Facility. The Awardee shall receive the (b) (4) provided materials and store them using inventory management practices in order to maximize performance integrity and shelf life.

2.2.3.3 The Awardee shall provide traceability of both consumable and non-consumable (b) (4) provided materials from procurement until the end of the material's life.

2.2.3.4 The Awardee shall order and receive any other biologics and process materials and components to complete the project.

2.2.4 Process Establishment Runs

2.2.4.1 The Awardee shall provide a Process Establishment Plan for (b) (4) Process Establishment Runs using the COVID-19 plasmid ((b) (4) [redacted] at the (b) (4) (b) (4) [redacted]

2.2.4.2 The Awardee shall provide Process Establishment Run Process Development Production Records (PDPRs) for the Process Establishment Runs.

2.2.4.3 The Awardee shall execute the (b) (4) Process Establishment Runs, including upstream and downstream processes using the (b) (4) [redacted]

2.2.4.4 The Awardee shall provide a Process Establishment Report.

2.3 Task 3: Working Cell Bank Manufacturing

2.3.1 The Awardee shall provide (b) (4) vials of WCB based on COVID-19 MCB vials and process documentation received (b) (4) .

2.3.2 The Awardee shall perform release testing and characterization of the WCB.

2.3.3 The Awardee shall provide a Working Cell Banking Report, including the WCB production batch record and a Certificate of Analysis (COA).

2.4 Task 4: Analytical Assay Development

Notes:

- Product-specific methods for in-process testing have been developed.
- Compendial methods are already in place and will only require verification.
- (b) (4) has current experience with the methods in **Table 2** and **Table 3**. (b) (4) assumes these are the methods that will be required for in-process and release testing.

2.4.1 The Awardee shall receive analytical SOPs and development reports (b) (4) . Product-specific QC assay information will be transferred to the Awardee (b) (4) in accordance with (b) (4) Consulting Agreement (b) (4) .

2.4.2 The Awardee shall update specifications and a final testing list upon receipt of (b) (4) analytical technology transfer package. Testing specification will allow for a direct comparison of previously produced plasmid material and reference standard.

2.4.3 The Awardee shall provide an Assay Qualification Plan. The Awardee will qualify the analytical methods in accordance with USP, FDA and Ph. Eur. requirements and guidance appropriate for use in clinical studies.

2.4.4 The Awardee shall perform Technology Transfer Feasibility assessments on (b) (4) provided methods for product testing. In accordance with the (b) (4) (4) Consulting Agreement, analytical specialized reagents and Reference Standards will be provided (b) (4) .

2.4.5 The Awardee will establish in-process and release testing methods for the plasmid DNA DS and DP to meet specifications mutually approved by (b) (4) (b) (4)

2.4.6 The Awardee shall assess the suitability of compendial methods.

2.4.7 The Awardee shall draft non-compendial test methods and execute non-compendial method qualification. (b) (4) [redacted]

(b) (4)

aiver

(b) (4)

Table 1. In-Process Assays

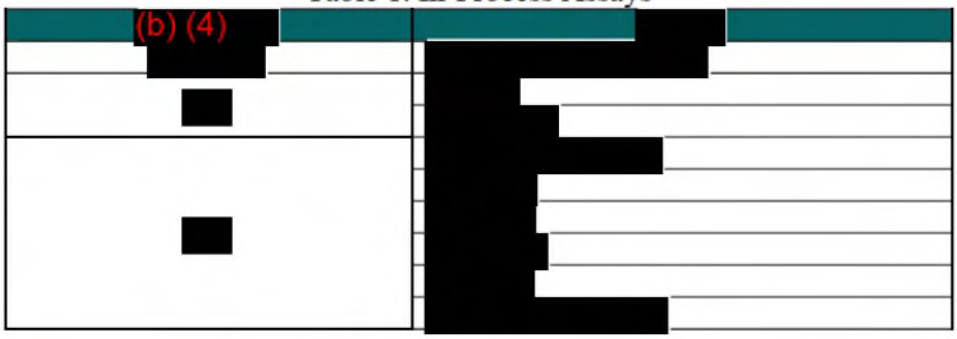
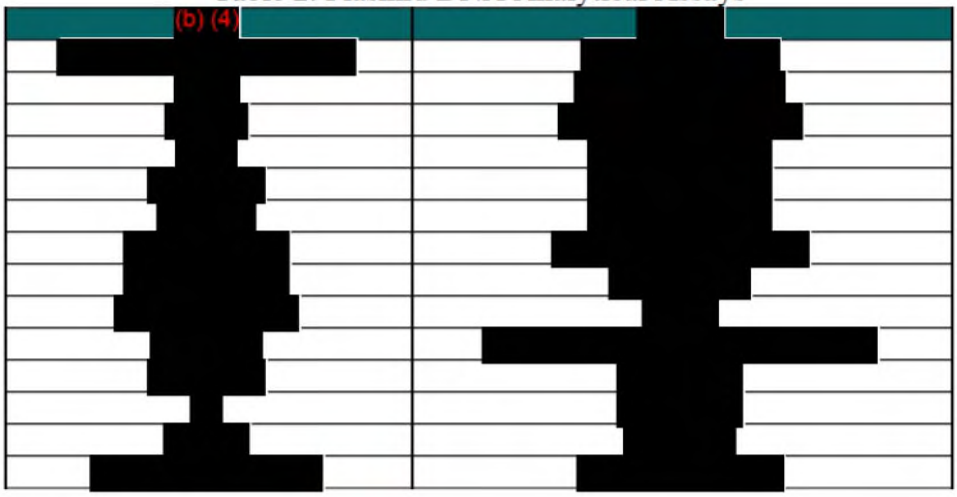


Table 2. Plasmid DNA Analytical Assays



2.5 Task 5: Engineering DS Runs(b) (4)

2.5.1 The Awardee shall prepare draft Master Batch Records (MBRs); raw material, product and label specifications; and draft BOM and MBR setup.

2.5.2 The Awardee shall proceed directly from the Process Establishment Runs to an Engineering DS Run at the (b) (4) scale, which the Awardee shall execute using draft MBRs.

2.5.3 The Awardee shall conduct the run in the CGMP manufacturing area of the DoD ADM Facility.

2.5.4 The Awardee shall use resins and filters dedicated for this project. The Awardee shall use the same columns/resins for both the Engineering and CGMP Runs.

2.5.5 The Awardee shall conduct in-process and release testing on Engineering DS based on the analytical tests from Task 4 and (b) (4)(b) (4)

2.5.6 The Awardee shall provide:

2.5.6.1 Engineering Run Report
2.5.6.2 Finalized CGMP Batch Record templates
2.5.6.3 Finalized CGMP specifications
2.5.6.4 Final BOM
2.5.6.5 Engineering non-CGMP DS CoT
2.5.6.6 Engineering non-CGMP DS MSDS

2.6 Task 6: CGMP DS Runs (b) (4)

2.6.1 The Awardee shall update the Technology Transfer Protocol (TTP) and MBRs as needed.

2.6.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.6.3 The Awardee shall execute (b) (4) runs for the CGMP DS using MBRs, with the number of runs based on the discretion of the USG and suggestions from (b) (4)

2.6.3.1 The Awardee shall conduct the CGMP Run using the (b) (4)

2.6.3.2 The Awardee shall conduct the in-process and release testing outlined in **Table 2** and **Table 3**.

2.6.3.3 The Awardee shall store the DS frozen pending DP fill/finish. All DS lots will be at the disposition of the USG and storage will be at the ADM Facility.

2.6.3.4 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.6.3.5 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.6.4 The Awardee shall provide manufacturing and testing information (e.g., raw data or summary reports as required) related to (b) (4) -produced DS (b) (4) for incorporation into their submission to their IND or Master File to support clinical development.

.

2.6.5 The Awardee shall provide the following for each CGMP DS Lot:

2.6.5.1 QA-Approved DS Executed Batch Production Records
2.6.5.2 QA-Approved DS COA
2.6.5.3 QA-Approved DS MSDS
2.6.5.4 CGMP DS Campaign Summary Report

2.7 Task 7: CGMP DP Runs

2.7.1 The Awardee shall determine the final dose and vial configuration in conjunction with the USG (b) (4) .

2.7.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.7.3 The Awardee shall perform three media fill qualification runs using the selected vial configuration and volume.

2.7.4 The Awardee shall provide a Media Fill Qualification Report.

2.7.5 The Awardee shall perform liquid fill operations using the CGMP DS from Task 6.

2.7.6 The Awardee shall fill (b) (4) (b) (4) This includes formulation, fill, inspection, labeling, packaging and QA review.

2.7.7 The Awardee shall conduct sampling and lot release testing per sponsor-provided specifications.

2.7.8 All DP lots will be at the disposition of the USG, and storage pending shipment will be at the ADM Facility.

2.7.9 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.7.10 The Awardee shall provide manufacturing and testing information related to (b) (4) DP (b) (4), for (b) (4) their IND.

2.7.11 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, executed CGMP batch records, and COA and MSDS for CGMP DP.

2.8 Task 8: Scale-(b) (4) and Transfer of (b) (4) (b) (4)

2.8.1 The Awardee shall coordinate (b) (4) for transfer the process for (b) (4), in parallel with Engineering and CGMP Runs in accordance with the (b) (4) (b) (4) Agreement.

2.8.2 The Awardee shall procure, (b) (4) (b) (4).

2.8.3 The Awardee shall provide a Process Scale-up Plan.

2.8.4 The Awardee shall prepare Process Scale-up PDPRs.

2.8.5 The Awardee shall conduct (b) (4) (b) (4) with the number of runs based on the discretion of the USG and suggestions from (b) (4)

2.8.6 The Awardee shall QC test the materials from these runs based on the analytical assays in **Table 2** and **Table 3**.

2.8.7 The Awardee shall prepare draft batch records for use in the Engineering Run(s).

2.8.8 The Awardee shall provide a Sampling Plan.

2.8.9 The Awardee shall provide a TTP.

2.8.10 The Awardee shall provide a Process Scale-Up Report.

2.9 Task 9: Engineering DS Run (b) (4)

2.9.1 The Awardee shall prepare a TTP; draft MBRs; raw material, product and label specifications; and draft BOM and MBR setup.

2.9.2 The Awardee shall execute (b) (4) Engineering DS lot using draft MBRs.

2.9.3 The Awardee shall use the scaled-up process from Task 8 and the (b) (4).

2.9.4 The Awardee shall use resins and filters dedicated for this project. The Awardee shall use the same columns/resins for both the Engineering and CGMP Runs.

2.9.5 The Awardee shall conduct the runs in the CGMP manufacturing area of the DoD ADM Facility.

2.9.6 The Awardee shall test the Engineering DS based on the analytical tests from Task 4 and (b) (4)(b) (4)

2.9.7 The Awardee shall provide:

2.9.7.1 Engineering Run Report
2.9.7.2 Finalized CGMP Batch Record templates
2.9.7.3 Finalized CGMP specifications
2.9.7.4 Final BOM
2.9.7.5 Engineering non-CGMP DS CoT
2.9.7.6 Engineering non-CGMP DS MSDS

2.10 Task 10: CGMP DS Run (b) (4)

2.10.1 The Awardee shall update the TTP and MBRs as needed.
2.10.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.
2.10.3 The Awardee shall execute (b) (4) run for the CGMP DS using MBRs and (b) (4) .
2.10.3.1 The Awardee shall conduct the in-process and release testing outlined in **Table 2** and **Table 3**.
2.10.3.2 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.
2.10.3.3 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.
2.10.4 The Awardee shall provide:
2.10.4.1 QA-Approved Executed DS Batch Production Records
2.10.4.2 QA-Approved DS COA
2.10.4.3 QA-Approved DS MSDS

2.11 Task 11: Optional: CGMP DP Fill/Finish (b) (4)

2.11.1 The Awardee shall determine the final dose and vial configuration in conjunction with the USG (b) (4) .
2.11.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.
2.11.3 The Awardee shall perform liquid fill operations using the CGMP DS from Task 10 (b) (4) .
2.11.4 The Awardee shall fill (b) (4) multi-dose vials of CGMP DP suitable for use in a Phase 1 clinical trial at a concentration TBD in collaboration with the client. This includes formulation, fill, inspection, labeling, packaging and QA review.
2.11.5 The Awardee shall conduct sampling and lot release testing.
2.11.6 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.
2.11.7 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and CoA and MSDS for CGMP DP.

2.12 Task 12: Optional: CGMP DS Runs (b) (4) (Additional runs)

2.12.1 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.12.2 The Awardee shall execute (b) (4) runs for the CGMP DS using MBRs; the number of runs will be based on the discretion of the USG and suggestions from (b) (4).

2.12.2.1 The Awardee shall conduct the in-process and release testing outlined in **Table 2** and **Table 3**.

2.12.2.2 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.12.2.3 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.12.3 The Awardee shall provide:

2.12.3.1 QA-Approved Executed DS Batch Production Records

2.12.3.2 QA-Approved DS COA

2.12.3.3 QA-Approved DS MSDS

2.13 Task 13: Optional: CGMP DP Fill/Finish (b) (4)

2.13.1 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.13.2 The Awardee shall perform liquid fill operations using the CGMP DS from Task 12.

2.13.3 The Awardee shall fill (b) (4) (b) (4) of CGMP DP suitable for use in a Phase 1 clinical trial at a concentration TBD in collaboration with the client. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.13.4 The Awardee shall conduct sampling and lot release testing.

2.13.5 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.13.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.14 Task 14: Stability Testing of DS and DP (b) (4)

2.14.1 Engineering DS

2.14.1.1 The Awardee shall provide a Stability Protocol for the Engineering DS, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.14.1.2 The Awardee shall execute the stability study using the Engineering Run DS.

2.14.1.3 The Awardee shall provide a Stability Report.

2.14.2 CGMP DS

2.14.2.1 The Awardee shall provide a Stability Protocol for the CGMP DS, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.14.2.2 The Awardee shall execute the stability study using the CGMP DS.

2.14.2.3 The Awardee shall provide a Stability Report.

2.14.3 CGMP DP

2.14.3.1 The Awardee shall provide a Stability Protocol for the CGMP DP, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.14.3.2 The Awardee shall execute the stability study using the CGMP DP.

2.14.3.3 The Awardee shall provide a Stability Report.

2.15 Task 15: Optional: Stability Testing of DS and DP (b) (4)

2.15.1 CGMP DS

2.15.1.1 The Awardee shall provide a Stability Protocol for the CGMP DS, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.15.1.2 The Awardee shall execute the stability study using the CGMP DS.

2.15.1.3 The Awardee shall provide a Stability Report.

2.15.2 CGMP DP

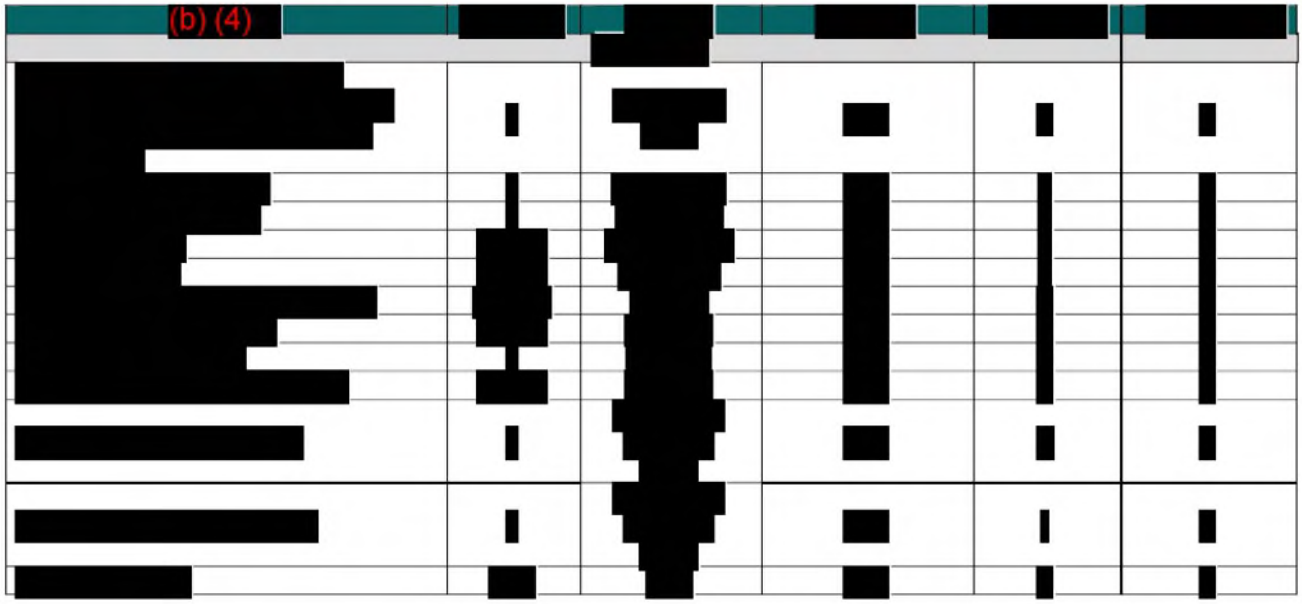
2.15.2.1 The Awardee shall provide a Stability Protocol for the CGMP DP, to be determined in collaboration with the Client, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

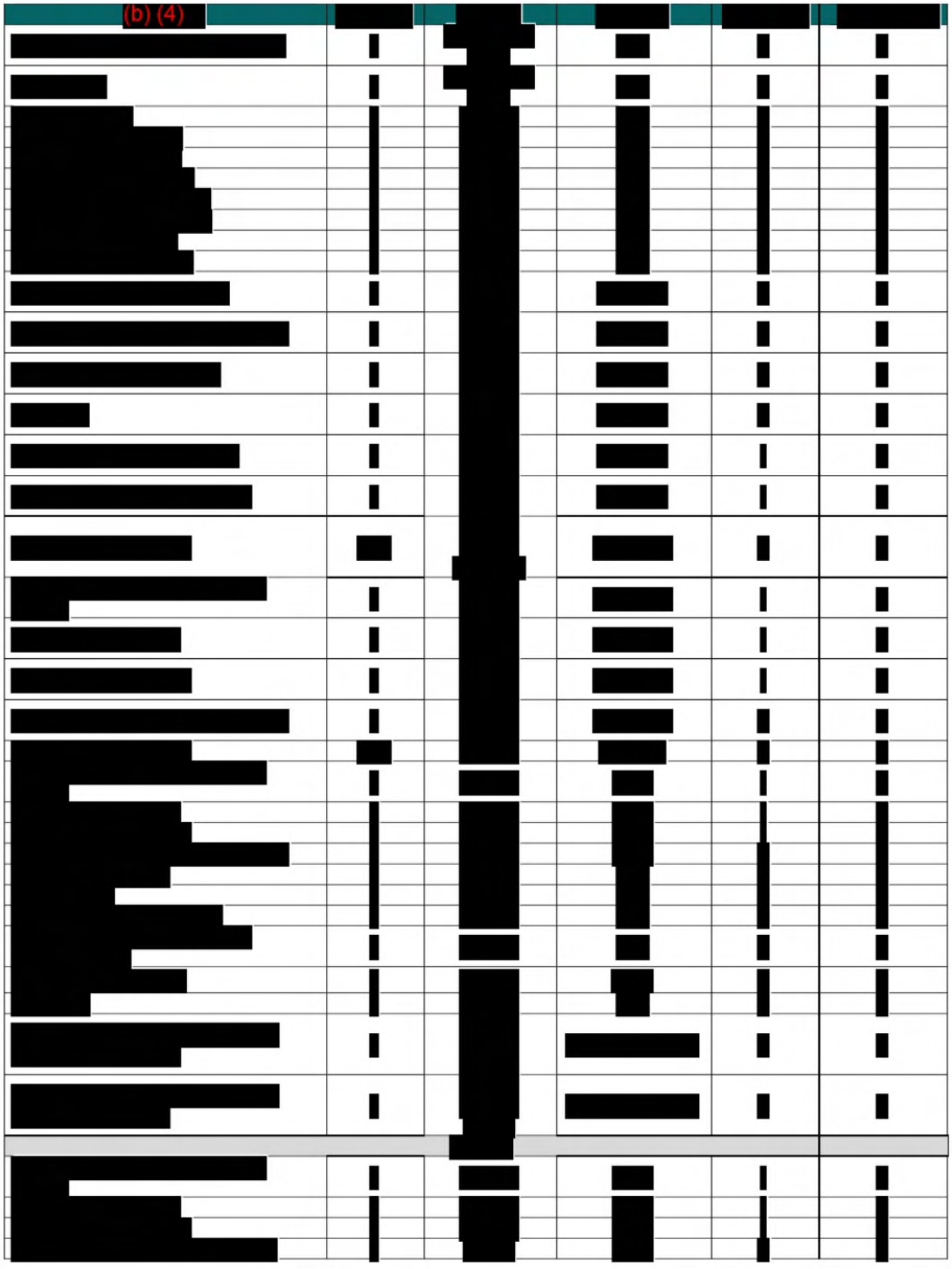
2.15.2.2 The Awardee shall execute the stability study using the CGMP DP.

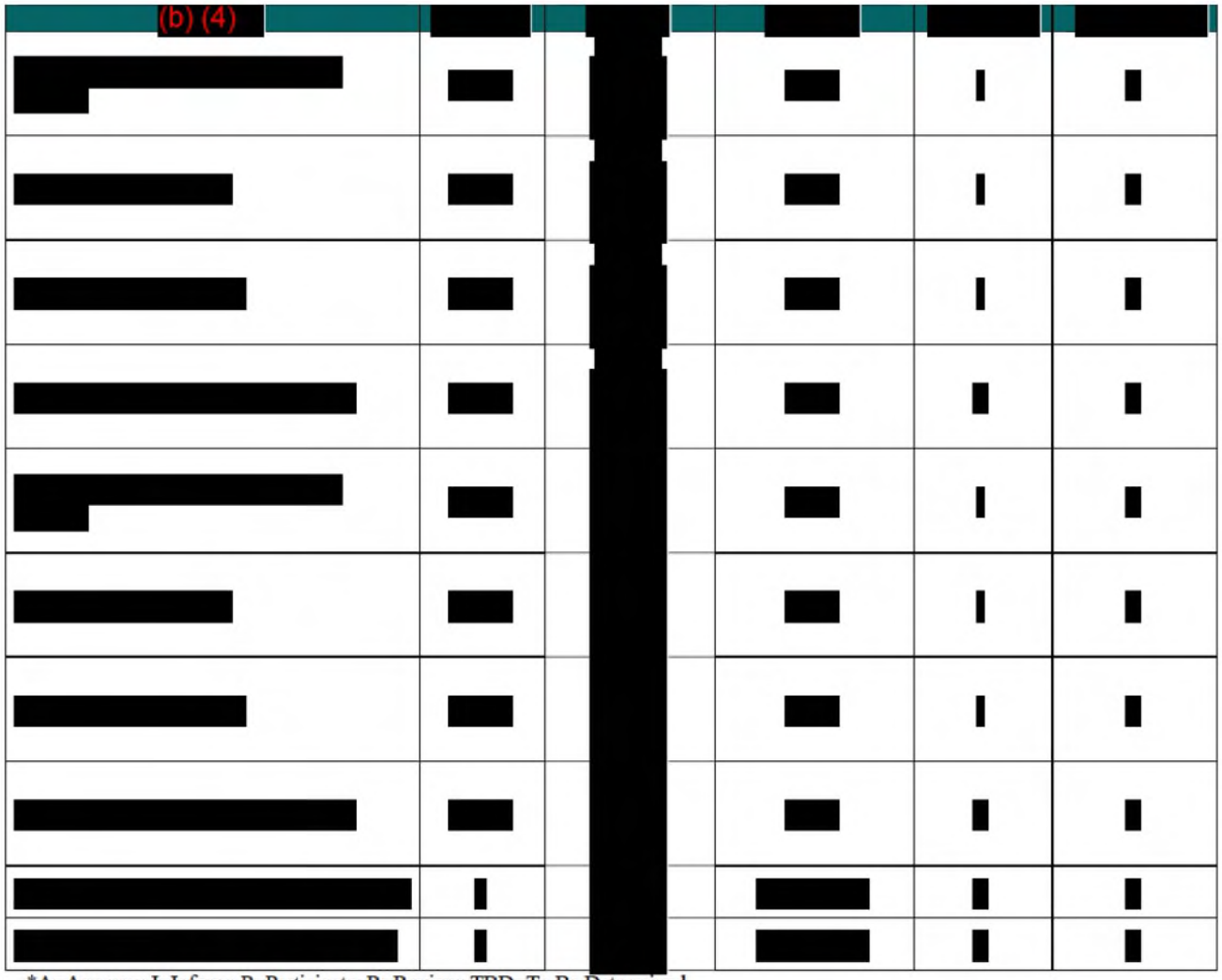
2.15.2.3 The Awardee shall provide a Stability Report.

3.0 DELIVERABLES

3.1 Data Deliverables




(b) (4)

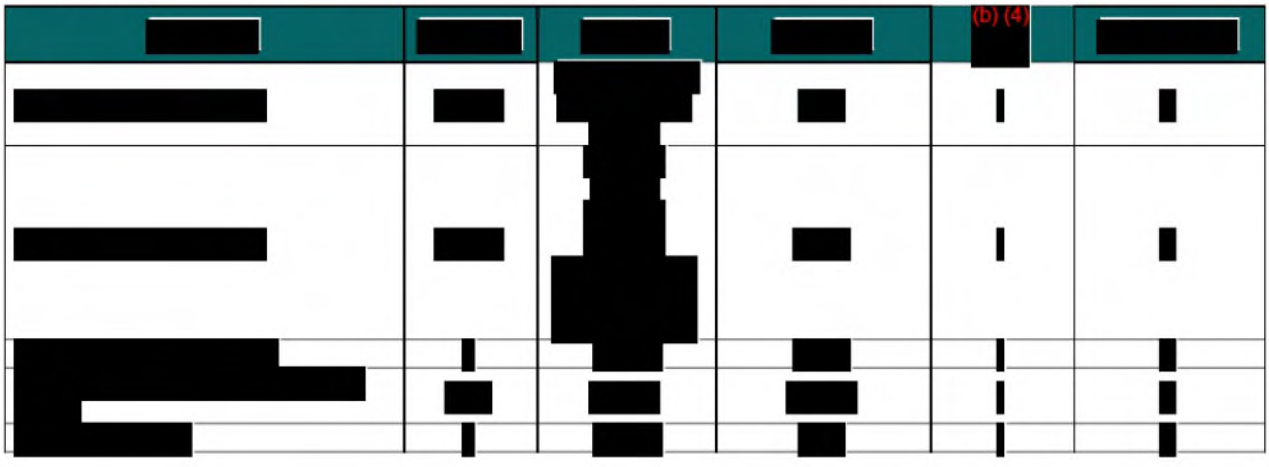


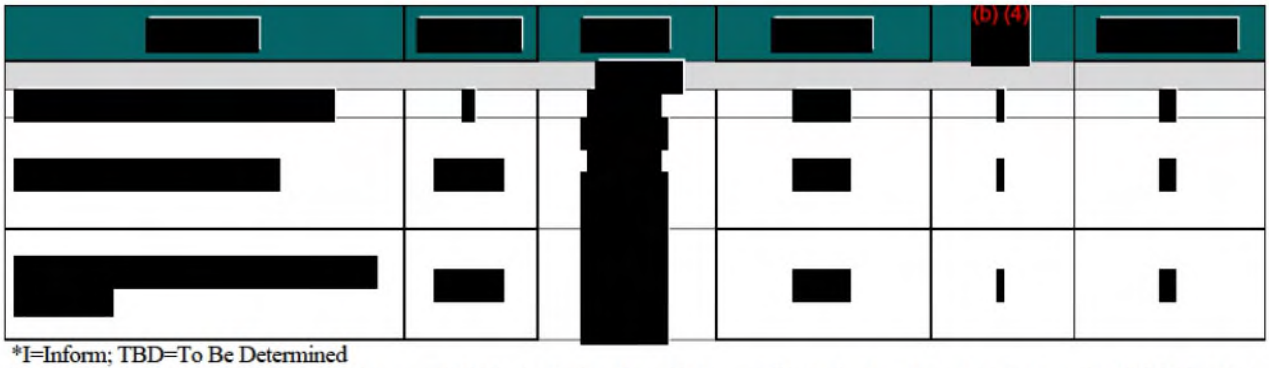
*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined

**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

*** Subject to IP disclosures. Any changes resulting will be incorporated in a separate modification.

3.2 Supply Deliverables





*I=Inform; TBD=To Be Determined

**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

3.3 Acceptance of Deliverables

The USG will provide review of all data deliverables within 30 days of delivery. The USG will acknowledge receipt of all supply deliverables within 60 days of delivery.

4.0 DATA RIGHTS

The Government shall have no rights in the data associated with (b) (4) Background Intellectual Property (IP) and Materials (b) (4) described in Section 5,subject to IP disclosures. Any changes resulting will be incorporated in a separate modification.

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

(b) (4) is not specifying any Background IP and Materials for this 2373 Agreement.

(b) (4)

(b) (4)

6.0 AOR AND ALTERNATE AOR CONTACT INFORMATION

AOR:	Alternate AOR:
TBD	TBD

[End of SOW]

STATEMENT OF WORK

Title: Rapid Production of Monoclonal Antibodies as Medical Countermeasures Against COVID-19

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated 21 February 2020 shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The scope of the proposed project includes the activities required to rapidly produce doses of monoclonal antibody (mAb) therapeutics against COVID-19 (the supply) suitable for use in future clinical trials to develop the best supplies, FDA-approved COVID-19 therapeutics, which are required by the Department of Defense (DoD). To facilitate manufacturing and release of the doses, the proposed effort includes technology transfer of the variable region sequences for (b) (4) human mAbs, computational manufacturability assessment, cloning into (b) (4) and (b) (4) Ology Bioservices, Inc. ("Ology Bio" or "the Awardee") will develop analytical methods specific for COVID-19 to support release of the CGMP material. Additionally, Ology Bio will conduct (b) (4) rounds of limited dilution cloning with imaging and create MCBs to support ongoing manufacturing requirements. Regulatory support will include a Pre-IND Meeting, a Regulatory Strategy (RS) to IND, Regulatory Risk Assessments, and preparation of an IND application that is complete for submission to FDA, excluding toxicology final reports.

Overarching Assumption:

This proposal outlines the tasks required for the production of two therapeutic mAb DS co-formulated in (b) (4) generated from the starting sequences provided by one US Government (USG) performer. At the USG Client request, Ology Bio will manufacture mAbs from the starting sequence information from additional providers by repeating Tasks 2, 3, 4, 5, 6, 7, 8, 15 and 16 to manufacture the initial lot of materials. If requested, subsequent cell banking and future CGMP manufacturing would proceed according to Tasks 9, 11, 12, 13, 14, 15 and 17.

The "USG Performer" referenced throughout the agreement will be a contractor of the Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Program (P3). The Agreements Officer's Representative (AOR) will communicate with DARPA to coordinate the transfer of material and/or information from the USG Performer to the Awardee. All materials and information transferred to the Awardee shall be labelled as Government Furnished Property, subject to the conditions contained in Appendix C of the 2373 Agreement, and as such Awardee will have sufficient rights to use the materials and information in performance of the tasks required by this Agreement.

2.0 REQUIREMENTS

2.1 Task 1: Project Initiation and Oversight

Assumptions:

- Labor for project oversight (Project Manager [PM], Principal Investigator [PI], contracts and finance) spans the lifecycle of the project.
- Data requirements span the lifecycle of the project through delivery of doses.
- The kick-off and quarterly meetings will be held virtually.

- If a due date for a deliverable is on a weekend or holiday, then the deliverable will be due on the next business day.
- Due date of Annual Reports will be based on award date and not the fiscal calendar year.

2.1.1 Planning

2.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) following the (b) (4) award, provide an agenda (b) (4) days prior to the meeting, and provide a meeting report (b) (4) .

2.1.1.2 The Awardee shall provide an Integrated Master Schedule (IMS) (b) (4) award. The Awardee shall provide an updated IMS (b) (4) each month identifying task progress, percent completion and schedule slippage.

2.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project Charter, Communication Plan, IMS, Work Breakdown Structure (WBS), Cost Management/Spend Plan and List of Deliverables.

2.1.2 Execution

2.1.2.1 Meetings

2.1.2.1.1 The Awardee shall conduct IPT meetings (b) (4) . The Awardee shall provide the agendas and IPT slide decks (b) (4) in advance of the IPT. Finalized meeting minutes shall be submitted to the USG (b) (4) following each teleconference.

2.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or USG request, to discuss issues as they arise. Minutes from these meetings shall be provided to the USG within five business days following the meeting.

2.1.2.2 Reports

2.1.2.2.1 The Awardee shall deliver a Monthly IMS and spend plan for the life cycle of the project. The Awardee shall submit each Monthly IMS and spend plan (b) (4) after the end of each month of performance. The USG will have (b) (4) to respond to the report with any comments, and the Awardee will have (b) (4) to revise the deliverable or respond to those comments.

2.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities.

2.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 20 calendar days after the end of each quarter of performance. The USG will have 30 calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

2.1.2.2.4 The Awardee shall perform, record and report physical inventory

results of all Contractor Acquired Property in the contractor's possession, if the Awardee purchases material or equipment using USG funds, as approved by the AOR during performance of the project.

2.1.2.2.5 Incident Reporting

2.1.2.2.5.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the USG in an incident report. In addition, the Awardee shall provide advanced notice of critical path schedule changes resulting in more than a 15-day calendar shift that are not handled as Incident Reports. The Ology Bio PM will provide written notification (via email) to the AOR.

2.1.2.2.5.2 The Awardee shall telephonically contact the program manager for the USG no later than 24 hours after the incident is identified.

2.1.2.2.5.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place. If additional time is required for the Root Cause Analysis, the Ology Bio PM will work with the AOR to agree on timing of the written summary report.

2.1.2.2.6 The Project Agreement Holder (PAH) shall provide the draft Quality Agreement within ten calendar days of project award. The draft Quality Agreement will be submitted via e-mail to the USG technical representatives. The USG shall respond with comments or acceptance ten calendar days following receipt of the draft Quality Agreement. The final agreement with incorporated changes shall be submitted five calendar days after receipt of USG comments. The USG will provide written acceptance.

2.1.2.2.7 The Awardee shall support USG quality audits of the Awardee's systems and procedures as outlined in the Quality Agreement, insofar as they relate to the service and control of the USG's product. These audits may be performed at times mutually agreed upon by the Awardee and the USG. The Awardee shall provide the USG with monthly follow-ups on the status of audit observation commitments found in the USG annual audit or regulatory inspection, as they apply to the USG's product.

2.2 Task 2: Technology Transfer and Plasmid Generation

Assumptions:

- The mAb sequences for (b) (4) mAbs from which the (b) (4) mAb candidates will be selected, will be provided by the USG Performer.

2.2.1 Task 2a: Information and Material Transfer

2.2.1.1 The Awardee shall coordinate with the USG Performer to obtain the (b) (4) cDNA sequences for the human anti–COVID-19 mAbs. There will initially be multiple sequences that will be provided by the USG provider. These will be analyzed (b) (4) for in (b) (4) . Based on these analyses and the data provided (b) (4) inding domains will be selected for plasmid generation and initial stable pool generation.

2.2.1.2 The mAbs will be selected based on (b) (4) and binding to different non-overlapping domains of the (b) (4)

2.2.2 Task 2b: Plasmid Generation

2.2.2.1 The Awardee shall clone the epitope-binding cDNA sequences into appropriate expression vectors.

2.2.2.2 The Awardee shall transform (b) (4) for production of Research Cell Banks (RCBs) to generate plasmid DNA.

2.2.2.3 Plasmid DNA will be used to stably transfect (b) (4) (see Task 5).

2.2.2.4 In parallel to the above-mentioned tasks, the Awardee will (b) (4) generate plasmid sequences to be used to transfect the same (b) (4) as above but using proprietary transfection reagents. Currently, the scope of work calls for (b) (4) mAb candidate sequences will be made into plasmids. The same mAb sequences as Ology Bio will be using will be made by the subcontractor. (b) (4)

2.2.3 Task 2c: Gap and Risk Analyses

2.2.3.1 The Awardee shall complete and provide an initial Risk Assessment and Risk Mitigation program, including all tasks in the program.

2.2.3.2 The Awardee shall conduct and provide a Gap Analysis to identify any potential gaps or weaknesses associated with any of the tasks.

2.2.4 Task 2d: Animal Protocol Writing for ACURO

2.2.4.1 The Awardee shall write the animal protocols that will be used for nonclinical studies in this project.

2.2.5 Task 2e: Computational Manufacturability Assessment

2.2.5.1 The Awardee shall perform a computational manufacturability assessment of the mAb candidates (not full optimization) to inform the down-select prior to further development and production, including:

2.2.5.1.1 *In silico* evaluation and rank order of (b) (4) (b) (4) mAb sequences; additional sequences may also be evaluated at additional costs

2.2.5.1.2 (b) (4)

2.2.5.2 The Awardee shall provide a (b) (4) Report.

2.3 Task 3: Pre-IND Consultation

Assumptions:

- Based on the urgent need for clinical evaluation of the product, the Pre-IND meeting will include an aggressive filing of the draft report (not in SEND format) if acceptable.
- Ology Bio will serve as the product Sponsor.

2.3.1 (b) (4)

[redacted]

2.4 Task 4: Analytical Development and Qualification

Assumptions:

- Ology Bio will develop and qualify product-specific methods for QC lot release and stability testing including identity and potency methods.
- All other release methods are standardized methods and/or compendial methods.

2.4.1 (b) (4)

[redacted]

[redacted] 5: Stable Transfections

2.5.1 (b) (4)

[redacted]

2.5.4 [redacted]

Table 1: Criteria for down-selection of the stable pools

(b) (4)	
Manufacturability	Pass Just criteria scale

2.6 Task 6: Process Development and Engineering Runs with Stable Pools (b) (4)

Assumptions:

- The (b) (4) -selected stably transfected cell pools generated during Task 5 will be used as the starting materials in this task.
- (b) (4) run will be performed to evaluate the success of the proposed media and feed rates, and the data from this run may be considered in the down-selection to the (b) (4) mAb candidates
- Ology Bio will leverage a formulation (b) (4) .
- The Engineering Run will be performed as a CGMP run and material from this run will be used for DP development (if successful).
- DS will be stored frozen based on experience with previous mAb formulations.

- The [redacted] mAbs will be co-formulated in one DP.
- The DP will be stored as a frozen liquid.
- DP concentrations will be determined in collaboration with the USG.
- [redacted] testing on the DS will not be performed.

2.6.1 Media and Feed Optimization

2.6.1.1 The Awardee shall perform [redacted] to evaluate the [redacted] selected pools from Task 5 to investigate media optimization, culture feeds, time of feeds, and titer maximization.

2.6.1.2 Information from this ambr run will be considered in the down-selection to the [redacted] that will be moved forward in this task

2.6.2 Process Development Runs [redacted]

2.6.2.1 The Awardee shall perform [redacted] Process Development Runs for each of the [redacted] selected top pools from Task 5 [redacted]

2.6.2.2 The materials from these runs will be used for analytical method development (Task 4). Process Development Runs will include downstream purification steps through to final DS.

2.6.2.3 The Awardee shall generate DS and DP Reference Standards from materials generated during the [redacted] Runs using the analytical methods described in Task 4.

2.6.2.4 The Awardee shall use material generated in the [redacted] runs in a viral clearance study for each mAb.

2.6.2.5 The Awardee shall execute aseptic formulation and fill validation (media fill validation), including vial fill and incubation.

2.6.2.6 The Awardee shall use [redacted]

2.6.2.8 The Awardee shall provide:

2.6.2.8.1 Process Development Report [redacted]

2.6.2.8.2 Reference Standard materials

2.6.2.8.3 Vials of DS and DP

2.6.2.8.4 Viral Clearance Reports

2.6.2.8.5 Aseptic Media Qualification Report

2.6.3 Engineering Run [redacted]

2.6.3.1 The Awardee shall perform [redacted] CGMP DS Engineering Run.

2.6.3.2 The Awardee shall consider this lot a CGMP lot if the run is successful and DS meets product specifications.

2.6.3.3 The Awardee shall perform a DP fill of these materials as outlined in the CGMP runs. Purified mAb will be diafiltered into an existing formulation and filled into vials at the DoD ADM Facility using a suitable container/closure (vial, stopper, seal).

2.6.3.4 The Awardee shall conduct sampling and lot release testing that was

developed under previous agreement (b) (4) for CGMP Engineering materials. Adventitious agent testing on the DS will not be performed.

2.6.3.5 The Awardee shall provide:

2.6.3.5.1 CGMP Engineering Summary Report, raw material Certificates of Analysis (COAs), analytical testing summary and analytical report, approved Master Batch Production Record, finalized CGMP specifications, finalized Bill of Materials, Engineering CGMP DS COAs, Engineering CGMP DS and MSDS

2.7 Task 7: CGMP DS Runs with Stable Pools (b) (4)

Assumptions:

- Stably transfected cell pools generated during Task 5 and down-selected in Task 6 will be used in this task.

2.7.1 The Awardee shall perform (b) (4) CGMP DS Run for each of the (b) (4) mAbs.

2.7.2 The Awardee shall conduct sampling and lot release testing that was successfully employed (b) (4) for CGMP materials.

2.7.3 The Awardee shall provide controlled and temperature-monitored transport of final released lots as directed by the AOR.

2.7.4 The Awardee shall complete (b) (b) (4) testing of the CGMP DS for each of the (b) (4) mAbs.

2.7.5 The Awardee shall provide:

2.7.5.1 CGMP DS Campaign Summary Reports, raw material COA(s), analytical testing summaries and analytical reports, executed CGMP batch records, and (b) (4) for each of the (b) (4) mAbs.

2.8 Task 8: CGMP DP Run (Ology Bio in-house fill)

Assumptions:

- The assumption for the basis of estimate is that vials will be filled (b) (4) .(b) (4)
- DP will be a combination of (b) (4) mAbs, dependent on efficacy of mAbs.
- No formulation development will be performed. Ology Bio will leverage a previously developed formulation (b) (4) for this effort.

2.8.1 The Awardee shall perform liquid fill operations using the CGMP DS of the (b) (4)

(b) (4)

2.8.4 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released DP lot as directed by the AOR.

2.8.5 The Awardee shall complete [redacted] potency release testing of the CGMP DP.

2.8.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.9 Task 9: Regulatory Support

Assumptions:

- This effort does not include publishing via the FDA Gateway but will result in a regulatory application that is complete for future electronic publishing and submission. Please note IND complete does not include toxicology reports, as the plan is to negotiate limited toxicology for the original submission.
- The IND will be prepared without toxicology information to expedite review.

2.9.1 The Awardee shall conduct a kick-off meeting for the regulatory submission, followed by development and review of an IND application. The IND will be delivered as complete for submission (i.e., MS Word deliverables ready to go to the electronic publisher).

2.9.2 The Awardee shall develop and provide a RS to support the program through IND submission, including a TPP as an attachment to the RS.

2.9.3 The Awardee shall conduct Regulatory Risk Assessments.

2.9.4 The Awardee shall draft eCTD sections for Modules 1-5 (MS Word format) and provide an IND that is complete for filing, with the exception of toxicology reports.

2.9.5 The Awardee shall support USG Emergency Use Authorization (EUA) requirements as needed to facilitate availability of the DP to the USG.

2.10 Task 10: Limiting Dilution Cloning

2.10.1 (b) (4) [redacted]

2.11 Task 11: Master Cell Banking

Assumptions:

- (b) (4) [redacted]

(b) (4)

2.11.3 The Awardee shall provide an MCB Report, including the MCB production batch record and a COA, for each of the (b) (4) mAbs.

2.12 Task 12: Optional: Process Confirmation Runs with MCBs (b) (4)

2.12.1 The Awardee shall perform (b) (4) Process Confirmation Run using the MCB produced in Task 11 for each of the (b) (4) mAbs.

2.12.2 The Awardee shall perform analytical characterization of the DS based on the reference standard for material from stable pools for each of the (b) (4) mAbs.

2.12.3 The Awardee shall provide an MCB Confirmation Run Report for each of the (b) (4) mAbs.

2.13 Task 13: Optional: CGMP DS Runs with MCBs (b) (4)

Assumptions:

- MCBs generated in Task 11 will be used in this task.
- As directed by the AOR, DS manufactured in Task 13 may be filled as DP in Task 14 or may be stored frozen.

2.13.1 The Awardee shall perform (b) (4) CGMP DS Run for each of the (b) (4) mAbs.

2.13.2 The Awardee shall conduct sampling and lot release testing that was developed under previous agreement (b) (4) for CGMP materials.

2.13.3 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot as directed by the AOR.

2.13.4 The Awardee shall provide CGMP DS Campaign Summary Reports, raw material COA(s), analytical testing summaries and analytical reports, and executed CGMP batch records, and COA and MSDS for CGMP DS for each of the (b) (4) mAbs.

2.14 Task 14: Optional: CGMP DP Run

2.14.1 The Awardee shall perform liquid fill operations using the CGMP DS of the (b) (4) mAbs from Task 13.

2.14.2 The Awardee shall fill (b) (4) vials of one CGMP DP suitable for use in a Phase 1 clinical trial at a concentration TBD in collaboration with the USG. This includes (b) (4) If additional vials are required, Ology Bio has the capability to perform an additional vial fill using the DS from the runs in Task 13. (b) (4)

2.14.3 The Awardee shall conduct sampling and lot release testing that was successfully employed (b) (4) for CGMP materials. A risk assessment will be performed to minimize the impact of sampling to the overall product yield.

2.14.4 The Awardee shall provide controlled and temperature-monitored transport of analytical

samples and final released DP lot as directed by the AOR.

2.14.5 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.15 Task 15: Nonclinical Safety

Assumptions:

- Material generated in Task 6 will be used to support these assays.
- A dose-ranging study is not included based on our toxicity risk assessment, which will be used to present a strategy in the Pre-IND interactions.

2.15.1 Task 15a: Develop and Perform *In Vitro* Cell-Based Neutralization Assays or (b) (4) to Support Pharmacokinetic (PK) Testing

2.15.1.1 (b) (4) [redacted]

2.15.1.2 The Awardee shall provide a PK Study Report for each of the (b) (4) mAbs.

2.15.2 Task 15b: Tissue Cross-Reactivity Studies

2.15.2.1 The Awardee shall conduct tissue cross-reactivity using material generated from the stable transfections and provide a Tissue Cross-Reactivity Report for each of the (b) (4) mAbs.

2.15.3 Task 15c: GLP Toxicology Study

2.15.3.1 The Awardee shall conduct a GLP repeat-dose study as the IND-enabling toxicology study and submit the Toxicology Study Report and SEND data tables when they are available to support the regulatory filing with FDA.

2.15.3.2 The Awardee shall conduct PK and anti-drug antibody testing for each of the (b) (4) mAbs.

2.15.3.3 The Awardee shall provide a Toxicology Study Report.

2.16 Task 16: Stability Studies (stable pool-produced material)

Assumptions:

- Material generated in Tasks 6, 7 and 8 will be used in this task.

2.16.1 The Awardee shall conduct stability testing per an approved stability protocol on the Engineering and CGMP DS and DP lots from the stable pools, including real-time and accelerated conditions for (b) (4), for each of the (b) (4) mAb DS and (b) (4) DP, along with reference standards. The Awardee will finalize stability testing as part of risk assessment to determine the minimum amount of material required.

2.16.2 The Awardee shall provide stability test results in annual reports.

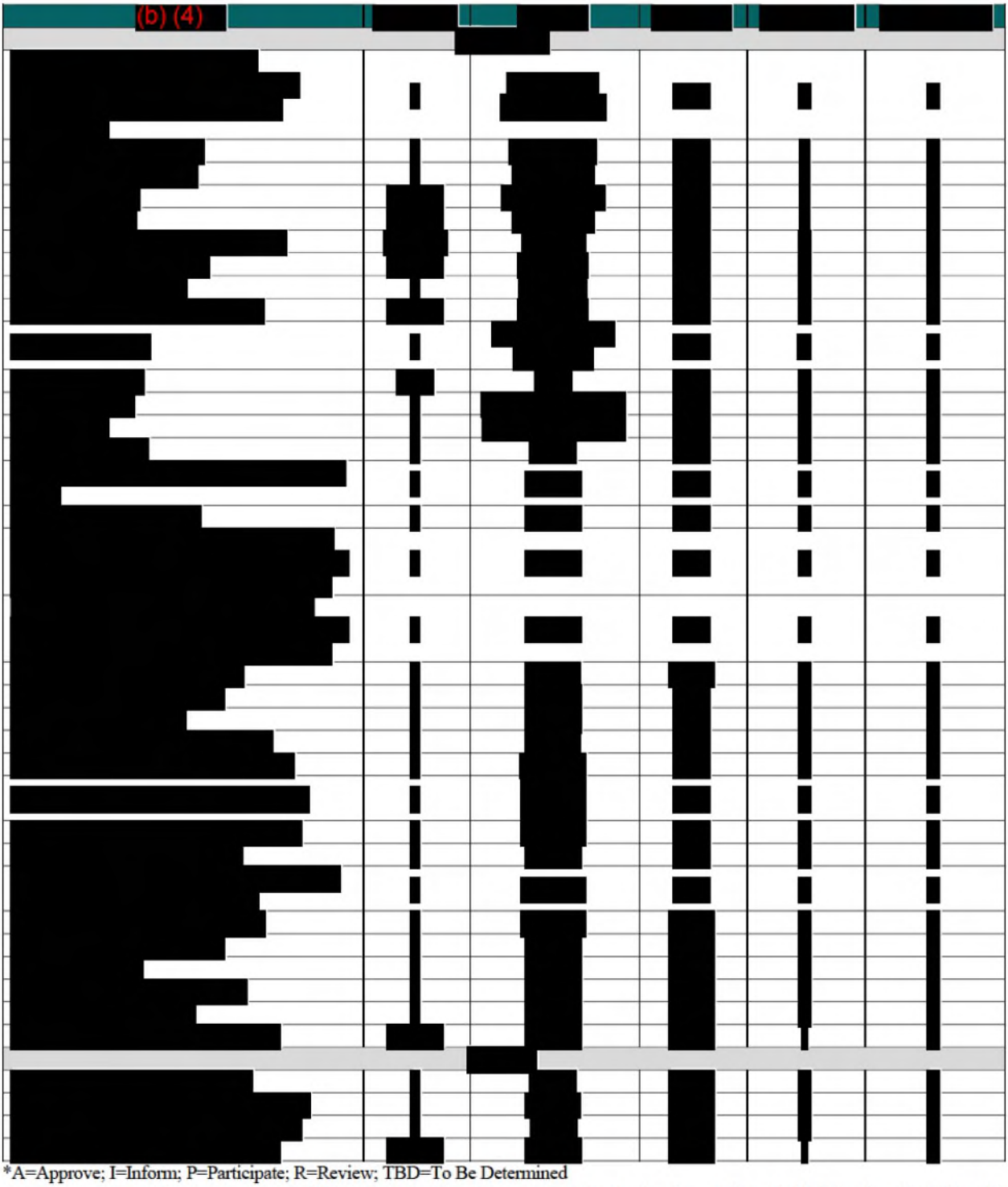
2.17 Task 17: Optional: Stability Studies (MCB-produced material)

2.17.1 The Awardee shall conduct stability testing per an approved stability protocol on the Engineering and CGMP DS and DP lots from the MCB, including real-time and accelerated conditions for (b) (4), for each of the (b) (4) mAb DS and (b) (4) DP.

2.17.2 The Awardee shall provide stability test results in annual reports.

3.0 DELIVERABLES

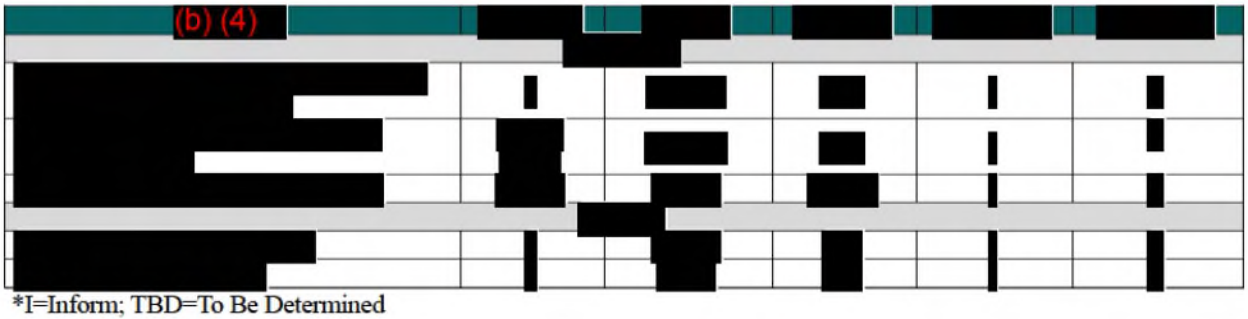
3.1 Data Deliverables



*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined

**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

3.2 Supply Deliverables



*I=Inform; TBD=To Be Determined

3.3 Acceptance of Deliverables

The USG will provide review of all data deliverables within (b) (4) of delivery. The USG will acknowledge receipt of all supply deliverables within (b) (4) of delivery.

4.0 DATA RIGHTS

The USG shall have no rights to any preexisting technical data associated with Ology Bio's non-exclusive license (b) (4)

(b) (4)

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

The following are Ology Bio's Background Intellectual Property (IP) and Materials, as defined in Article 9, Section A of the 2373 Agreement. Ology Bio holds a non-exclusive license to develop and manufacture products using (b) (4)
(b) (4)
. Ology Bio's Background IP and Materials shall remain the property of Ology Bio. No license(s) to Ology Bio's Background IP and Materials shall be granted under this SOW or Agreement. The Background IP listed above is specifically excluded from the definition of "Agreement Invention" contained in Article 9 Section B of the 2373 Agreement.

(b) (4)

For purposes of this effort the material to be transferred and the associated IP will be labeled as "Government Furnished Information." The AOR will manage the transfer from USG performer to Ology Bio.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 9

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00008	07-May-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: (b) (6)

The purpose of this amendment is to incorporate Project 20-07 under CLIN 0007, incorporate Project 20-08 under CLIN 0008, incorporate Appendix A-2 Rev 1, increase the value of Project 20-05 under CLIN 0002, and incorporate incremental funding. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	(b) (6) TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	May 6, 2020	BY (b) (6) (Signature of Contracting Officer)	06 May 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00008

A. The purpose of this Amendment is as follows:

a. (b) (4)

(b) (4)

c. Appendix A-2 Rev 1 is hereby incorporated into the agreement. This revision supersedes the previously incorporated Appendix A-2 in full.

d. The Project AOR for Project 20-05 is hereby changed from (b) (4) .

e. The value of CLIN 0002 is hereby increased by (b) (4) from $(b) (4) 0 to (b) (4) .

f. SubCLIN 000202 is hereby added to the Agreement to incorporate incremental funding in the amount of (b) (4) under ACRN AG.

g. (b) (4)

B. The total value of this Agreement is increased by by (b) (4) from (b) (4) to (b) (4) .

C. Total funding for this Agreement is increased by (b) (4) from (b) (4) to (b) (4)

D. The parties hereby agree that changes effected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this Agreement resulting from the incorporation of (b) (4) Appendix A-2 Rev 1.

E. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002

The CLIN extended description has changed from:

Project 20-05: Rapid mAB COVID 19 labor, materials, equipment and associated costs delineated the in Statement of Work entitled, "Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19", hereby incorporated into the Agreement under Appendix A.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project. The project level AOR does not supersede the roles and duties of the Agreement AOR.
The Project AOR's contact Information is below:Name: (b) (6)

To:

Project 20-05: Rapid mAB COVID 19 labor, materials, equipment and associated costs delineated the in Statement of Work entitled, "Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19", hereby incorporated into the Agreement as Appendix A-2 Rev 1.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project. The project level AOR does not supersede the roles and duties of the Agreement AOR.
The Project AOR's contact Information is below:Name: (b) (4)

.

The estimated/max cost has increased by (b) (4) from (b) (4) to (b) (4)
The fixed fee has increased by (b) (4) from (b) (4) to $1,061,495.00.
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4)

(b) (4)

SUBCLIN 000202 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000202					$0.00
	(b) (4)				
	FFP				
	(b) (4)				
	PURCHASE REQUEST NUMBER: 0011495606				

NET AMT $0.00

ACRN AG (b) (4)
CIN: GFEBS001149560600001

SUBCLIN 000402 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000402					$0.00
	Optimization/Production of a DNA vaccine				
	FFP				
	Optimization/Production of a DNA vaccine				
	PURCHASE REQUEST NUMBER: 0011495607				

NET AMT $0.00

ACRN AH (b) (4)
CIN: GFEBS001149560700001

CLIN 0007 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
[redacted]	[redacted]		[redacted]		[redacted]

SUBCLIN 000701 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000701					$0.00

CB10891 - Burk OMV Mfg - Viking
FFP
CB10891 - Burk OMV Mfg - Viking
PURCHASE REQUEST NUMBER: 0011492534-0001

NET AMT $0.00

ACRN AF (b) (4)
CIN: GFEBS001149253400003

CLIN 0008 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
[redacted]	[redacted]		[redacted]		[redacted]

SUBCLIN 000801 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000801					$0.00

CB10876 - VEE DNA Vacc Mfg
FFP
CB10876 - VEE DNA Vacc Mfg
PURCHASE REQUEST NUMBER: 0011492534-0001

NET AMT $0.00

ACRN AF (b) (4)
CIN: GFEBS001149253400002

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000202:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000402:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for CLIN 0007:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000701:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for CLIN 0008:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000801:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN [redacted] has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
23-AUG-2023		MCS 110 THOMAS JOHNSON DR. FREDERICK MD 21702 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule for CLIN 0008 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
23-MAR-2023		MCS 110 THOMAS JOHNSON DR. FREDERICK MD 21702 (b) (6) FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to $50,318,531.37.

SUBCLIN 000202:
Funding on SUBCLIN 000202 is initiated as follows:

ACRN: AG

CIN: GFEBS001149560600001

Acctng Data: 097202020210130000181705515192 52 S.0025760.7.5.4.1 6100.9000021001

Increase: $17,336,141.00

Total: (b) (4)

Cost Code: AHPII

SUBCLIN 000402:
Funding on SUBCLIN 000402 is initiated as follows:

ACRN: AH

CIN: GFEBS001149560700001

Acctng Data: 097202020210130000181705515192 52 S.0025760.7.5.4.2 6100.9000021001

Increase: (b) (6)

Total: (b) (6)

Cost Code: AHPII

SUBCLIN 000701:
Funding on SUBCLIN 000701 is initiated as follows:

ACRN: AF

CIN: GFEBS001149253400003

Acctng Data:
^^^097^2020^2021^^0400^000^^255^D^0603384BP^^^^^2600^00008522^044315^DTRA^RCM,VACCINES/TH
^0603384BP_TM3_CPM_R

Increase: (b) (6)

Total: (b) (4)

Cost Code: A

SUBCLIN 000801:
Funding on SUBCLIN 000801 is initiated as follows:

ACRN: AF

CIN: GFEBS001149253400002

Acctng Data:
^^^097^2020^2021^^0400^000^^255^D^0603384BP^^^^^2600^00008522^044315^DTRA^RCM,VACCINES/TH
^0603384BP_TM3_CPM_R

Increase: (b) (6)

Total: (b) (4) 0

Cost Code: A

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00009	07-May-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 22-Feb-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 4 of the agreement.

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: (b) (6)

The purpose of this modification is to authorize purchases under project 20-09. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) TEL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		B (b) (6)	07-May-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00009

A. This unpriced change order is being issued to authorize the Awardee to proceed with efforts delineated in notification, dated 7 May 2020, entitled (b) (4) [redacted], hereby effecting the following changes:

1. Ology is hereby authorized to proceed with the (b) (4) [redacted] fermentors and (b) (4) [redacted] bioreactors.

2. Funding for the above efforts is available under ACRN AB for CLIN 0002.

B. Prior to definitization, reimbursement of costs resulting from this change order shall not exceed (b) (4) [redacted]. Application of fee is subject to negotiation and will be finalized upon award of the supplemental modification.

C. Appendix A of the Agreement shall be revised to incorporate the identified efforts, and shall be finalized upon supplemental agreement. Negotiations shall be conducted in accordance with the terms of the Agreement.

D. All other terms and conditions remain unchanged and in full force and effect.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00010	14-May-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 4 of the agreement.

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this change order is to incorporate additional costs specific to Project 20-09 under CLN 0009, and incorporate incremental funding. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	14-May-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00010

A. Change order P00009 is hereby rescinded and replaced as follows:

1.The Awardee is hereby authorized to proceed with efforts delineated in notification, dated 8 May 2020 titled "Quotes for (b) (4) " and 14 May 2020 titled "Request for ATP to order long lead-time equipment (b) (4) ".

2. Ology is hereby authorized to proceed with the purchase of the supplies identified in the requests identified in paragraph A.

3. CLIN 0009 in the amount of (b) (4) is hereby added.

4. CLIN 000901 is hereby added to incorporate incremental funding in the amount of (b) (4) .

B. Prior to definitization, reimbursement of costs resulting from this change order shall not exceed (b) (4) . Application of fee is subject to negotiation and will be finalized upon award of the supplemental modification. Definitization of costs and schedule is expected prior to 21 May 2020.

C. Appendix A of the Agreement shall be revised to incorporate the identified efforts, and shall be finalized upon supplemental agreement. Negotiations shall be conducted in accordance with the terms of the Agreement.

D. All other terms and conditions remain unchanged and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0009 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0009			Job		(b) (4)

PROJECT 20-09: Helios/Asimov Equipment
CPFF
Project 20-09: Equipment/supplies in support of (b) (4) inclusive of labor, materials, equipment and associated allowable costs delineated the request for Authorization to Proceed, dated 14 May 2014. The Project Level Agreements Officer Representitive shall be the Government's representative on technical matters related solely to this project. The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:
(b) (6)
FOB: Destination
PSC CD: AN14

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	(b) (4)

SUBCLIN 000901 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000901					$0.00

FY 2020 Funding
CPFF
PURCHASE REQUEST NUMBER: 0011499801

ESTIMATED COST	$0.00
FIXED FEE	$0.00
TOTAL EST COST + FEE	$0.00

ACRN AJ (b) (4)
CIN: GFEBS001149980100001

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0009:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000901:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0009 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
23-MAR-2023		MCS 110 THOMAS JOHNSON DR. FREDERICK MD 21702 (b) (6) FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000901:
Funding on SUBCLIN 000901 is initiated as follows:

ACRN: AJ

CIN: GFEBS001149980100001

Acctng Data: 097202020210130000181705515192 52 S.0025760.7.5.4.4 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPII

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00012	10-Jun-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 22-Feb-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance w ith Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to incorporate Appendix A-4 Rev 1, increase the value of Project 20-04 under CLIN 0004, and incorporate incremental funding. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	(b) (6) TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	June 10, 2020	BY (b) (6) (Signature of Contracting Officer)	10 Jun 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00013

A. The purpose of this Amendmenet is as follows:
   a. Appendix A-4 Rev. 1 is hereby incorporated into the Agreement. This revision supersedes the previously incorporated Appendix A-4 in full.
   b. The value of CLIN 0004 is hereby increased to retroactively apply Awardee's recently approved indirect rates from DCAA.
   c. The value of CLIN 0004 is hereby increased by (b) (4) from (b) (4) to (b) (4)
   d. SubCLIN 000403 is hereby added to the Agreement to incorporate incremental funding in the amount of (b) (4) under ACRN AK.
   e. SubCLIN 000404 is hereby added to the Agreement to incorporate incremental funding in the amount of $(b) (4) under ACRN AK.
B. The total value of this Agreement is increased by (b) (4) from (b) (4) to (b) (4)
C. Total funding for this Agreement is increased by (b) (4) from (b) (4) to (b) (4)
D. The parties hereby agree that changes affected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this Agreement resulting from incorporation of Appendix A-4 Rev. 1 and Awardee's newly approved indirect rates.
E. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4).

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0004

The CLIN extended description has changed from:

Project 20-04: Rapid COVID-19 Plasmid Manufacturing for Phase 1 Clinical Programs labor, materials, equipment and associated allowable costs delineated the in Statment of Work entitled, "Procurement, Commissioning and Qualification of (b) (4) (b) (4) at the DoD ADM Facility," hereby incorporated into the

Agreement as Appendix A-4.The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:Name (b) (4)

To:

Project 20-04: Rapid COVID-19 Plasmid Manufacturing for Phase 1 Clinical Programs labor, materials, equipment and associated allowable costs delineated the in Statment of Work entitled, "Rapid COVID-19 Plasmid Manufacturing for Clinical Programs," hereby incorporated into the Agreement as Appendix A-4 Rev 1.The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:Name (b) (4)

.

The estimated/max cost has increased by (b) (4) from (b) (4) to (b) (4)
The fixed fee has increased by (b) (4) from (b) (4) to $837,596.00.
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000403 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000403	(b) (4)				$0.00

NET AMT $0.00

ACRN AK (b) (4)
CIN: GFEBS001150568000001

SUBCLIN 000404 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000404					$0.00

Overhead Rate Change @ Ology - (b) (4)

Overhead Rate Change @ Ology - (b) (4)

NET AMT $0.00

ACRN AK (b) (4)
CIN: GFEBS001150684000001

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000403:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000404:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000403:
Funding on SUBCLIN 000403 is initiated as follows:

ACRN: AK

CIN: GFEBS001150568000001

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.2 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

SUBCLIN 000404:
Funding on SUBCLIN 000404 is initiated as follows:

ACRN: AK

CIN: GFEBS001150684000001

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.2 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

(End of Summary of Changes)

STATEMENT OF WORK

Title: Rapid COVID-19 Plasmid Manufacturing for Clinical Programs

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated *21 February 2020* shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The purpose of this project is to manufacture vials of CGMP plasmid DNA DP suitable for use in a clinical trial (the supply), to support Department of Defense requirements for an FDA-approved COVID-19 vaccine (the best supplies). Based on information provided (b) (4) Yield projection (b) (4) indicate that at the (b) (4) scale, (b) (4) doses can be manufactured per lot.

The project will include technology transfer of the (b) (4) plasmid DNA manufacturing process to the DoD ADM Facility; Process Establishment runs at the (b) (4) scale (using COVID-19 plasmid RCB or MCB); manufacturing of WCB from (b) (4) provided MCB; analytical assay development; an Engineering DS Run at the (b) (4) scale; (b) (4) 21 C.F.R Part 210 (here to referred to as CGMP) compliant DS and DP Runs at the (b) (4) scale; scale-up and transfer of the (b) (4) downstream process at the (b) (4) scale; an Engineering DS Run (b) (4) scale; a CGMP DS Run at the (b) (4) scale, with a fill of DP; (b) (4) CGMP DS and DP Runs; stability studies (b) (4), respectively, for Engineering DS and CGMP DS/DP from the (b) (4) runs; and (b) (4) and (b) (4) stability studies for CGMP DS and DP, respectively, from the (b) (4) runs. Additionally, we will evaluate current procedures and processes to align with requirements for CGMP Phase 3 in preparation for anticipated Emergency Use Authorization (EUA) or Expanded Access prior to product approval, included vendor audit and enhanced raw material testing. The initial Technology Transfer Establishment (b) (4) runs will be performed with COVID-19 plasmid, either RCB or MCB depending on availability. All runs following the initial Process Establishment will be completed using Ology Bio WCB for the plasmid DNA.

2.0 REQUIREMENTS

2.1 Task 1: Project Initiation and Oversight

Notes:

- Labor for project oversight (Project Manager [PM], Principal Investigator [PI], contracts and finance) spans the lifecycle of the project.
- Data requirements span the lifecycle of the project through delivery of doses.
- If a due date for a deliverable is on a weekend or holiday, then the deliverable will be due on the next business day.

2.1.1 Planning

2.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) following the (b) (4) contract award, provide an agenda (b) (4) prior to the meeting, and provide a meeting report (b) (4). The kickoff meeting will be held virtually.

2.1.1.2 The Awardee shall provide an Integrated Master Schedule (IMS) (b) (4) of contract award. The Awardee shall provide an updated IMS (b) (4)

(b) (4) after the end of each month identifying task progress, percent completion and schedule slippage.

2.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project Charter, Communication Plan, IMS, Work Breakdown Structure (WBS), Cost Management/Spend Plan and List of Deliverables.

2.1.2 Execution

2.1.2.1 Meetings

2.1.2.1.1 The Awardee shall conduct IPT meetings no less than twice per month. The Awardee shall provide the agendas and IPT slide decks within 24 hours in advance of the IPT. Finalized meeting minutes shall be submitted to the USG within five business days following each teleconference.

2.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or USG request, to discuss issues as they arise. Minutes from these meetings shall be provided to the USG within five business days following the meeting.

2.1.2.2 Reports

2.1.2.2.1 The Awardee shall deliver a Monthly IMS and spend plan for the life cycle of the project. The Awardee shall submit each Monthly IMS and spend plan within 20 calendar days after the end of each month of performance. The USG will have 10 calendar days to respond to the report with any comments, and the Awardee will have an additional five calendar days to revise the deliverable or respond to those comments.

2.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities. Delivery dates for Quarterly and Annual Progress reports will be based on award date and not the calendar year.

2.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 20 calendar days after the end of each quarter of performance. The USG will have 30 calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

2.1.2.2.4 The Awardee shall perform, record and report physical inventory results of all Contractor Acquired Property in the contractor's possession, if the Awardee purchases material or equipment using USG funds, as approved by the Agreement Officer's Representative (AOR) during performance of the project.

2.1.2.2.5 Incident Reporting

2.1.2.2.5.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the

USG in an incident report. In addition, the Awardee shall provide advance notice of critical path schedule changes resulting in more than a 15 calendar-day shift that are not handled as Incident Reports. The Ology Bio PM shall provide written notification (via email) to the AOR.

2.1.2.2.5.2 The Awardee shall telephonically contact the program manager for the USG no later than 24 hours after the incident is identified.

2.1.2.2.5.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place. If additional time is required for the Root Cause Analysis, the Ology Bio PM will work with the AOR to agree on timing of the written summary report.

2.1.2.2.6 The Project Agreement Holder (PAH) shall establish a Quality Agreement with the USG. The PAH shall provide the draft Quality Agreement within ten calendar days of project award. The draft Quality Agreement will be submitted via e-mail to the USG technical representatives. The USG shall respond with comments or acceptance ten calendar days following receipt of the draft Quality Agreement. The final agreement with incorporated changes shall be submitted five calendar days after receipt of USG comments. The USG will provide written acceptance.

2.1.2.2.7 The PAH shall also develop a Quality Agreement with Inovio that defines the roles and responsibilities of both parties. The Quality Agreement with Inovio will be provided to the USG for informational purposes rather than review and approval.

2.1.2.2.8 The Awardee shall support USG quality audits of the Awardee's systems and procedures, insofar as they relate to the service and control of the USG's product. These audits may be performed at times mutually agreed upon by the Awardee and the USG. The Awardee shall provide the USG with monthly follow-ups on the status of audit observation commitments found in the USG annual audit or regulatory inspection, as they apply to the USG's product.

2.1.3 Regulatory/CMC Support

2.1.3.1 The Awardee shall provide support to the product sponsor to enabling updating of their CMC sections with manufacturing data and technical information.

2.1.4 Equipment Maintenance and Service

2.1.4.1 The Awardee shall maintain and service equipment purchased under Contract W911QY2090003, (b) (4) and used for this Project 20-04.

2.2 Task 2: Technology Transfer

Note:

- Process Establishment Runs will be performed with COVID-19 plasmid and upstream parameters and the existing (b) (4) [redacted]

2.2.1 Inovio Information Transfer, Gap Analysis and Risk Assessment

2.2.1.1 The awardee will perform technology transfer (b) (4) . In accordance with a Consulting Agreement and Quality Agreement that will be finalized and signed after execution of this agreement, the awardee will manage the following support (b) (4) :

2.2.1.1.1 Review of all required documentation including analytical assay protocols and specifications, development records, batch records, list of equipment and any other documentation to support this project

2.2.1.1.2 Receipt of the necessary cell lines to support the technology transfer and WCB development

2.2.1.1.3 (b) (4) support the technology transfer of the upstream and downstream processing for manufacture of their DNA plasmid vaccine candidate

2.2.1.1.4 (b) (4) [redacted]

2.2.1.1.5 Test plan for analytical comparability and assistance in demonstration comparability

2.2.1.1.6 Under the terms of Quality Agreement (b) (4) : 1) upon confirmation of comparability, (b) (4) add Ology Bio as a manufacturer in their IND; 2) (b) (4) shall provide all correspondence to and from the FDA related to the addition of Ology's manufacturing facility. Awardee shall provide all FDA correspondence to the USG within 3 days of receipt (b) (4) [redacted]; and 3) (b) (4) shall provide a Letter of Authorization to their Master File as needed by the USG.

2.2.1.2 The Awardee shall complete an initial Risk Assessment and Mitigation Strategy including all tasks and supply chain management.

2.2.1.3 The Awardee shall conduct a Gap Analysis of the transferred information to identify any potential gaps or weaknesses associated with any of the tasks.

2.2.2 Review of (b) (4) Documentation

2.2.2.1 The Awardee shall review all project-related documents provided (b) (4) .

2.2.2.2 The Awardee shall draft a Development Plan, including relevant information from the documents provided (b) (4) , that will outline the relevant scope of work and revise it based on the client's feedback.

2.2.3 Transfer of Product-Specific Materials (b) (4) and Procurement of Materials and Components

2.2.3.1 The Awardee shall develop a preliminary BOM using approved suppliers.

2.2.3.2 Upon completion of risk assessments and required permits, the Awardee shall

coordinate (b) (4) for the shipment of materials to the DoD ADM Facility. The Awardee shall receive the (b) (4) provided materials and store them using inventory management practices in order to maximize performance integrity and shelf life.

2.2.3.3 The Awardee shall provide traceability of both consumable and non-consumable (b) (4) provided materials from procurement until the end of the material's life.

2.2.3.4 The Awardee shall order and receive any other biologics and process materials and components to complete the project.

2.2.4 Process Establishment Runs

2.2.4.1 The Awardee shall provide a Process Establishment Plan for (b) (4) Process Establishment Runs using the COVID-19 plasmid (RCB or MCB vials provided (b) (4)) at the (b) (4) fermentor scale.

2.2.4.2 The Awardee shall provide Process Establishment Run Process Development Production Records (PDPRs) for the Process Establishment Runs.

2.2.4.3 The Awardee shall execute the (b) (4) Process Establishment Runs, including upstream and downstream processes using the (b) (4) upstream process (including process parameters and media components) and the Ology Bio downstream process previously established.

2.2.4.4 The Awardee shall provide a Process Establishment Report.

2.3 Task 3: Working Cell Bank Manufacturing

2.3.1 The Awardee shall provide (b) (4) vials of WCB based on COVID-19 MCB vials and process documentation received (b) (4) .

2.3.2 The Awardee shall perform release testing and characterization of the WCB.

2.3.3 The Awardee shall provide a Working Cell Banking Report, including the WCB production batch record and a Certificate of Analysis (COA).

2.4 Task 4: Analytical Assay Development

Notes:

- Product-specific methods for in-process testing have been developed.
- Compendial methods are already in place and will only require verification.
- Ology Bio QC has current experience with the methods in **Table 1** and
- **Table** 2. Ology Bio assumes these are the methods that will be required for in-process and release testing.

2.4.1 The Awardee shall receive analytical SOPs and development reports (b) (4) . Product-specific QC assay information will be transferred to the Awardee (b) (4) in accordance with Ology Bio's Consulting Agreement (b) (4) .

2.4.2 The Awardee shall update specifications and a final testing list upon receipt of (b) (4) analytical technology transfer package. Testing specification will allow for a direct comparison of previously produced plasmid material and reference standard.

2.4.3 The Awardee shall provide an Assay Qualification Plan. The Awardee will qualify the analytical methods in accordance with USP, FDA and Ph. Eur. requirements and guidance appropriate for use in clinical studies.

2.4.4 The Awardee shall perform Technology Transfer Feasibility assessments on (b) (4)

provided methods for product testing. In accordance with the Ology Bio (b) (4) Consulting Agreement, analytical specialized reagents and Reference Standards will be provided (b) (4) .

2.4.5 The Awardee will establish in-process and release testing methods for the plasmid DNA DS and DP to meet specifications mutually approved (b) (4) and Ology Bio.

2.4.6 The Awardee shall assess the suitability of compendial methods.

2.4.7 The Awardee shall draft non-compendial test methods and execute non-compendial method qualification. If sufficient materials (b) (4) **are not readily available for the establishment of these assays, Ology Bio shall perform qualification concurrent with DS release.**

2.4.8 The Awardee shall provide an Assay Qualification Report, to describe:

2.4.8.1 Compendial method suitability or waiver

2.4.8.2 Non-compendial method transfer

Table 1. In-Process Assays

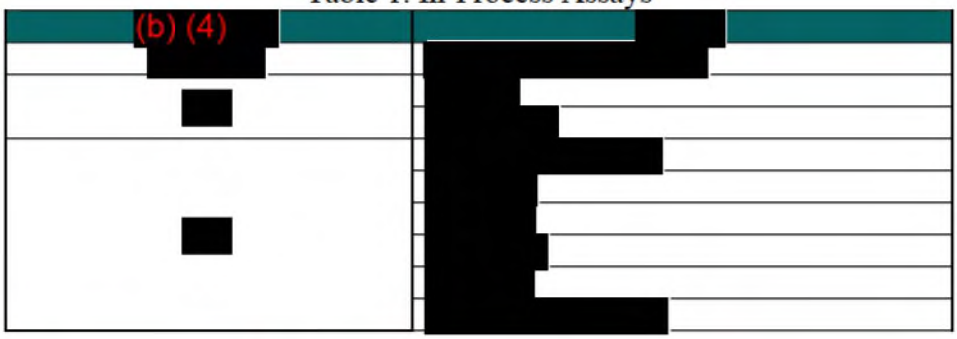
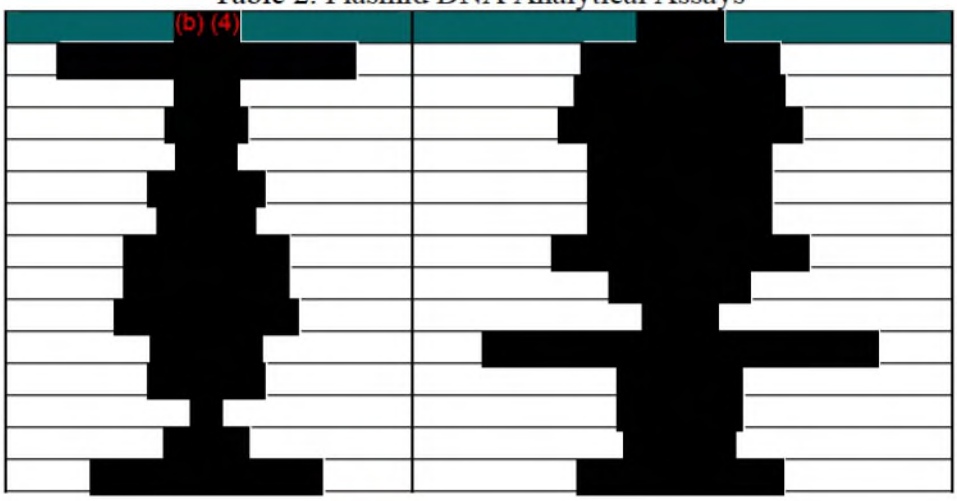


Table 2. Plasmid DNA Analytical Assays



2.5 Task 5: Engineering DS Runs (b) (4)

2.5.1 The Awardee shall prepare draft Master Batch Records (MBRs); raw material, product and label specifications; and draft BOM and MBR setup.

2.5.2 The Awardee shall proceed directly from the Process Establishment Runs to an Engineering DS Run at the (b) (4) scale, which the Awardee shall execute using draft MBRs.

2.5.3 The Awardee shall conduct the run in the CGMP manufacturing area of the DoD ADM

Facility.

2.5.4 The Awardee shall use resins and filters dedicated for this project. The Awardee shall use the same columns/resins for both the Engineering and CGMP Runs.

2.5.5 The Awardee shall conduct in-process and release testing on Engineering DS based on the analytical tests from Task 4 and (b) (4) provided specifications for purity and impurity levels.

2.5.6 The Awardee shall provide:

2.5.6.1 Engineering Run Report
2.5.6.2 Finalized CGMP Batch Record templates
2.5.6.3 Finalized CGMP specifications
2.5.6.4 Final BOM
2.5.6.5 Engineering non-CGMP DS CoT
2.5.6.6 Engineering non-CGMP DS MSDS

2.6 Task 6: CGMP DS Runs (b) (4)

2.6.1 The Awardee shall update the Technology Transfer Protocol (TTP) and MBRs as needed.

2.6.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.6.3 The Awardee shall execute (b) (4) runs for the CGMP DS using MBRs, with the number of runs based on the discretion of the USG and suggestions from Ology Bio.

2.6.3.1 The Awardee shall conduct the CGMP Run using the Ology Bio-manufactured WCB.

2.6.3.2 The Awardee shall conduct the in-process and release testing outlined in **Table 1** and

2.6.3.3 **Table** 2.

2.6.3.4 The Awardee shall store the DS frozen pending DP fill/finish. All DS lots will be at the disposition of the USG and storage will be at the ADM Facility.

2.6.3.5 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.6.3.6 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.6.4 The Awardee shall provide manufacturing and testing information (e.g., raw data or summary reports as required) related to Ology Bio-produced DS (b) (4) for incorporation into their submission to their IND or Master File to support clinical development.

2.6.5 The Awardee shall provide the following for each CGMP DS Lot:

2.6.5.1 QA-Approved DS Executed Batch Production Records
2.6.5.2 QA-Approved DS COA
2.6.5.3 QA-Approved DS MSDS
2.6.5.4 CGMP DS Campaign Summary Report

2.7 Task 7: CGMP DP Runs

2.7.1 The Awardee shall determine the final dose and vial configuration in conjunction with the USG (b) (4) .

2.7.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.7.3 The Awardee shall perform three media fill qualification runs using the selected vial configuration and volume.

2.7.4 The Awardee shall provide a Media Fill Qualification Report.

2.7.5 The Awardee shall perform liquid fill operations using the CGMP DS from Task 6.

2.7.6 The Awardee shall fill (b) (4) multi-dose vials of CGMP DP suitable for use in a Phase 2 clinical trials or EUA (see Task 16) using DS from the first CGMP (b) (4) runs. The concentration TBD in collaboration with the client. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.7.7 The Awardee will explore and present possibilities for pooling and filling and use the plan acceptable to the client and sponsor. The materials from this DP Lot will be suitable for Phase 2 clinical trials or EUA (see Task 16) at a concentration TBD in collaboration with the USG.

2.7.8 The material from the remaining four CGMP (b) (4) runs may be pooled and filled as a single lot, based on final discussions with the USG. Upon agreement with the USG, this DP lot may be formulated and filled at an outside vendor agreed upon with the USG. The final fill volume is assumed to be (b) (4) in a (b) (4) vial unless a different fill volume is requested. The Awardee shall conduct sampling and lot release testing per sponsor-provided specifications from this lot.

2.7.9 All DP lots will be at the disposition of the USG, and storage pending shipment will be at the ADM Facility.

2.7.10 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.7.11 The Awardee shall provide manufacturing and testing information related to Ology Bio-produced DP (b) (4) to add to their IND.

2.7.12 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, executed CGMP batch records, and COA and MSDS for CGMP DP.

2.8 Task 8: Scale-up to (b) (4) and Transfer of Inovio Downstream Purification Process

2.8.1 The Awardee shall coordinate (b) (4) for transfer of the process for the cell lysis step using equipment information from their current CDMO, (b) (4) in parallel with Engineering and CGMP Runs in accordance with the Ology Bio (b) (4) Consulting Agreement.

2.8.2 The Awardee shall procure, install and qualify the cell lysis equipment with support (b) (4) .

2.8.3 The Awardee shall procure, install, and qualify (b) (4) system (b) (4) along with any other necessary components, systems, documentation, or services.

2.8.3.1 The Awardee shall conduct an Engineering review, including generating a User Requirements Specification Component Criticality Assessment and System Level Impact Assessment.

2.8.3.2 The Awardee shall purchase (b) (4) system.

2.8.3.3 The Awardee shall install (b) (4) System at the DoD ADM facility and perform SAT.

2.8.3.4 The Awardee shall perform IQ of the (b) (4) system.

2.8.3.5 The Awardee shall perform OQ of the (b) (4) system.

2.8.3.6 The Awardee shall prepare a Qualification Report for the (b) (4) system.

2.8.4 **The Awardee shall procure a stockpile of single-use flow paths to ensure on-going use is possible following qualification.** The Awardee shall scale-up their existing lysis step in preparation of the larger scales.

2.8.5 The Awardee shall provide a Process Scale-up Plan.

2.8.6 The Awardee shall prepare Process Scale-up PDPRs.

2.8.7 The Awardee shall conduct (b) (4) Scale-up Runs at (b) (4) scale, with the number of runs based on the discretion of the USG and suggestions from Ology Bio.

2.8.8 The Awardee shall QC test the materials from these runs based on the analytical assays in **Table 1** and

2.8.9 **Table 2**.

2.8.10 The Awardee shall prepare draft batch records for use in the Engineering Run(s).

2.8.11 The Awardee shall provide a Sampling Plan.

2.8.12 The Awardee shall provide a TTP.

2.8.13 The Awardee shall provide a Process Scale-Up Report.

2.9 Task 9: Engineering DS Run (b) (4)

2.9.1 The Awardee shall prepare a TTP; draft MBRs; raw material, product and label specifications; and draft BOM and MBR setup.

2.9.2 The Awardee shall execute (b) (4) Engineering DS lot using draft MBRs.

2.9.3 The Awardee shall use the scaled-up process from Task 8 and the Ology Bio-manufactured WCB.

2.9.4 The Awardee shall use resins and filters dedicated for this project. The Awardee shall use the same columns/resins for both the Engineering and CGMP Runs.

2.9.5 The Awardee shall conduct the runs in the CGMP manufacturing area of the DoD ADM Facility.

2.9.6 The Awardee shall test the Engineering DS based on the analytical tests from Task 4 and (b) (4) provided specifications for purity and impurity levels.

2.9.7 The Awardee shall provide:

2.9.7.1 Engineering Run Report

2.9.7.2 Finalized CGMP Batch Record templates

2.9.7.3 Finalized CGMP specifications

2.9.7.4 Final BOM

2.9.7.5 Engineering non-CGMP DS CoT

2.9.7.6 Engineering non-CGMP DS MSDS

2.10 Task 10: CGMP DS Run (b) (4)

2.10.1 The Awardee shall update the TTP and MBRs as needed.

2.10.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.10.3 The Awardee shall execute (b) (4) run for the CGMP DS using MBRs and Ology Bio-manufactured WCB.

2.10.3.1 The Awardee shall conduct the in-process and release testing outlined in **Table 1** and

2.10.3.2 **Table** 2.

2.10.3.3 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.10.3.4 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.10.4 The Awardee shall provide:

2.10.4.1 QA-Approved Executed DS Batch Production Records

2.10.4.2 QA-Approved DS COA

2.10.4.3 QA-Approved DS MSDS

2.10.4.4 Materials from these runs

2.11 Task 11: CGMP DP Fill/Finish (Large-scale)

2.11.1 The Awardee shall determine the final dose and vial configuration in conjunction with the USG (b) (4) .

2.11.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.11.3 The Awardee shall perform liquid fill operations using the CGMP DS from Task 10. The Awardee shall qualify and monitor a large-scale fill finish subcontractor capable of performing CGMP Phase 3 activities listed within this task. Successful qualification of the subcontractor will require onsite audit and monitoring to allow for Awardee Person-in-Plant during scope of work performed (b) (4) .

2.11.4 The Awardee shall fill (b) (4) multi-dose vials of CGMP DP suitable for use in a Phase 3 clinical trial or EUA (see Task 16) at a concentration TBD in collaboration with the client. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.11.5 The Awardee shall conduct sampling and lot release testing.

2.11.6 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.11.7 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.11.8 The Awardee shall provide CGMP DP to client or client designated recipient.

2.12 Task 12: CGMP DS Runs (b) (4)

2.12.1 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.12.2 The Awardee shall execute (b) (4) runs (b) (4) for the CGMP DS using MBRs; (b) (4)

2.12.2.1 The Awardee shall conduct the in-process and release testing outlined in **Table 1** and

2.12.2.2 **Table** 2.

2.12.2.3 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.12.2.4 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.12.3 The Awardee shall provide:

2.12.3.1 QA-Approved Executed DS Batch Production Records

2.12.3.2 QA-Approved DS COA

2.12.3.3 QA-Approved DS MSDS

2.12.3.4 Materials from these studies to be used for DP fill/finish (Task 13)

2.13 Task 13: CGMP DP Fill/Finish (Additional large-scale runs)

2.13.1 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.13.2 (b) (4)

2.13.3 The Awardee's subcontractor shall fill (b) (4) doses filled into multi-dose vials of CGMP DP suitable for use in a Phase 3 clinical trial or EUA (see Task 16) at a concentration TBD in collaboration with the client and sponsor. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.13.4 The Awardee shall conduct sampling and lot release testing.

2.13.5 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.13.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.13.7 The Awardee shall provide CGMP DP to the USG or USG designated recipient

2.14 Task 14: Stability Testing of DS and DP (b) (4)

2.14.1 Engineering DS

2.14.1.1 The Awardee shall provide a Stability Protocol for the Engineering DS, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.14.1.2 The Awardee shall execute the stability study using the Engineering Run DS.

2.14.1.3 The Awardee shall provide a Stability Report.

2.14.2 CGMP DS

2.14.2.1 The Awardee shall provide a Stability Protocol for the CGMP DS from Task 6, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG

prior to the start of stability.

2.14.2.2 The Awardee shall execute the stability study using the CGMP DS.

2.14.2.3 The Awardee shall provide a Stability Report.

2.14.3 CGMP DP

2.14.3.1 The Awardee shall provide a Stability Protocol for the CGMP DP from Task 7, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.14.3.2 The Awardee shall execute the stability study using the CGMP DP.

2.14.3.3 The Awardee shall provide Stability Reports.

2.15 Task 15: Stability Testing of DS and DP (b) (4)

2.15.1 CGMP DS

2.15.1.1 The Awardee shall provide a Stability Protocol for the CGMP DS, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.15.1.2 The Awardee shall execute the stability study using the CGMP DS.

2.15.1.3 The Awardee shall provide a Stability Report.

2.15.2 CGMP DP

2.15.2.1 The Awardee shall provide a Stability Protocol for the CGMP DP, to be determined in collaboration with the Client, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.15.2.2 The Awardee shall execute the stability study using the CGMP DP.

2.15.2.3 The Awardee shall provide Stability Reports.

2.16 Task 16: Emergency Use Authorization Preparation

2.16.1 Preparation

2.16.1.1 The Awardee shall evaluate current procedures and processes to align with requirements for CGMP Phase 3 in preparation for anticipated EUA or Expanded Access prior to product approval.

2.16.1.2 The Awardee shall revise necessary procedures from identified gaps to ensure compliance with applicable regulations.

2.16.1.3 The Awardee shall provide all necessary information and data to the IND holder.

2.16.2 Execution

2.16.2.1 The Awardee shall conduct an in-depth audit for this scope of work to represent an FDA inspection consistent with CGMP Phase 3 for EUA. This may be conducted by Awardee, qualified subcontractor(s) or a combination thereof as identified in coordination with the USG. USG shall have the option of sending a representative to participate in or observe the audit.

2.16.2.2 The Awardee shall develop and provide a comprehensive audit report detailing the audit activities and findings for the areas inspected.

2.16.2.3 The Awardee shall host and manage any applicable necessary regulatory

inspection (e.g. FDA EUA) to support the requirements within this Scope of Work.

2.16.3 Closure

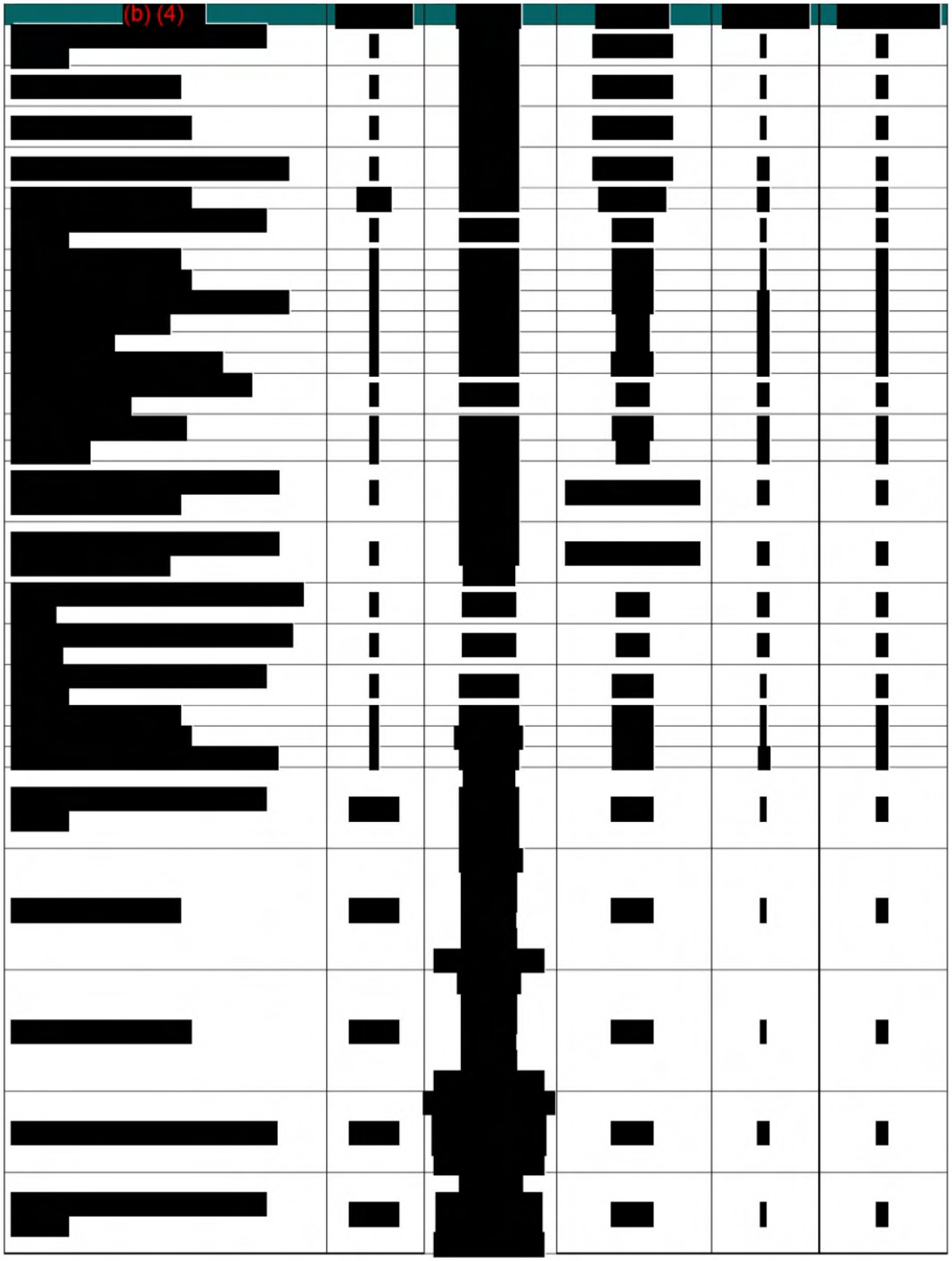
2.16.3.1 The Awardee shall evaluate the audit report(s) resulting from inspection(s) associated with this task.

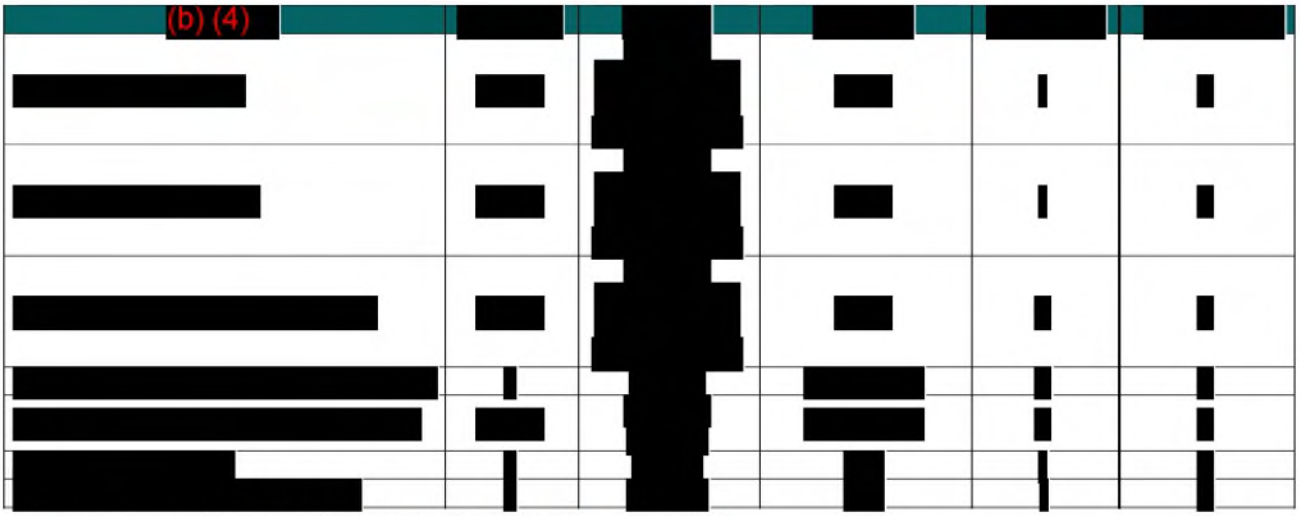
2.16.3.2 The Awardee shall provide a comprehensive audit response with CAPA plan to all observations within the audit report(s).

2.16.3.3 The Awardee may require additional labor to execute requirements for regulatory activities resulting from an inspection needed to demonstrate correction or compliance.

3.0 DELIVERABLES

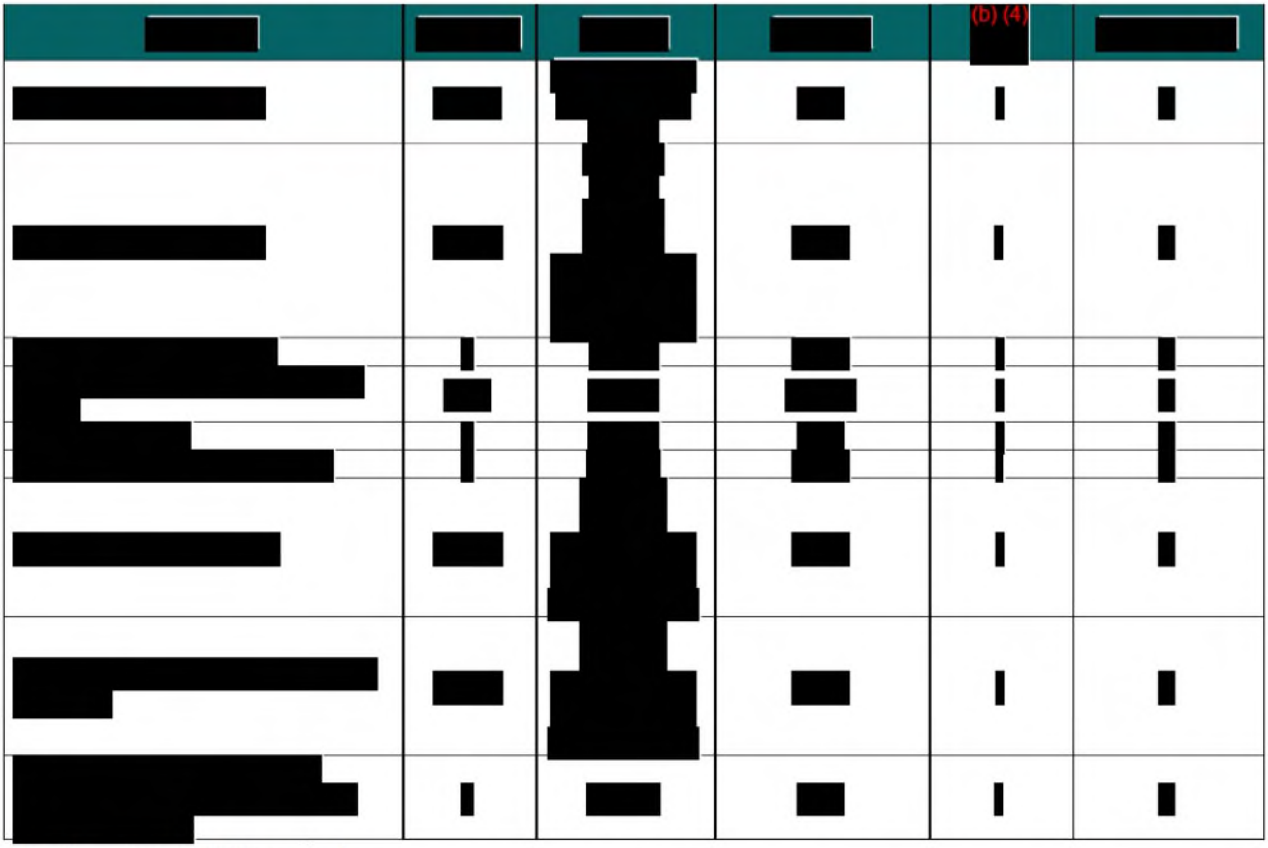
3.1 Data Deliverables


(b) (4)



*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined
**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.
*** Subject to IP disclosures. Any changes resulting will be incorporated in a separate modification.

3.2 Supply Deliverables



*I=Inform; TBD=To Be Determined
**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

3.3 Acceptance of Deliverables

The USG will provide review of all data deliverables within (b) (4) of delivery. The USG will acknowledge receipt of all supply deliverables within (b) (4) of delivery.

4.0 DATA RIGHTS

The Government shall have no rights in the data associated with Ology Bio's Background Intellectual Property (IP) and Materials (b) (4) described in Section 5, subject to IP disclosures. Any changes resulting will be incorporated in a separate modification.

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

Ology Bio is not specifying any Background IP and Materials for this 2373 Agreement.

(b) (4)

6.0 AOR AND ALTERNATE AOR CONTACT INFORMATION

AOR:	Alternate AOR:
TBD	TBD

[End of SOW]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 5

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00014	12-Jun-2020	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 22-Feb-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to incorporate Appendix A-2 Rev 2, incorporate Appendix A-9, increase the agreement value, and incorporate incremental funding. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6)	12-Jun-2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00014

A. The purpose of this Amendment is as follows:
   a. Appendix A-2 Rev 2 is hereby incorporated into the Agreement. This revision supersedes the previously incorporated Appendix A-2 Rev 1 in full.
   b. (b) (4) [redacted]
   c. The total cost of CLIN 0002 is increased by (b) (4) [redacted] from (b) (4) [redacted] to (b) (4) [redacted]
   d. (b) (4) [redacted]
   e. The total cost of this agreement is increased by (b) (4) [redacted] from (b) (4) [redacted] to (b) (4) [redacted]
   f. SubCLIN 000203 is hereby added to the agreement to incorporate incremental funding in the amount of (b) (4) [redacted] under ACRN AL.
   g. (b) (4) [redacted]
   h. Total funding for this agreement is increased by (b) (4) [redacted] from (b) (4) [redacted] to (b) (4) [redacted]

B. The Parties hereby agree that changes effected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this agreement resulting from the incorporation of Appendix A-2 Rev 2 (b) (4) [redacted]

C. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) [redacted] from (b) (4) [redacted] to (b) (4) [redacted]

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002

The CLIN extended description has changed from:

Project 20-05: Rapid mAB COVID 19 labor, materials, equipment and associated costs delineated the in Statement of Work entitled, "Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19", hereby incorporated into the Agreement as Appendix A-2 Rev 1.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project. The project level AOR does not supersede the roles and duties of the Agreement AOR.
The Project AOR's contact Information is below:Name: (b) (4)

To:

Project 20-05: Rapid mAB COVID 19 labor, materials, equipment and associated costs delineated the in Statement of Work entitled, "Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19", hereby incorporated into the Agreement as Appendix A-2 Rev 2.
The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project. The project level AOR does not supersede the roles and duties of the Agreement AOR.
The Project AOR's contact Information is below:Name: (b) (4)

.

The estimated/max cost has increased by (b) (4) from (b) (4) to $(b) (4)
The fixed fee has increased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4).

(b) (4)

SUBCLIN 000203 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000203					$0.00
	Ology mABS Scale up & Manufacturing FFP Ology mABS Scale up & Manufacturing PURCHASE REQUEST NUMBER: 0011506795				
				NET AMT	$0.00
	ACRN AL CIN: GFEBS001150679500001				(b) (4)

SUBCLIN 000902 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000902					$0.00
	Equipment for mABS & DNA Suites @ Ology FFP Equipment for mABS & DNA Suites @ Ology PURCHASE REQUEST NUMBER: 0011505679				
				NET AMT	$0.00
	ACRN AM CIN: GFEBS001150567900001				(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000203:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000902:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000203:
Funding on SUBCLIN 000203 is initiated as follows:

ACRN: AL

CIN: GFEBS001150679500001

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.6 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

SUBCLIN 000902:
Funding on SUBCLIN 000902 is initiated as follows:

ACRN: AM

CIN: GFEBS001150567900001

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

(End of Summary of Changes)

STATEMENT OF WORK

Title: Procurement, Commissioning and Qualification of CGMP Equipment at the DoD ADM Facility

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated *21 February 2020* shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The purpose of this SOW is to procure, commission, and qualify a suite of CGMP compliant equipment (the supplies) to support CGMP (b) (4) mAb production and (b) (4) pDNA production scales at the DoD ADM facility. This suite of equipment will be utilized in support of developmental work at the ADM facility to include production of MCMs under cGMPs leading to the development of FDA approved medical countermeasures (the best supplies). Current equipment does not provide sufficient volume for the full scale production runs necessary on advanced development projects.

The following tasks are required to complete this effort:

Task 1: Purchase, Installation and Qualification of Equipment to Support (b) (4) mAb Production

Task 2: Purchase, Installation and Qualification of Equipment to Support (b) (4) to Support pDNA Manufacturing

Task 3: Purchase, Installation and Qualification of QC and Support Equipment

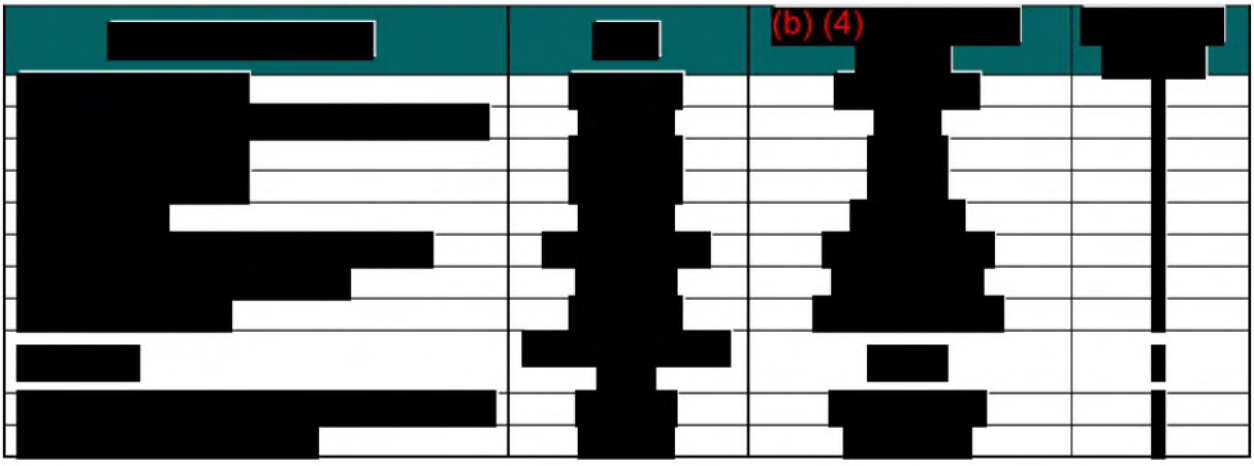
2.0 REQUIREMENTS

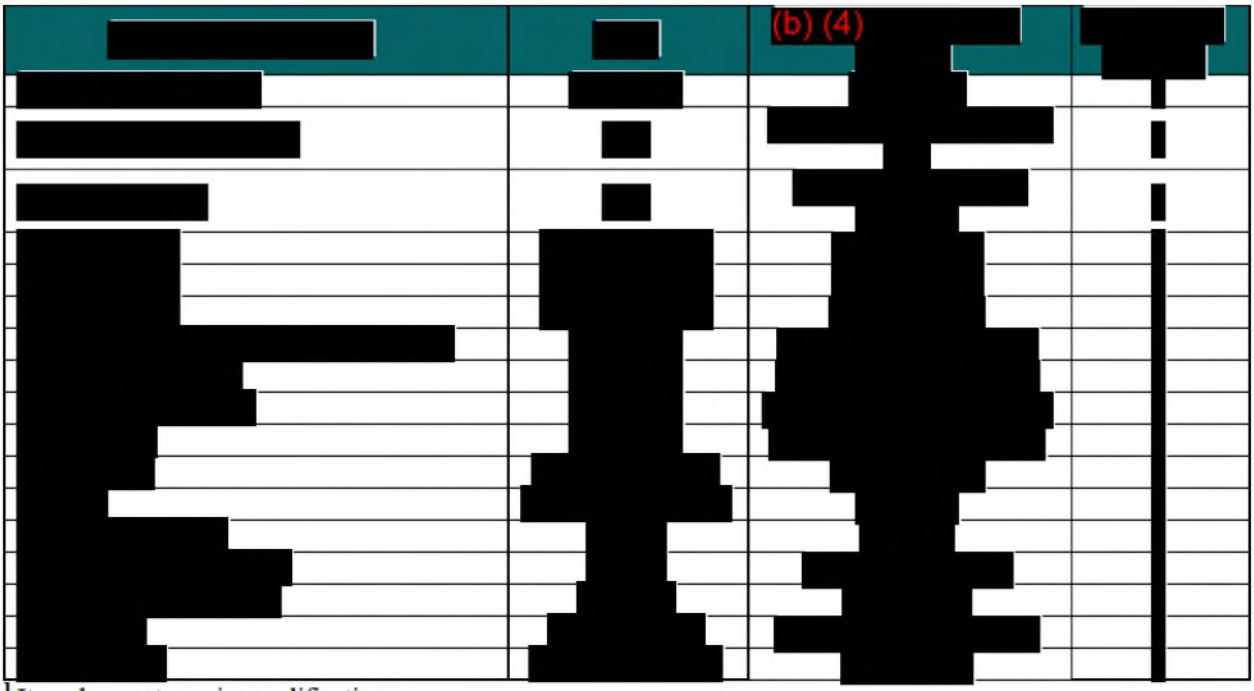
2.1 Task 1: Purchase, Installation and IQ/OQ of Equipment to Support (b) (4) mAb Production

Notes:

- Equipment that appears in both Task 1 and Task 2 will be ordered on the same purchase order and qualified at the same time to avoid duplication of effort.

***Table 1**. mAb Capacity Expansion Equipment List*





[1] Item does not require qualification

2.1.1 The Awardee shall conduct an engineering review, including generating a URS, CCA and SLIA for each piece of equipment.

2.1.2 The Awardee shall purchase the equipment listed in **Table 1** to support manufacturing of mAbs (b) (4) with (b) (4) available as a backup to ensure maximum production capacity

2.1.3 The Awardee shall perform a FAT prior to shipment (b) (4) . No other equipment listed in **Table 1** requires a FAT. (b) (4)

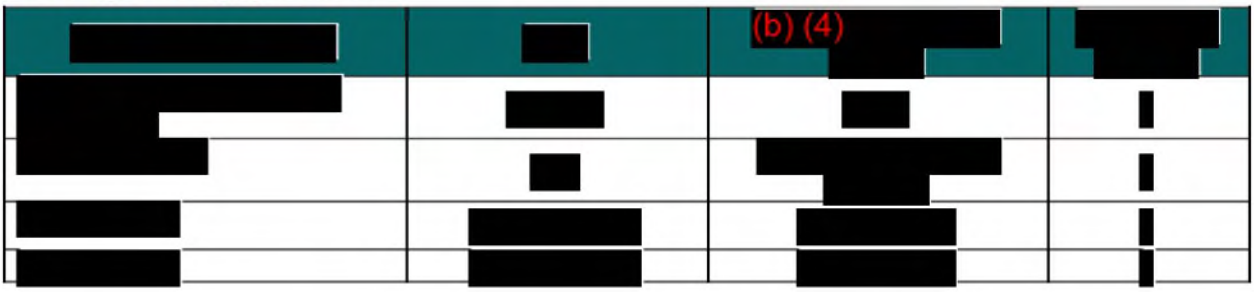
2.1.4 The Awardee shall install equipment at the DoD ADM Facility.

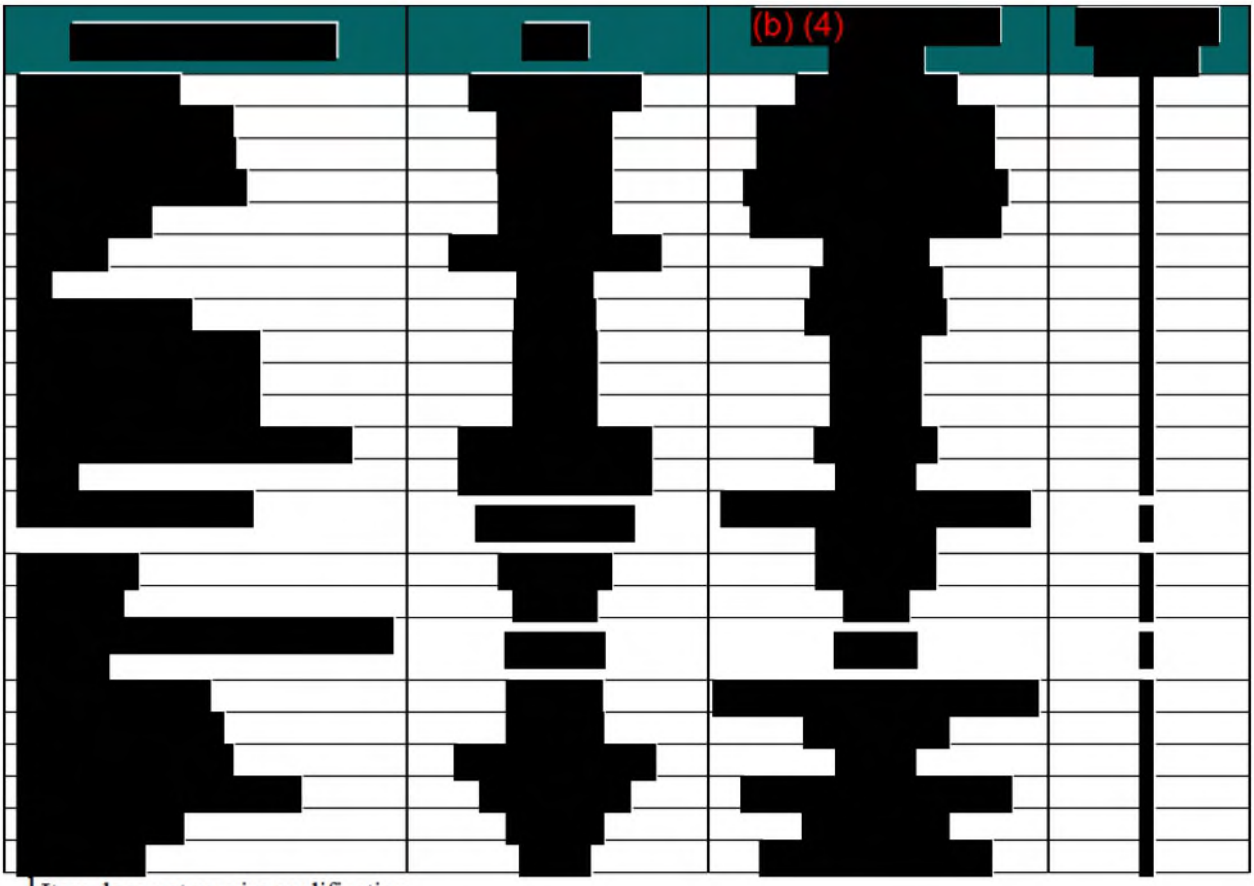
2.1.5 The Awardee shall perform Commissioning Test Procedure (CTP) or IQ/OQ of the equipment based on the requirements identified in the SLIA.

2.1.6 The Awardee shall prepare a Qualification Report for each Direct Impact piece of equipment.

2.2 Task 2: Purchase, Installation and IO/OQ of Equipment to Support (b) (4) to Support pDNA Manufacturing

Table 2. *pDNA Equipment List*





[1] Item does not require qualification

2.2.1 The Awardee shall conduct an engineering review, including generating a URS, CCA and SLIA for each piece of equipment.

2.2.2 The Awardee shall purchase the equipment listed in **Table 2** to support manufacturing of mAbs (b) (4) with (b) (4) available as a back-up to ensure maximum production capacity.

2.2.3 The Awardee shall perform a FAT prior to shipment (b) (4). No other equipment listed in **Table 2** requires a FAT. (b) (4)

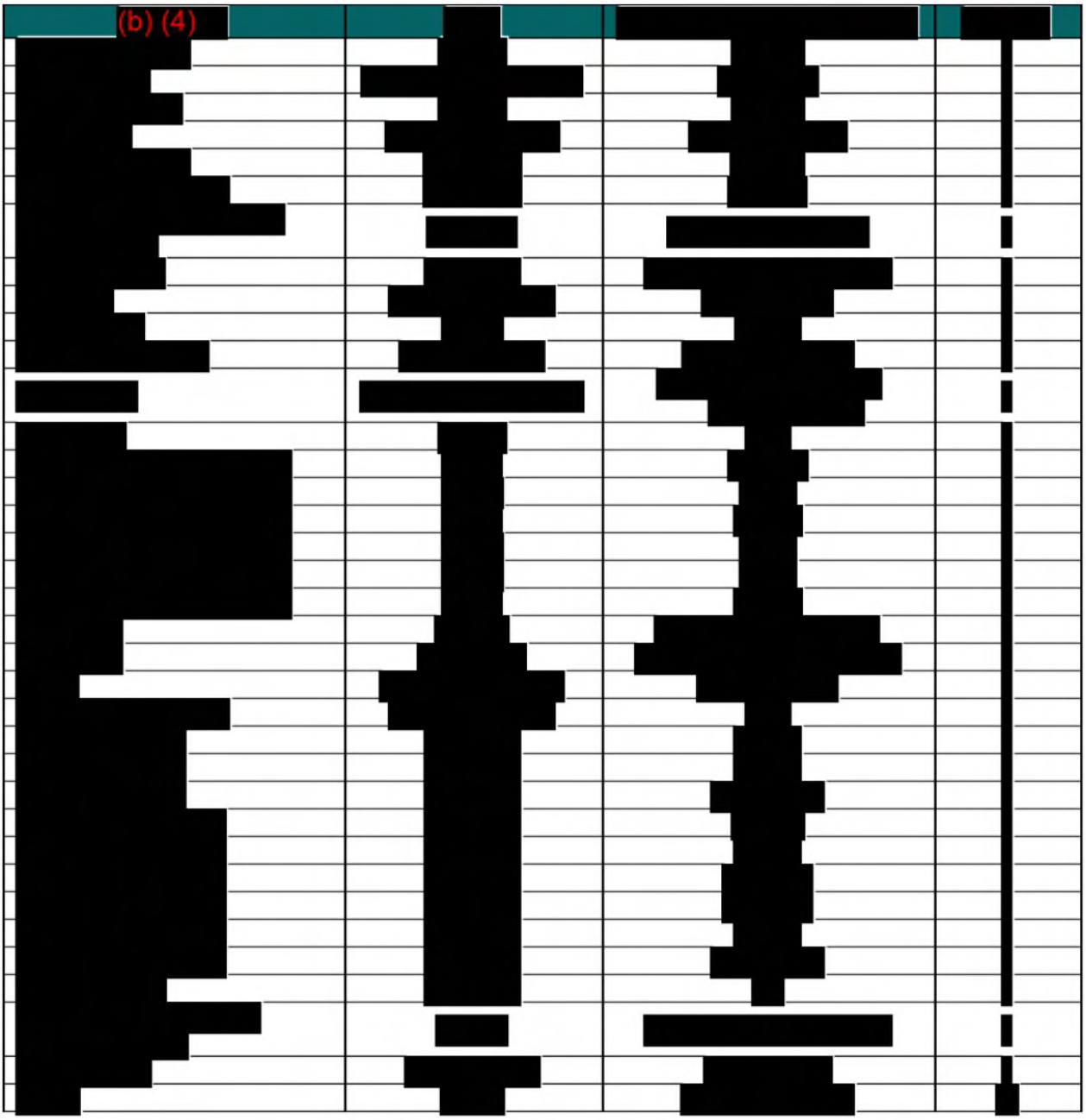
2.2.4 The Awardee shall install equipment at the DoD ADM Facility.

2.2.5 The Awardee shall perform CTP or IQ/OQ of the equipment based on the requirements identified in the SLIA.

2.2.6 The Awardee shall prepare a Qualification Report for each Direct Impact piece of equipment.

2.3 Task 3: Purchase, Installation and IO/OO of QC and Support Equipment

Table 3. *QC and Support Equipment List*



2.3.1 The Awardee shall conduct an Engineering review, including generating a URS, CCA and SLIA for each piece of equipment.

2.3.2 The Awardee shall purchase the equipment listed in **Table 3** in order to support QC testing activities resulting from continuous production at the specified scales and provide for baseline equipment such as cold storage units.

2.3.3 The Awardee shall install equipment at the DoD ADM Facility.

2.3.4 The Awardee shall perform CTP or IQ/OQ of the equipment based on the requirements identified in the SLIA.

2.3.5 The Awardee shall prepare a Qualification Report for each Direct Impact piece of equipment.

3.0 DELIVERABLES

3.1 Data Deliverables

(b) (4)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

**Category C=Data developed solely with USG funding allotted for this project.

3.2 Supply Deliverables

(b) (4)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

**Category C=Data developed solely with USG funding allotted for this project.

3.3 Acceptance of Deliverables

The U.S. Government (USG) will provide review of all data deliverables within (b) (4) of delivery. The USG will acknowledge receipt of all supply deliverables within (b) (4) of delivery.

[End of SOW]

STATEMENT OF WORK

Title: Rapid Production of Monoclonal Antibodies as Medical Countermeasures Against COVID-19

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated 21 February 2020 shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The scope of this project includes the activities required to rapidly produce doses of monoclonal antibody (mAb) therapeutics against COVID-19 (the supply) suitable for use in future clinical trials to develop the best supplies, FDA-approved COVID-19 therapeutics, which are required by the Department of Defense (DoD). To facilitate manufacturing and release of the doses, the proposed effort includes technology transfer of the variable region sequences for (b) (4) human mAbs, computational manufacturability assessment, cloning into IgG expression vectors, and generation of plasmids for stable CHO transfections. These will be down-selected (b) (4) for large-scale manufacturing as stable pools. Manufacturing runs using stably transfected CHO cell pools will be performed at the (b) (4) and (b) (4) scales, including CGMP Runs for Drug Substance (DS) and Drug Product (DP) with one-year stability studies. Ology Bioservices, Inc. ("Ology Bio" or "the Awardee") will develop analytical methods specific for COVID-19 to support release of the CGMP material. (b) (4) Regulatory support will include a Pre-IND Meeting, a Regulatory Strategy (RS) to IND, Regulatory Risk Assessments, and preparation of an IND application that is complete for submission to FDA, excluding toxicology final reports.

Background:

This SOW outlines the tasks required to produce (b) (4) therapeutic mAb DS co-formulated in one DP generated from the starting sequences provided by one US Government (USG) performer. At USG request, Ology Bio will manufacture mAbs from the starting sequence information from additional providers by repeating Tasks 2, 3, 4, 5, 6, 7, 8, 15 and 16 to manufacture the initial lot of materials. If requested, subsequent cell banking and future CGMP manufacturing would proceed according to Tasks 9, 11, 12, 13, 14, 15 and 17.

The "USG Performer" referenced throughout this SOW will be a contractor of the Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Program (P3). The Agreements Officer's Representative (AOR) will communicate with DARPA to coordinate the transfer of material and/or information from the USG Performer to the Awardee. All materials and information transferred to the Awardee shall be labelled as Government Furnished Property, subject to the conditions contained in Appendix C of the 2373 Agreement, and as such Awardee will have sufficient rights to use the materials and information in performance of the tasks required by this SOW

2.0 REQUIREMENTS

2.1 Task 1: Project Initiation and Oversight

Notes:

- Labor for project oversight (Project Manager [PM], Principal Investigator [PI], contracts and finance) spans the lifecycle of the project.
- Data requirements span the lifecycle of the project through delivery of doses.
- The kick-off and quarterly meetings will be held virtually.

- If a due date for a deliverable is on a weekend or holiday, then the deliverable will be due on the next business day.
- Due date of Annual Reports will be based on award date and not the fiscal calendar year.

2.1.1 Planning

2.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) following the (b) (4) award, provide an agenda (b) (4) days prior to the meeting, and provide a meeting report (b) (4).

2.1.1.2 The Awardee shall provide an Integrated Master Schedule (IMS) (b) (4). The Awardee shall provide an updated IMS (b) (4) identifying task progress, percent completion and schedule slippage.

2.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project Charter, Communication Plan, IMS, Work Breakdown Structure (WBS), Cost Management/Spend Plan and List of Deliverables.

2.1.2 Execution

2.1.2.1 Meetings

2.1.2.1.1 The Awardee shall conduct IPT meetings no less than twice per month. The Awardee shall provide the agendas and IPT slide decks (b) (4) in advance of the IPT. Finalized meeting minutes shall be submitted to the USG (b) (4) following each teleconference.

2.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or USG request, to discuss issues as they arise. Minutes from these meetings shall be provided to the USG within five business days following the meeting.

2.1.2.2 Reports

2.1.2.2.1 The Awardee shall deliver a Monthly IMS and spend plan for the life cycle of the project. The Awardee shall submit each Monthly IMS and spend plan within 20 calendar days after the end of each month of performance. The USG will have 10 calendar days to respond to the report with any comments, and the Awardee will have an additional five calendar days to revise the deliverable or respond to those comments.

2.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities.

2.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 20 calendar days after the end of each quarter of performance. The USG will have 30 calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

2.1.2.2.4 The Awardee shall perform, record and report physical inventory results of all Contractor Acquired Property in the contractor's possession, if the

Awardee purchases material or equipment using USG funds, as approved by the AOR during performance of the project.

2.1.2.2.5 Incident Reporting

2.1.2.2.5.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the USG in an incident report. In addition, the Awardee shall provide advanced notice of critical path schedule changes resulting in more than a 15-day calendar shift that are not handled as Incident Reports. The Ology Bio PM will provide written notification (via email) to the AOR.

2.1.2.2.5.2 The Awardee shall telephonically contact the program manager for the USG no later than 24 hours after the incident is identified.

2.1.2.2.5.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place. If additional time is required for the Root Cause Analysis, the Ology Bio PM will work with the AOR to agree on timing of the written summary report.

2.1.2.2.6 The Awardee shall provide the draft Quality Agreement (b) (4) [redacted]. The draft Quality Agreement will be submitted via e-mail to the USG technical representatives. The USG shall respond with comments or acceptance ten calendar days following receipt of the draft Quality Agreement. The final agreement with incorporated changes shall be submitted five calendar days after receipt of USG comments. The USG will provide written acceptance.

2.1.2.2.7 The Awardee shall support USG quality audits of the Awardee's systems and procedures as outlined in the Quality Agreement, insofar as they relate to the service and control of the USG's product. These audits may be performed at times mutually agreed upon by the Awardee and the USG. The Awardee shall provide the USG with monthly follow-ups on the status of audit observation commitments found in the USG annual audit or regulatory inspection, as they apply to the USG's product.

2.2 Task 2: Technology Transfer and Plasmid Generation

Notes:

- The mAb sequences for (b) (4) [redacted] mAbs from which the (b) (4) mAb candidates will be selected, will be provided by the USG Performer.

2.2.1 Task 2a: Information and Material Transfer

2.2.1.1 The Awardee shall coordinate with the USG Performer to obtain the (b) (4) [redacted] cDNA sequences for the human anti-COVID-19 mAbs. There will initially be (b) (4) sequences that will be provided by the USG provider. These will be analyzed (b) (4) [redacted] (b) (4) [redacted] analyses. Based on these analyses and the data provided by (b) (4)

(b) (4) (b) (4) domains will be selected for plasmid generation and initial stable pool generation.

2.2.1.2 The mAbs will be selected based on microneutralization tests and binding to different non-overlapping domains of the (b) (4)

2.2.2 Task 2b: Plasmid Generation

2.2.2.1 The Awardee shall clone the (b) (4) domain encoding cDNA sequences into appropriate expression vectors. Awardee will also generate (b) (4) additional versions of the top DNA sequences. These will include (b) (4)

2.2.2.2 (b) (4)

2.2.2.3 Plasmid DNA will be used to stably transfect (b) (4) (see Task 5).

2.2.2.4 In parallel to the above-mentioned tasks, the Awardee will (b) (4) generate plasmid sequences to be used to transfect the same (b) (4) as above but using proprietary transfection reagents. Currently, the scope of work calls for (b) (4) mAb candidate sequences will be made into plasmids. (b) (4) Additional candidate sequences may be included at an additional price that was provided by the subcontractor. (b) (4)

2.2.3 Task 2c: Gap and Risk Analyses

2.2.3.1 The Awardee shall complete and provide an initial Risk Assessment and Risk Mitigation program, including all tasks in the program.

2.2.3.2 The Awardee shall conduct and provide a Gap Analysis to identify any potential gaps or weaknesses associated with any of the tasks.

2.2.4 Task 2d: Animal Protocol Writing for ACURO

2.2.4.1 (b) (4)

2.2.5 Task 2e: Computational Manufacturability Assessment

2.2.5.1 The Awardee shall perform a computational manufacturability assessment of the mAb candidates (not full optimization) to inform the down-select prior to further development and production, including:

2.2.5.1.1 (b) (4) evaluation and rank order of (b) (4) human mAb sequences; (b) (4)

2.2.5.1.2 Analysis of (b) (4) down-selected sequences using multi-attribute methods will be performed prior to the down-selection to the (b) (4) mAb candidates (see Task 5)

2.2.5.2 The Awardee shall provide a Computational Manufacturability Assessment Report.

2.3 Task 3: Pre-IND Consultation

Notes:

- Based on the (b) (4) need for clinical evaluation of the product, the Pre-IND meeting will include an aggressive filing of the draft report (not in SEND format) if acceptable.
- Ology Bio will serve as the product Sponsor.

2.3.1 The Awardee, as Sponsor, shall consult FDA's Pre-IND Consultation program to support development of a novel mAb therapeutic to facilitate development of a RS with attached Target Product Profile (TPP) to expedite the IND filing.

2.3.2 (b) (4) .

2.3.3 The RS will also include the use of the material generated from the stable pool transfections for toxicology, efficacy and Phase 1 clinical programs.

2.3.4 The Awardee shall support program objectives by developing risk assessment reports in areas where the Awardee's Regulatory Affairs (RA) team are developing high-risk strategies to include limiting stability timepoints to support Phase 1, limiting nonclinical safety data, (b) (4) in the original IND application.

2.3.5 The Awardee shall develop a Phase 1 clinical synopsis to include in the Pre-IND briefing package. The Awardee shall provide the Pre-IND briefing package to the USG.

2.4 Task 4: Analytical Development and Qualification

Notes:

- Ology Bio will develop and qualify product-specific methods for QC lot release and stability testing including identity and potency methods.
- All other release methods are standardized methods and/or compendial methods.

2.4.1 The Awardee shall leverage experience from the (b) (4) programs to develop the analytical assays to support in process and release testing of the mAbs.

2.4.2 The Awardee shall qualify analytical assays in a phase-appropriate manner.

2.4.3 The Awardee shall provide, for USG review onsite at the DoD ADM Facility or via a terminal in the Ology Bio MD office for remote review, an Analytical Method Qualification Report, with summary reports for each of the assays developed.

2.4.4 The Awardee shall develop, qualify and provide, for USG review onsite at the DoD ADM Facility or via a terminal in the Ology Bio MD office for remote review, a Qualification Report for *in vitro* potency methods for the (b) (4) DS and (b) (4) DP.

2.5 Task 5: Stable Transfections

2.5.1 The Awardee shall develop stable pools of (b) (4) cells by transfection of the mAb-encoding expression plasmids created in Task 2 (b) (4) .

2.5.2 The Awardee shall perform the stable transfections using Good Documentation Practices and document all source materials.

2.5.3 The Awardee shall expand the stable pools, use production assays to identify robust pools expressing the highest mAb levels, and select the top pool for initial scale-up and manufacturing.

2.5.4 The Awardee shall prepare and characterize cell banks like CGMP MCBs. The Awardee shall generate (b) (4) vials for each stable pool Cell Bank.

2.5.5 (b) (4) (2.5.6)

2.5.5.1 A comparison of overall titers will be made between the stable pools of the vendor and the Awardee.

2.5.5.2 (b) (4)

2.5.5.3 (b) (4)

2.5.5.4 The Awardee shall receive stable pool materials from the vendor for *in vitro* evaluation.

2.5.5.5 The Awardee shall provide (b) (4) vials for each of the stable pools produced by the vendor.

2.5.5.6 (b) (4)

2.5.5.7 The Awardee shall prepare and characterize cell banks in a similar fashion as CGMP MCBs.

(b) (4)

2.5.14 The Awardee shall provide a Cell Line Development Report for each of the (b) (4) mAbs based on the generation of the stably transfected pools.

Table 1. Criteria for down-selection of the stable pools

(b) (4)	

2.6 Task 6: Process Development

Notes:

- Awardee will use the down-selected stably transfected cell pools generated during Task 5 as the starting materials in this task.
- (b) (4)
- (b) (4)

2.6.1 Media and Feed Optimization

2.6.1.1 (b) (4)

2.6.2 Process Development Runs (b) (4)

2.6.2.1 The Awardee shall perform (b) (4) Process Development Runs for each of (b) (4) selected pools from Task 5 (b) (4). The selection of which pools to use will be made in collaboration with the USG. Awardee will store DS frozen based on experience with previous mAb formulations.

2.6.2.2 Awardee will not perform (b) (4) testing on these DS runs.

2.6.2.3 Awardee may use the materials from these runs for analytical method development (Task 4). Process Development Runs will include (b) (4) purification steps through to final DS.

2.6.2.4 The Awardee shall execute (b) (4) formulation and fill validation (b) (4).

2.6.2.5 The Awardee shall use (b) (4) vials per lot in a mutually approved container/closure system (vial, stopper, seal) for the media fill validation runs. (b) (4)

(b) (4)

2.6.2.6 The awarded shall comply with FDA Guidance for Industry, Sterile Drug Products Produced by (b) (4) Processing–Current Good Manufacturing Practice, Sept 2004.

2.6.2.7 The Awardee shall provide:

2.6.2.7.1 Process Development Report (b) (4)

2.6.2.7.2 DS materials

2.6.2.7.3 (b) (4) Media Qualification Report

2.7 Task 7: CGMP DS Runs with Stable Pools (b) (4)

Notes:

- Stably transfected cell pools generated during Task 5 and down-selected in Task 6 will be used in this task.

2.7.1 The Awardee shall perform (b) (4) CGMP DS Runs as required to generate sufficient CGMP material for each of the (b) (4) mAb candidates.

2.7.2 The Awardee shall conduct sampling and lot release testing that was successfully employed (b) (4) for CGMP materials.

2.7.3 The Awardee shall generate DS and DP Reference Standards from materials generated during the (b) (4) Runs using the analytical methods described in Task 4.

2.7.4 The Awardee shall use in-process material generated in the (b) (4) runs in a viral clearance study for each mAb.

2.7.5 The Awardee shall provide controlled and temperature-monitored transport of final released lots as directed by the AOR.

2.7.6 The Awardee shall complete *in vitro* potency release testing of the CGMP DS for each of the (b) (4) mAbs.

2.7.7 The Awardee shall provide:

2.7.7.1 Reference standard materials for each mAb DS

2.7.7.2 Viral Clearance Reports for each mAb

2.7.7.3 CGMP DS Campaign Summary Reports, raw material COA(s), analytical testing summaries and analytical reports, executed CGMP batch records, and COA and MSDS for CGMP DS for each of the (b) (4) mAbs.

2.7.7.4 CGMP DS for generation of CGMP DP (Task 8).

2.8 Task 8: CGMP DP Run (b) (4)

Notes:

- (b) (4)
- DP will be a combination of (b) (4) mAbs, dependent on efficacy of mAbs.
- No formulation development will be performed. (b) (4)

2.8.1 The Awardee shall perform (b) (4) using the CGMP DS of (b) (4) mAbs from Task 7.

2.8.2 The Awardee shall fill (b) (4) vials of one CGMP DP suitable for use in a Phase 1 clinical trial at a concentration as directed by the AOR. This includes co-formulation, fill, inspection, labeling, packaging and QA review. (b) (4)

2.8.3 The Awardee shall conduct sampling and lot release testing that was developed (b) (4) for CGMP materials. A risk assessment will be performed to minimize the impact of sampling to the overall product yield.

2.8.4 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released DP lot as directed by the AOR.

2.8.5 The Awardee shall complete (b) (4) release testing of the CGMP DP.

2.8.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.9 Task 9: Regulatory Support

Notes:

- This effort does not include publishing via the FDA Gateway but will result in a regulatory application that is complete for future electronic publishing and submission. Please note IND complete does not include toxicology reports, as the plan is to engage with the FDA to determine the necessary toxicology for the original submission.
- The IND will be prepared without toxicology information to expedite review.

2.9.1 The Awardee shall conduct a kick-off meeting for the regulatory submission, followed by development and review of an IND application. The IND will be delivered as complete for submission (i.e., MS Word deliverables ready to go to the electronic publisher).

2.9.2 The Awardee shall develop and provide a RS to support the program through IND submission, including a TPP as an attachment to the RS.

2.9.3 The Awardee shall conduct Regulatory Risk Assessments.

2.9.4 The Awardee shall draft eCTD sections for Modules 1-5 (MS Word format) and provide an IND that is complete for filing, except for toxicology reports.

2.9.5 The Awardee shall draft eCTD section for Module 3 for (b) (4) generated DS and DP produced in Task 18.

2.9.6 The Awardee shall support USG Emergency Use Authorization (EUA) requirements as needed to facilitate availability of the DP manufactured under this Agreement to the USG.

2.10 Task 10: Limiting Dilution Cloning

2.10.1 The Awardee shall conduct (b) (4) rounds of limiting dilution cloning from the (b) (4) lead stable pools (produced in Task 5) that were used above for the generation of clinical trial material, (b) (4) .

2.10.2 In addition to growth, viability and titer, the Awardee shall evaluate mAbs produced

from the top clones (b) (4)

2.10.3 The Awardee shall test the top clones (b) (4) and use the (b) (4) clones with the highest level of expression and acceptable product quality to generate RCBs for each of the (b) (4) mAbs.

2.10.4 The Awardee shall provide a (b) (4) for each of the (b) (4) mAbs.

2.11 Task 11: Master Cell Banking

Notes:

- The (b) (4) MCBs will be available to USG for use in future efforts to produce additional clinical trial material.

2.11.1 The Awardee shall produce a CGMP MCB of (b) (4) vials (b) (4) (from Task 18) for each of the (b) (4) selected mAbs.

2.11.2 The Awardee shall release and characterize the (b) (4) MCBs. (b) (4)

2.11.3 The Awardee shall provide an MCB Report, including the MCB production batch record and a COA, for each of the (b) (4) mAbs.

2.12 Task 12: Process Confirmation Runs with MCBs (b) (4)

2.12.1 The Awardee shall perform (b) (4) Process Confirmation Run using the MCB produced in Task 11 for each of the (b) (4) mAbs.

2.12.2 The Awardee shall perform analytical characterization of the DS based on the reference standard for material from stable pools for each of the (b) (4) mAbs.

2.12.3 The Awardee shall provide an MCB Confirmation Run Report for each of the (b) (4) mAbs.

2.13 Task 13: CGMP DS Runs with MCBs (b) (4)

Notes:

- MCBs generated in Task 11 will be used in this task.
- As directed by the AOR, DS manufactured in this task may be filled as DP in Task 14 or may be stored frozen.

2.13.1 The Awardee shall perform (b) (4) CGMP DS Run for each of the (b) (4) mAbs for [redacted] Runs.

2.13.2 The Awardee shall conduct sampling and lot release testing that was developed (b) (4) for CGMP materials.

2.13.3 The Awardee shall provide controlled and temperature-monitored transport of

analytical samples and final released lot as directed by the AOR.

2.13.4 The Awardee shall provide CGMP DS Campaign Summary Reports, raw material COA(s), analytical testing summaries and analytical reports, and executed CGMP batch records, and COA and MSDS for CGMP DS for each of the (b) (4) mAbs.

2.14 Task 14: CGMP DP Run

Notes:

- (b) (4)

(b) (4)

2.14.5 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released DP lot as directed by the AOR.

2.14.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for each CGMP DP lot.

2.15 Task 15: Nonclinical Safety

Notes:

- Material generated in Task 6 will be used to support these assays.
- A dose-ranging study is not included based on toxicity risk assessment, which will be used to present a strategy in the Pre-IND interactions.

2.15.1 (b) (4)

2.15.2 (b) (4)

2.15.3 Task 15c: GLP Toxicology Study

2.15.3.1 The Awardee shall conduct a GLP repeat-dose study as the IND-enabling toxicology study using material generated from the stable transfections and materials generated using the (b) (4) (Task 18) and submit the Toxicology Study Report and SEND data tables when they are available to support the regulatory filing with FDA.

2.15.3.2 The Awardee shall conduct PK and anti-drug antibody testing for each of the mAbs generated from the stable transfections and the (b) (4) system.

2.15.3.3 The Awardee shall provide a Toxicology Study Report and SEND data tables.

2.16 Task 16: Stability Studies (stable pool-produced material)

Notes:

- Material generated in Tasks 7 and 8 will be used in this task.

2.16.1 The Awardee shall conduct stability testing per an approved stability protocol on the CGMP DS and DP lots from the stable pools, including real-time and accelerated conditions (b) (4) for each of the (b) (4) mAb DS and (b) (4) DP, along with reference standards. The Awardee will finalize stability testing as part of risk assessment to determine the minimum amount of material required.

2.16.2 The Awardee shall provide stability test results in annual reports.

2.17 Task 17: Stability Studies (MCB-produced material)

2.17.1 The Awardee shall conduct stability testing per approved stability protocol on the CGMP DS and DP lots from the MCB, including real-time and accelerated conditions (b) (4) for each of the (b) (4) mAb DS and (b) (4) DP.

2.17.2 DS and DP stability studies will be matrixed to reduce testing load.

2.17.3 The Awardee shall provide stability test results in annual reports.

2.18 Task 18: Proof-of-Concept of mAb Production (b) (4)

Notes:

- (b) (4)

2.18.1 Task 18a: Demonstrate (b) (4) Expression (b) (4)

2.18.1.1 (b) (4)

(b) (4)

2.18.2 Task 18b: Demonstrate (b) (4) Recovered Intermediate (b) (4)

(b) (4)

2.18.3 Task 18c: CGMP Manufacturing of (b) (4) mAb Candidates (b) (4)

(b) (4)

2.18.4 Task 18d. Fill/Finish of CGMP mAb DP (Ology Bio)

2.18.4.1 The Awardee shall provide for purification, fill and finish of the CGMP API for the (b) (4) mAbs into a (b) (4) DP. CGMP fill/finish will be performed as described in Task 8.

2.18.4.2 The Awardee shall perform release of the CGMP DP.

2.18.5 Task 18e. Product Comparability (Ology Bio)

2.18.5.1 The Awardee shall perform analytical comparability testing on the (b) (4) mAbs DS and the (b) (4) DP to the existing CHO manufacturing process (Task 7 and 8 material).

2.18.5.2 The Awardee shall perform stability studies on the (b) (4) DS and DP material, including real-time and accelerated conditions (b) (4) for each of the (b) (4) mAb DS and (b) (4) DP, along with reference standards. The Awardee will finalize stability testing as part of risk assessment to determine the minimum amount of material required.

2.18.5.3 The Awardee shall provide stability test results in annual reports.

2.19 Task 19: Bioanalytical Development

2.19.1 The Awardee shall develop and validate (b) (4) bioanalytical assays (b) (4)

2.19.2 The Awardee shall develop and validate assays (b) (4) bioanalytical assays (b) (4)

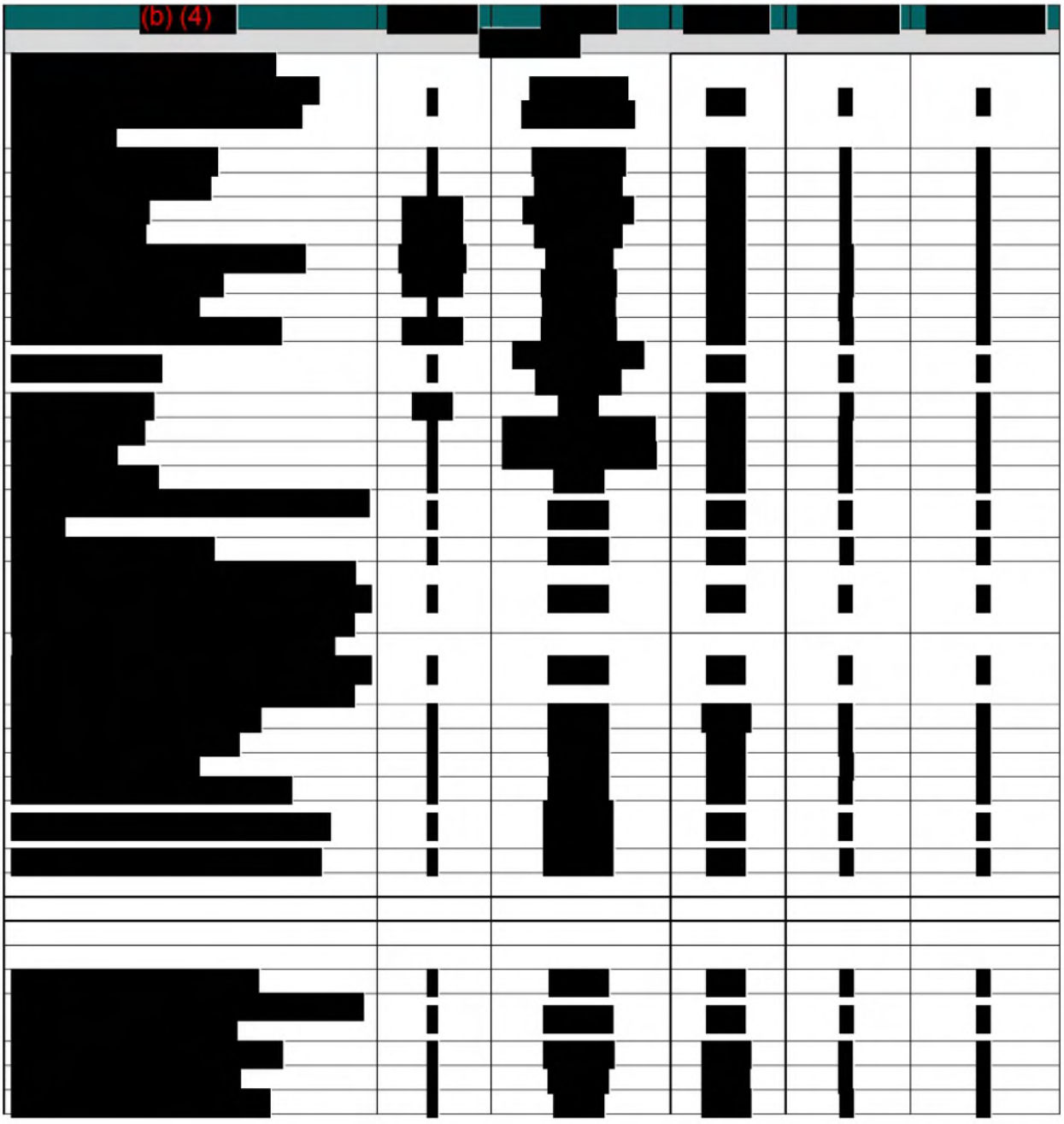
2.19.3 The Awardee shall perform the PK and ADA assays to support the Phase 1 trial. (b) (4) PK assays and (b) (4) ADA for [redacted] subjects in Phase 1 Part A, and (b) (4) PK and (b) (4) ADA for [redacted] subjects in Phase 1 Part B.

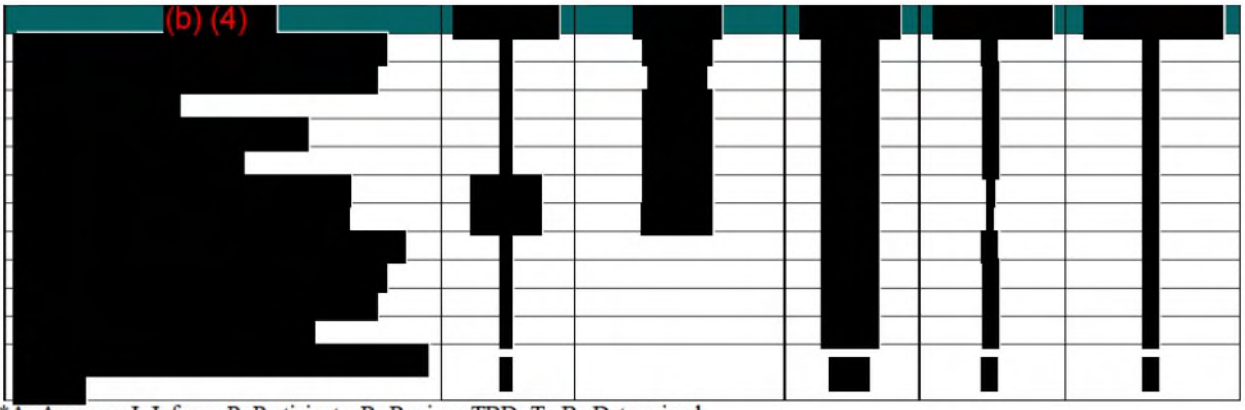
2.19.4 The Awardee shall perform [redacted] microneutralization assays per [redacted] subjects in the Phase 1 clinical trial (b) (4).

3.0 DELIVERABLES

3.1 Data Deliverables

NOTE: Schedule will be updated once scope is reviewed and finalized for Mod 2.

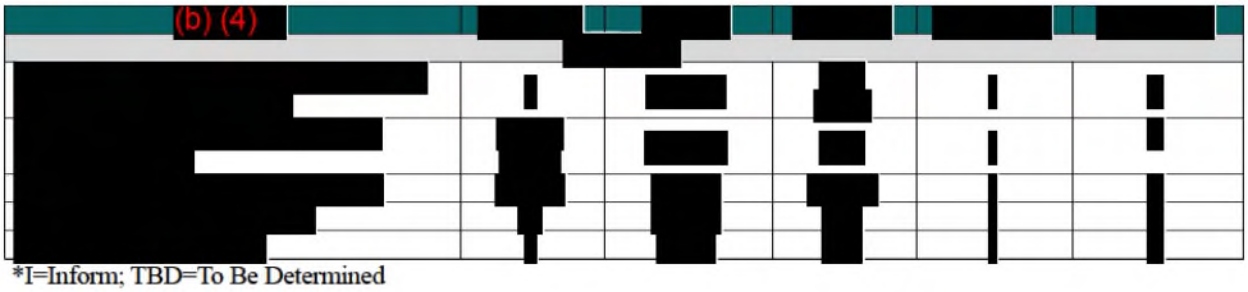




*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined

**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

3.2 Supply Deliverables



*I=Inform; TBD=To Be Determined

3.3 Acceptance of Deliverables

The USG will provide review of all data deliverables within 30 days of delivery. The USG will acknowledge receipt of all supply deliverables within 60 days of delivery.

4.0 DATA RIGHTS

(b) (4)

(b) (4)

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

The following are Ology Bio's Background Intellectual Property (IP) and Materials, as defined in Article 9, Section A of the 2373 Agreement. (b) (4)

Ology Bio's Background IP and Materials shall remain the property of Ology Bio. No license(s) to Ology Bio's Background IP and Materials shall be granted under this SOW or

Agreement. The Background IP listed above is specifically excluded from the definition of "Agreement Invention" contained in Article 9 Section B of the 2373 Agreement.

(b) (4) [redacted]

For purposes of this effort the material to be transferred and the associated IP will be labeled as "Government Furnished Information." The AOR will manage the transfer from USG performer to Ology Bio.

6.0 AOR AND ALTERNATE AOR CONTACT INFORMATION

AOR	Alternate AOR
[Name]	[Name]

7.0 AWARDEE KEY PERSONNEL

(b) (6) [redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

STATEMENT OF WORK

Title: Rapid COVID-19 Plasmid Manufacturing for Clinical Programs

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated *21 February 2020* shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The purpose of this project is to manufacture vials of CGMP plasmid DNA DP suitable for use in a clinical trial (the supply), to support Department of Defense requirements for an FDA-approved COVID-19 vaccine (the best supplies). (b) (4)

(b) (4)

2.0 REQUIREMENTS

2.1 Task 1: Project Initiation and Oversight

Notes:

- Labor for project oversight (Project Manager [PM], Principal Investigator [PI], contracts and finance) spans the lifecycle of the project.
- Data requirements span the lifecycle of the project through delivery of doses.
- If a due date for a deliverable is on a weekend or holiday, then the deliverable will be due on the next business day.

2.1.1 Planning

2.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) following the effective date of contract award, provide an agenda at least three business days prior to the meeting, and provide a meeting report (b) (4) . The kickoff meeting will be held virtually.

2.1.1.2 The Awardee shall provide an Integrated Master Schedule (IMS) within (b) (4) . The Awardee shall provide an updated IMS

calendar days after the end of each month identifying task progress, percent completion and schedule slippage.

2.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project Charter, Communication Plan, IMS, Work Breakdown Structure (WBS), Cost Management/Spend Plan and List of Deliverables.

2.1.2 Execution

2.1.2.1 Meetings

2.1.2.1.1 The Awardee shall conduct IPT meetings (b) (4) [redacted] The Awardee shall provide the agendas and IPT slide decks within 24 hours in advance of the IPT. Finalized meeting minutes shall be submitted to the USG within five business days following each teleconference.

2.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or USG request, to discuss issues as they arise. Minutes from these meetings shall be provided to the USG within five business days following the meeting.

2.1.2.2 Reports

2.1.2.2.1 The Awardee shall deliver a Monthly IMS and spend plan for the life cycle of the project. The Awardee shall submit each Monthly IMS and spend plan within 20 calendar days after the end of each month of performance. The USG will have 10 calendar days to respond to the report with any comments, and the Awardee will have an additional five calendar days to revise the deliverable or respond to those comments.

2.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities. Delivery dates for Quarterly and Annual Progress reports will be based on award date and not the calendar year.

2.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 20 calendar days after the end of each quarter of performance. The USG will have 30 calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

2.1.2.2.4 The Awardee shall perform, record and report physical inventory results of all Contractor Acquired Property in the contractor's possession, if the Awardee purchases material or equipment using USG funds, as approved by the Agreement Officer's Representative (AOR) during performance of the project.

2.1.2.2.5 Incident Reporting

2.1.2.2.5.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the

USG in an incident report. In addition, the Awardee shall provide advance notice of critical path schedule changes resulting in more than a 15 calendar-day shift that are not handled as Incident Reports. The Ology Bio PM shall provide written notification (via email) to the AOR.

2.1.2.2.5.2 The Awardee shall telephonically contact the program manager for the USG no later than 24 hours after the incident is identified.

2.1.2.2.5.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place. If additional time is required for the Root Cause Analysis, the Ology Bio PM will work with the AOR to agree on timing of the written summary report.

2.1.2.2.6 The Project Agreement Holder (PAH) shall establish a Quality Agreement with the USG. The PAH shall provide the draft Quality Agreement within ten calendar days of project award. The draft Quality Agreement will be submitted via e-mail to the USG technical representatives. The USG shall respond with comments or acceptance ten calendar days following receipt of the draft Quality Agreement. The final agreement with incorporated changes shall be submitted five calendar days after receipt of USG comments. The USG will provide written acceptance.

2.1.2.2.7 The PAH shall also develop a Quality Agreement with Inovio that defines the roles and responsibilities of both parties. The Quality Agreement with Inovio will be provided to the USG for informational purposes rather than review and approval.

2.1.2.2.8 The Awardee shall support USG quality audits of the Awardee's systems and procedures, insofar as they relate to the service and control of the USG's product. These audits may be performed at times mutually agreed upon by the Awardee and the USG. The Awardee shall provide the USG with monthly follow-ups on the status of audit observation commitments found in the USG annual audit or regulatory inspection, as they apply to the USG's product.

2.1.3 Regulatory/CMC Support

2.1.3.1 The Awardee shall provide support to the product sponsor to enabling updating of their CMC sections with manufacturing data and technical information.

2.1.4 Equipment Maintenance and Service

2.1.4.1 The Awardee shall maintain and service equipment purchased under Contract W911QY2090003, (b) (4) [redacted]

2.2 Task 2: Technology Transfer

Note:

- Process Establishment Runs will be performed with COVID-19 plasmid and upstream parameters and the existing Ology Bio cell lysis and purification methods to enable comparison of material generated by Ology Bio methods to existing product data.

2.2.1 (b) (4) Information Transfer, Gap Analysis and Risk Assessment

2.2.1.1 The awardee will perform technology transfer (b) (4) In accordance with a Consulting Agreement and Quality Agreement that will be finalized and signed after execution of this agreement, the awardee will manage the following support (b) (4) :

2.2.1.1.1 Review of all required documentation including analytical assay protocols and specifications, development records, batch records, list of equipment and any other documentation to support this project

2.2.1.1.2 Receipt of the necessary cell lines to support the (b) (4) transfer and WCB development

2.2.1.1.3 (b) (4) Person in plant to support the technology transfer of the upstream and downstream processing for manufacture of their (b) (4) vaccine candidate

2.2.1.1.4 Support for development of the equipment required (b) (4)

2.2.1.1.5 Test plan for analytical comparability and assistance in demonstration comparability

2.2.1.1.6 Under the terms of Quality Agreement (b) (4) : 1) upon confirmation of comparability, (b) (4) will add Ology Bio as a manufacturer in their IND; 2) (b) (4) shall provide all correspondence to and from the FDA related to the addition of Ology's manufacturing facility. Awardee shall provide all FDA correspondence to the USG (b) (4) and 3) (b) (4) shall provide a Letter of Authorization to their Master File as needed by the USG.

2.2.1.2 The Awardee shall complete an initial Risk Assessment and Mitigation Strategy including all tasks and supply chain management.

2.2.1.3 The Awardee shall conduct a Gap Analysis of the transferred information to identify any potential gaps or weaknesses associated with any of the tasks.

2.2.2 Review of (b) (4) Documentation

2.2.2.1 The Awardee shall review all project-related documents provided (b) (4) .

2.2.2.2 The Awardee shall draft a Development Plan, including relevant information from the documents provided (b) (4) , that will outline the relevant scope of work and revise it based on the client's feedback.

2.2.3 Transfer of Product-Specific Materials from (b) (4) Procurement of Materials and Components

2.2.3.1 The Awardee shall develop a preliminary BOM using approved suppliers.

2.2.3.2 Upon completion of risk assessments and required permits, the Awardee shall

coordinate (b) (4) for the shipment of materials to the DoD ADM Facility. The Awardee shall receive the (b) (4) provided materials and store them using inventory management practices in order to maximize performance integrity and shelf life.

2.2.3.3 The Awardee shall provide traceability of both consumable and non-consumable (b) (4) provided materials from procurement until the end of the material's life.

2.2.3.4 The Awardee shall order and receive any other biologics and process materials and components to complete the project.

2.2.4 Process Establishment Runs

2.2.4.1 The Awardee shall provide a Process Establishment Plan for (b) (4) Process Establishment Runs using the COVID-19 plasmid (b) (4)

2.2.4.2 (b) (4)

2.2.4.4 The Awardee shall provide a Process Establishment Report.

2.3 Task 3: Working Cell Bank Manufacturing

2.3.1 The Awardee shall provide (b) (4) vials of WCB based on COVID-19 MCB vials and process documentation received (b) (4).

2.3.2 The Awardee shall perform release testing and characterization of the WCB.

2.3.3 The Awardee shall provide a Working Cell Banking Report, including the WCB production batch record and a Certificate of Analysis (COA).

2.4 Task 4: Analytical Assay Development

Notes:

- Product-specific methods for in-process testing have been developed.
- Compendial methods are already in place and will only require verification.
- Ology Bio QC has current experience with the methods in **Table 1** and
- **Table** 2. Ology Bio assumes these are the methods that will be required for in-process and release testing.

2.4.1 The Awardee shall receive analytical SOPs and development reports (b) (4). Product-specific QC assay information will be transferred to the Awardee (b) (4) in accordance with Ology Bio's Consulting Agreement (b) (4).

2.4.2 The Awardee shall update specifications and a final testing list upon receipt of (b) (4) analytical technology transfer package. Testing specification will allow for a direct comparison of previously produced plasmid material and reference standard.

2.4.3 The Awardee shall provide an Assay Qualification Plan. The Awardee will qualify the analytical methods in accordance with USP, FDA and Ph. Eur. requirements and guidance appropriate for use in clinical studies.

2.4.4 The Awardee shall perform Technology Transfer Feasibility assessments on (b) (4)

provided methods for product testing. In accordance with the Ology Bio (b) (4) Consulting Agreement, (b) (4)

2.4.5 The Awardee will establish in-process and release testing methods for the plasmid DNA DS and DP to meet specifications mutually approved by (b) (4) Ology Bio.

2.4.6 The Awardee shall assess the suitability of compendial methods.

2.4.7 The Awardee shall draft non-compendial test methods and execute non-compendial method qualification. If sufficient materials from (b) (4)

2.4.8 The Awardee shall provide an Assay Qualification Report, to describe:

2.4.8.1 Compendial method suitability or waiver

2.4.8.2 Non-compendial method transfer

Table 1. In-Process Assays

(b) (4)	

Table 2. Plasmid DNA Analytical Assays

(b) (4)	

2.5 Task 5: Engineering DS Runs (b) (4)

2.5.1 The Awardee shall prepare draft Master Batch Records (MBRs); raw material, product and label specifications; and draft BOM and MBR setup.

2.5.2 The Awardee shall proceed directly from the Process Establishment Runs to an Engineering DS Run (b) (4) , which the Awardee shall execute using draft MBRs.

2.5.3 The Awardee shall conduct the run in the CGMP manufacturing area of the DoD ADM

Facility.

2.5.4 The Awardee shall use resins and filters dedicated for this project. The Awardee shall use the same columns/resins for both the Engineering and CGMP Runs.

2.5.5 The Awardee shall conduct in-process and release testing on Engineering DS based on the analytical tests from Task 4 and (b) (4) provided specifications for purity and impurity levels.

2.5.6 The Awardee shall provide:

- **2.5.6.1** Engineering Run Report
- **2.5.6.2** Finalized CGMP Batch Record templates
- **2.5.6.3** Finalized CGMP specifications
- **2.5.6.4** Final BOM
- **2.5.6.5** Engineering non-CGMP DS CoT
- **2.5.6.6** Engineering non-CGMP DS MSDS

2.6 Task 6: CGMP DS Runs – (b) (4)

2.6.1 The Awardee shall update the Technology Transfer Protocol (TTP) and MBRs as needed.

2.6.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.6.3 The Awardee shall execute (b) (4) runs for the CGMP DS using MBRs, with the number of runs based on the discretion of the USG and suggestions from Ology Bio.

- **2.6.3.1** The Awardee shall conduct the CGMP Run using the Ology Bio-manufactured WCB.
- **2.6.3.2** The Awardee shall conduct the in-process and release testing outlined in **Table 1** and
- **2.6.3.3** **Table** 2.
- **2.6.3.4** The Awardee shall store the DS frozen pending DP fill/finish. All DS lots will be at the disposition of the USG and storage will be at the ADM Facility.
- **2.6.3.5** The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.
- **2.6.3.6** The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.6.4 To investigate the issues encountered in the (b) (4) CGMP runs, the Awardee will perform (b) (4) and (b) (4) Upstream Runs. These runs will reduce the risk to the subsequent (b) (4) CGMP Runs.

2.6.5 The Awardee shall provide manufacturing and testing information (e.g., raw data or summary reports as required) related to Ology Bio-produced DS (b) (4) for incorporation into their submission to their IND or Master File to support clinical development.

2.6.6 The Awardee shall provide the following for each CGMP DS Lot:

- **2.6.6.1** QA-Approved DS Executed Batch Production Records
- **2.6.6.2** QA-Approved DS COA
- **2.6.6.3** QA-Approved DS MSDS
- **2.6.6.4** CGMP DS Campaign Summary Report

2.7 Task 7: CGMP DP Runs

2.7.1 The Awardee shall determine the final dose and vial configuration in conjunction with the USG (b) (4) .

2.7.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.7.3 The Awardee shall perform (b) (4) media fill qualification runs using the selected vial configuration and volume.

2.7.4 The Awardee shall provide a Media Fill Qualification Report.

2.7.5 The Awardee shall perform liquid fill operations using the CGMP DS from Task 6.

2.7.6 The Awardee shall fill (b) (4) multi-dose vials of CGMP DP suitable for use in a Phase 2 clinical trials or EUA (see Task 16) using DS from the (b) (4) CGMP (b) (4) runs. The concentration TBD in collaboration with the client. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.7.7 The Awardee will explore and present possibilities for pooling and filling and use the plan acceptable to the client and sponsor. The materials from this DP Lot will be suitable for Phase 2 clinical trials or EUA (see Task 16) at a concentration TBD in collaboration with the USG.

2.7.8 The material from the remaining (b) (4) CGMP (b) (4) runs may be pooled and filled as a single lot, based on final discussions with the USG. Upon agreement with the USG, this DP lot may be formulated and filled at an outside vendor agreed upon with the USG. (b) (4) The Awardee shall conduct sampling and lot release testing per sponsor-provided specifications from this lot.

2.7.9 All DP lots will be at the disposition of the USG, and storage pending shipment will be at the ADM Facility.

2.7.10 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.7.11 The Awardee shall provide manufacturing and testing information related to Ology Bio-produced DP to (b) (4)

2.7.12 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, executed CGMP batch records, and COA and MSDS for CGMP DP.

2.8 Task 8: (b) (4) and Transfer of (b) (4)

2.8.1 The Awardee shall coordinate (b) (4) for (b) (4)

2.8.2 The Awardee shall procure, install and qualify the cell lysis equipment with support (b) (4) .

2.8.3 The Awardee shall procure, install, and qualify (b) (4) system (b) (4) along with any other necessary components, systems, documentation, or services.

2.8.3.1 (b) (4)

2.8.3.2 The Awardee shall purchase (b) (4) system.
2.8.3.3 The Awardee shall install (b) (4) at the DoD ADM facility and perform SAT.
2.8.3.4 The Awardee shall perform IQ of the (b) (4) system.
2.8.3.5 The Awardee shall perform OQ of the (b) (4) system.
2.8.3.6 The Awardee shall prepare a Qualification Report for the (b) (4) system.

2.8.4 **The Awardee shall procure a stockpile of single-use flow paths to ensure on-going use is possible following qualification.** The Awardee shall scale-up their existing lysis step in preparation of the larger scales.

2.8.5 The Awardee shall provide a Process Scale-up Plan.

2.8.6 The Awardee shall prepare Process Scale-up PDPRs.

2.8.7 The Awardee shall conduct (b) (4) Scale-up Runs at (b) (4) scale, (b) (4)

2.8.8 The Awardee shall QC test the materials from these runs based on the analytical assays in **Table 1** and

2.8.9 **Table 2**.

2.8.10 The Awardee shall prepare draft batch records for use in the Engineering Run(s).

2.8.11 The Awardee shall provide a Sampling Plan.

2.8.12 The Awardee shall provide a TTP.

2.8.13 The Awardee shall provide a Process Scale-Up Report.

2.9 Task 9: Engineering DS Run (b) (4)

2.9.1 The Awardee shall prepare a TTP; draft MBRs; raw material, product and label specifications; and draft BOM and MBR setup.

2.9.2 The Awardee shall execute (b) (4) Engineering DS lot using draft MBRs.

2.9.3 The Awardee shall use the scaled-up process from Task 8 and the Ology Bio-manufactured WCB.

2.9.4 The Awardee shall use resins and filters dedicated for this project. The Awardee shall use the same columns/resins for both the Engineering and CGMP Runs.

2.9.5 The Awardee shall conduct the runs in the CGMP manufacturing area of the DoD ADM Facility.

2.9.6 The Awardee shall test the Engineering DS based on the analytical tests from Task 4 and (b) (4) provided specifications for purity and impurity levels.

2.9.7 The Awardee shall provide:

2.9.7.1 Engineering Run Report
2.9.7.2 Finalized CGMP Batch Record templates
2.9.7.3 Finalized CGMP specifications
2.9.7.4 Final BOM
2.9.7.5 Engineering non-CGMP DS CoT
2.9.7.6 Engineering non-CGMP DS MSDS

2.10 Task 10: CGMP DS Run (b) (4)

2.10.1 The Awardee shall update the TTP and MBRs as needed.

2.10.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.10.3 The Awardee shall execute (b) (4) run for the CGMP DS using MBRs and Ology Bio-manufactured WCB.

2.10.3.1 The Awardee shall conduct the in-process and release testing outlined in **Table 1** and

2.10.3.2 **Table** 2.

2.10.3.3 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.10.3.4 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.10.4 The Awardee shall provide:

2.10.4.1 QA-Approved Executed DS Batch Production Records

2.10.4.2 QA-Approved DS COA

2.10.4.3 QA-Approved DS MSDS

2.10.4.4 Materials from these runs

2.11 Task 11: CGMP DP Fill/Finish (Large-scale)

2.11.1 The Awardee shall determine the final dose and vial configuration in conjunction with the USG (b) (4)

2.11.2 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.11.3 The Awardee shall perform liquid fill operations using the CGMP DS from Task 10. The Awardee shall qualify and monitor a large-scale fill finish subcontractor capable of performing CGMP Phase 3 activities listed within this task. Successful qualification of (b) (4) will require onsite audit and monitoring to allow for Awardee Person-in-Plant during scope of work performed at subcontractor.

2.11.4 The Awardee shall fill (b) (4) multi-dose vials of CGMP DP suitable for use in a Phase 3 clinical trial or EUA (see Task 16) at a concentration TBD in collaboration with the client. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.11.5 The Awardee shall conduct sampling and lot release testing.

2.11.6 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.11.7 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.11.8 The Awardee shall provide CGMP DP to client or client designated recipient.

2.12 Task 12: CGMP DS Runs (b) (4)

2.12.1 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.12.2 (b) (4)

2.12.2.1 The Awardee shall conduct the in-process and release testing outlined in **Table 1** and

2.12.2.2 **Table** 2.

2.12.2.3 The Awardee shall provide the final QA review of the PBR and QC data and release of the CGMP DS with a COA and MSDS, ensuring that it meets all technical specifications and is acceptable for subsequent CGMP formulation and fill.

2.12.2.4 The Awardee shall write a CGMP DS Campaign Summary Report including Batch Production Documents, Process Flow Diagrams, final BOM, COA and MSDS.

2.12.3 The Awardee shall provide:

2.12.3.1 QA-Approved Executed DS Batch Production Records

2.12.3.2 QA-Approved DS COA

2.12.3.3 QA-Approved DS MSDS

2.12.3.4 Materials from these studies to be used for DP fill/finish (Task 13)

2.13 Task 13: CGMP DP Fill/Finish (Additional large-scale runs)

2.13.1 The Awardee shall perform all CGMP manufacturing campaigns in accordance with CGMP per U.S. Code of Federal Regulations and all applicable regulatory guidance.

2.13.2 (b) (4) [redacted]

2.13.3 The Awardee's (b) (4) shall fill (b) (4) doses filled into multi-dose vials of CGMP DP suitable for use in a Phase 3 clinical trial or EUA (see Task 16) at a concentration TBD in collaboration with the client and sponsor. This includes formulation, fill, inspection, labeling, packaging and QA review.

2.13.4 The Awardee shall conduct sampling and lot release testing.

2.13.5 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot.

2.13.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for CGMP DP.

2.13.7 The Awardee shall provide CGMP DP to the USG or USG designated recipient

2.14 Task 14: Stability Testing of DS and DP (b) (4)

2.14.1 Engineering DS

2.14.1.1 The Awardee shall provide a Stability Protocol for the Engineering DS, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.14.1.2 The Awardee shall execute the stability study using the Engineering Run DS.

2.14.1.3 The Awardee shall provide a Stability Report.

2.14.2 CGMP DS

2.14.2.1 The Awardee shall provide a Stability Protocol for the CGMP DS from Task 6, including (b) (4) real-time stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG

prior to the start of stability.

2.14.2.2 The Awardee shall execute the stability study using the CGMP DS.

2.14.2.3 The Awardee shall provide a Stability Report.

2.14.3 CGMP DP

2.14.3.1 The Awardee shall provide a Stability Protocol for the CGMP DP from Task 7, including (b) (4) [redacted]

2.14.3.2 The Awardee shall execute the stability study using the CGMP DP.

2.14.3.3 The Awardee shall provide Stability Reports.

2.15 Task 15: Stability Testing of DS and DP (b) (4) [redacted]

2.15.1 CGMP DS

2.15.1.1 The Awardee shall provide a Stability Protocol for the CGMP DS, including (b) (4) stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.15.1.2 The Awardee shall execute the stability study using the CGMP DS.

2.15.1.3 The Awardee shall provide a Stability Report.

2.15.2 CGMP DP

2.15.2.1 The Awardee shall provide a Stability Protocol for the CGMP DP, to be determined in collaboration with the Client, including (b) (4) [redacted] stability studies and accelerated and stressed temperature stability studies, to be determined in collaboration with the USG prior to the start of stability.

2.15.2.2 The Awardee shall execute the stability study using the CGMP DP.

2.15.2.3 The Awardee shall provide Stability Reports.

2.16 Task 16: Emergency Use Authorization Preparation

2.16.1 Preparation

2.16.1.1 The Awardee shall evaluate current procedures and processes to align with requirements for CGMP Phase 3 in preparation for anticipated EUA or Expanded Access prior to product approval.

2.16.1.2 The Awardee shall revise necessary procedures from identified gaps to ensure compliance with applicable regulations.

2.16.1.3 The Awardee shall provide all necessary information and data to the IND holder.

2.16.2 Execution

2.16.2.1 The Awardee shall conduct an in-depth audit for this scope of work to represent an FDA inspection consistent with CGMP Phase 3 for EUA. This may be conducted by Awardee, qualified subcontractor(s) or a combination thereof as identified in coordination with the USG. USG shall have the option of sending a representative to participate in or observe the audit.

2.16.2.2 The Awardee shall develop and provide a comprehensive audit report detailing the audit activities and findings for the areas inspected.

2.16.2.3 The Awardee shall host and manage any applicable necessary regulatory

inspection (e.g. FDA EUA) to support the requirements within this Scope of Work.

2.16.3 Closure

2.16.3.1 The Awardee shall evaluate the audit report(s) resulting from inspection(s) associated with this task.

2.16.3.2 The Awardee shall provide a comprehensive audit response with CAPA plan to all observations within the audit report(s).

2.16.3.3 The Awardee may require additional labor to execute requirements for regulatory activities resulting from an inspection needed to demonstrate correction or compliance.

3.0 DELIVERABLES

3.1 Data Deliverables

Deliverable	Frequency	Schedule	SOW Ref.	Gov't Role*	Data Rights**
QA-Approved (b) (4) [redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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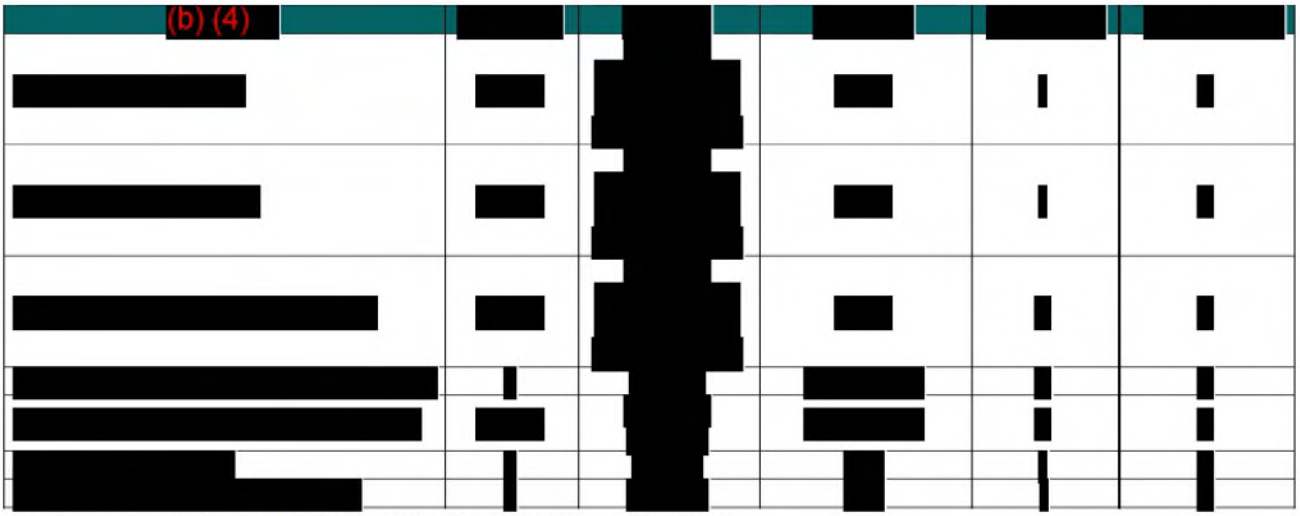
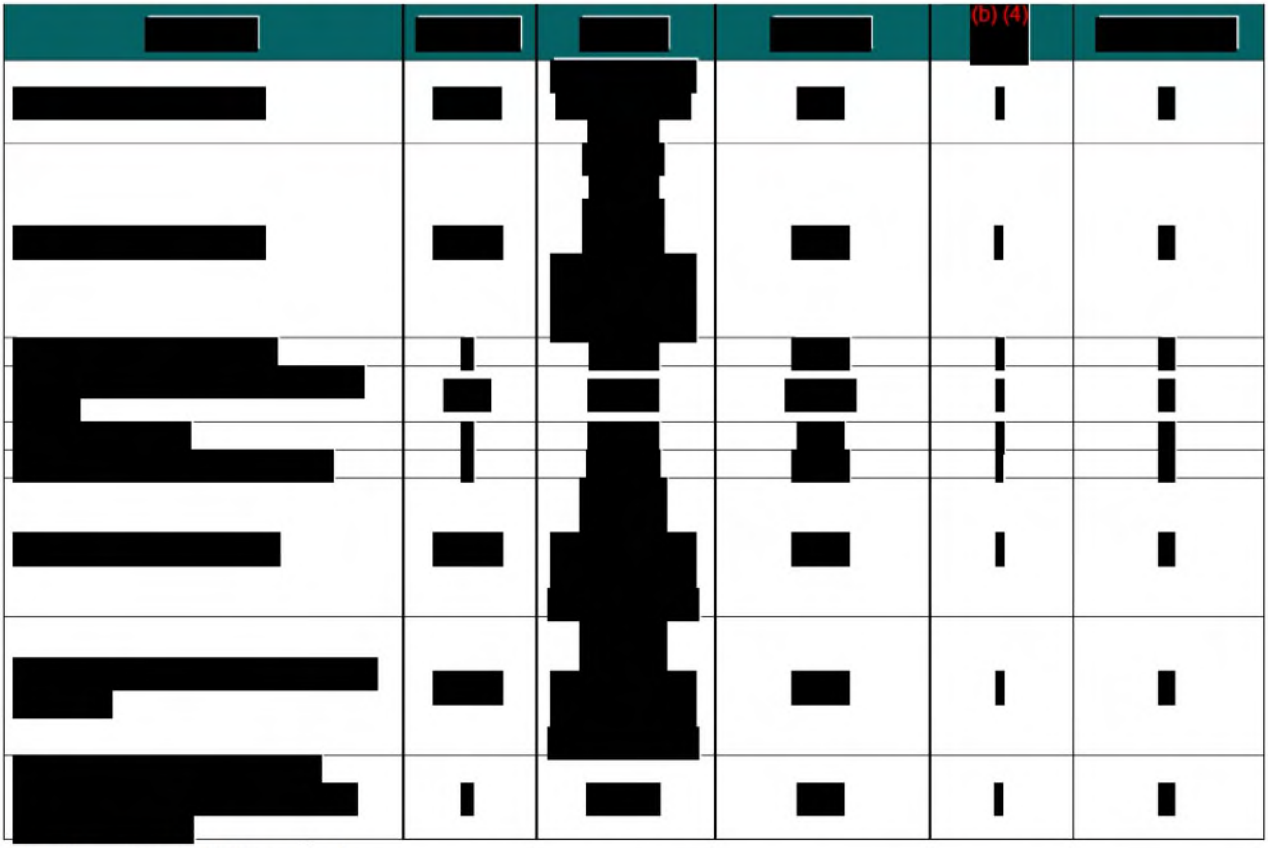


*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined
**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.
*** Subject to IP disclosures. Any changes resulting will be incorporated in a separate modification.

3.2 Supply Deliverables



*I=Inform; TBD=To Be Determined
**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

3.3 Acceptance of Deliverables

The USG will provide review of all data deliverables within (b) (4) The USG will acknowledge receipt of all supply deliverables within (b) (4).

4.0 DATA RIGHTS

The Government shall have no rights in the data associated with Ology Bio's Background Intellectual Property (IP) and Materials (b) (4) described in Section 5, subject to IP disclosures. Any changes resulting will be incorporated in a separate modification.

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

Ology Bio is not specifying any Background IP and Materials for this 2373 Agreement.

(b) (4)

6.0 AOR AND ALTERNATE AOR CONTACT INFORMATION

AOR:	Alternate AOR:
TBD	TBD

[End of SOW]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 2

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00015	10-Jul-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this Amendment is to incorporate Appendix A-2 Rev 3, incorporate Appendix A-4 Rev 2, and increase the value of Project 20-04 under CLIN 0004. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. CONTRACTING OFFICER (Type or print)
(b) (6)	(b) (6) TEL: (b) (6) EMAIL:

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (b) (6) (Signature of person authorized to sign)	July 9, 2020	BY (b) (6) (Signature of Contracting Officer)	09 Jul 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00015

A. The purpose of this Amendment is as follows:
   a. Appendix A-2 Rev 3 is hereby incorporated into the Agreement. This revision corrects the task numbering and revision supersedes the previoulsy incorporated Appendix A-2 Rev 2 in full.
   b. (b) (4)
   c. (b) (4)
B. The total value of this Agreement is increased by (b) (4) from (b) (4) to (b) (4)
C. The parties hereby agree that changes affected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this Agreement resulting from incorporation of Appendix A-2 Rev 3 (b) (4)
D. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $(b) (4) from $(b) (4) to (b) (4).

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0004

The estimated/max cost has increased by (b) (4) from (b) (4) to (b) (4)
The fixed fee has increased by (b) (4) from (b) (4) to $841,457.00.
The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4)

(End of Summary of Changes)

STATEMENT OF WORK

Title: Procurement, Commissioning and Qualification of CGMP Equipment at the DoD ADM Facility

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated *21 February 2020* shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The purpose of this SOW is to procure, commission, and quality a suite of CGMP compliant equipment (the supplies) to support CGMP (b) (4) mAb production and (b) (4) pDNA production scales at the DoD ADM facility. This suite of equipment will be utilized in support of developmental work at the ADM facility to include production of MCMs under CGMPs leading to the development of FDA approved medical countermeasures (the best supplies). Current equipment does not provide sufficient volume for the full-scale production runs necessary on advanced development projects.

The following tasks are required to complete this effort:

Task 1: Purchase, Installation and Qualification of Equipment to Support (b) (4) mAb Production

Task 2: Purchase, Installation and Qualification of Equipment to Support (b) (4) to Support pDNA Manufacturing

Task 3: Purchase, Installation and Qualification of QC and Support Equipment

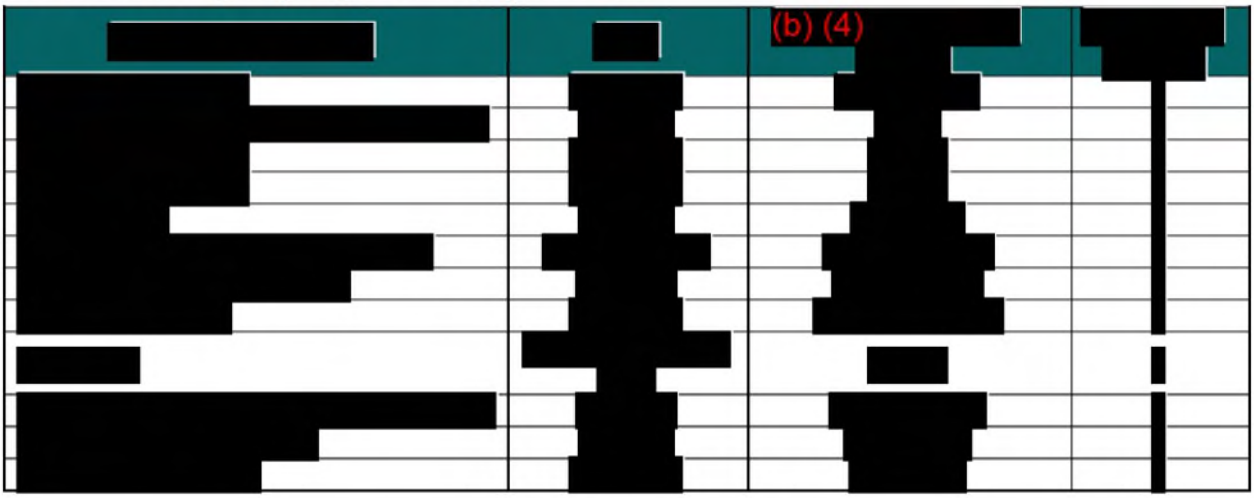
2.0 REQUIREMENTS

2.1 Task 1: Purchase, Installation and IQ/OQ of Equipment to Support (b) (4) mAb Production

Notes:

- Equipment that appears in both Task 1 and Task 2 will be ordered on the same purchase order and qualified at the same time to avoid duplication of effort.

***Table 1**. mAb Capacity Expansion Equipment List*



[redacted]	[redacted]	(b) (4) [redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]

[1] Item does not require qualification

2.1.1 The Awardee shall conduct an engineering review, including generating a (b) (4) [redacted].

2.1.2 The Awardee shall purchase the equipment listed in **Table 1** to support manufacturing of mAbs at a scale (b) (4) [redacted] available as a backup to ensure maximum production capacity

2.1.3 The Awardee shall perform a FAT prior to shipment (b) (4) [redacted]. No other equipment listed in **Table 1** requires a FAT. FAT (b) (4) [redacted] will be witnessed by Ology Bio Engineers/Responsible System Owner (RSO) remotely.

2.1.4 The Awardee shall install equipment at the DoD ADM Facility.

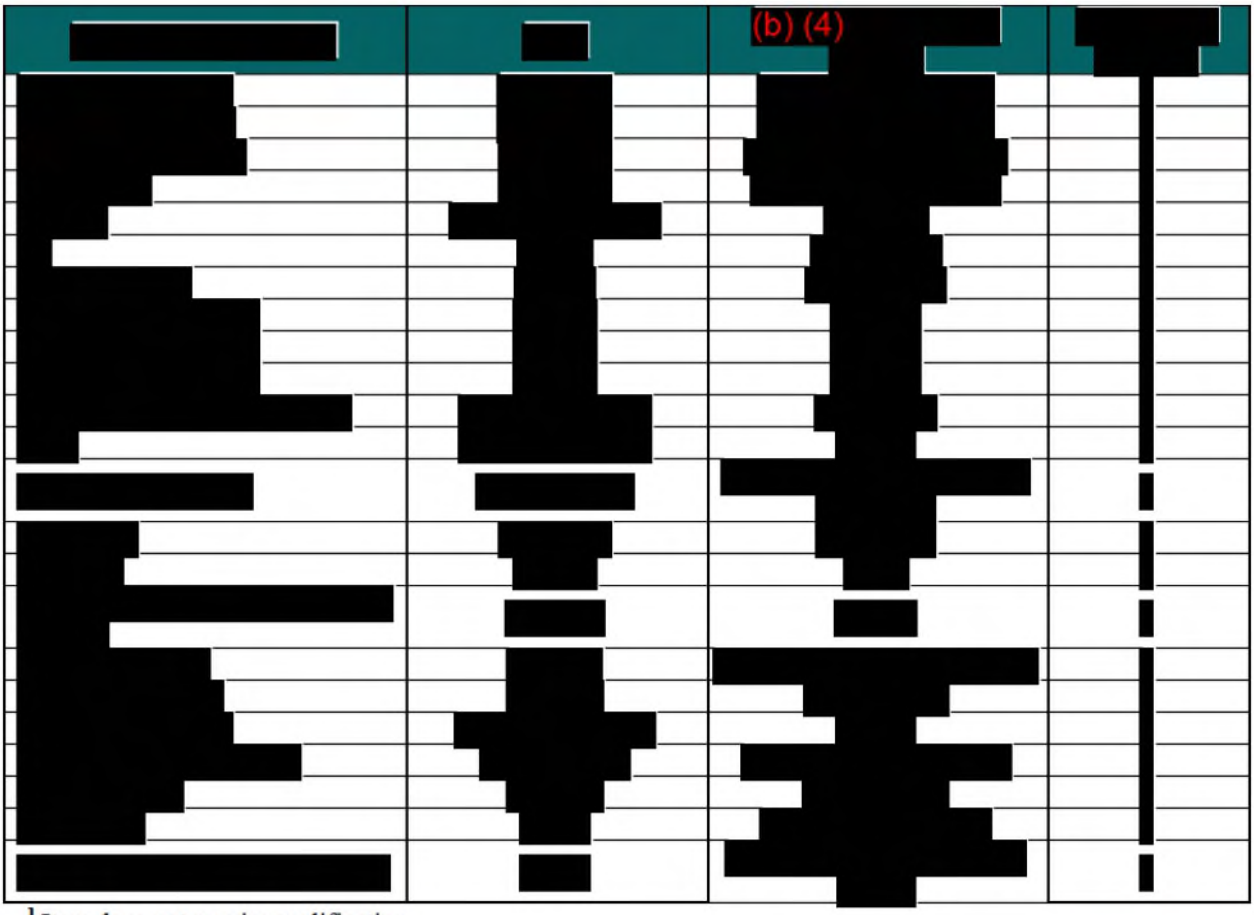
2.1.5 The Awardee shall perform Commissioning Test Procedure (CTP) or IQ/OQ of the equipment based on the requirements identified in the SLIA.

2.1.6 The Awardee shall prepare a Qualification Report for each Direct Impact piece of equipment.

2.2 Task 2: Purchase, Installation and IQ/OQ of Equipment to Support (b) (4) Fermentation Capacity to Support pDNA Manufacturing

***Table 2.** pDNA Equipment List*

[redacted]	[redacted]	(b) (4) [redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]



[1] Item does not require qualification

2.2.1 The Awardee shall conduct an engineering review, including generating a (b) (4)

2.2.2 The Awardee shall purchase the equipment listed in **Table 2** to support manufacturing of mAbs (b) (4) (b) (4) (b) (4) single-use f(b) (4) available (b) (4) to ensure maximum production capacity.

2.2.3 The Awardee shall perform a FAT prior to shipment of the (b) (4) (b) (4). No other equipment listed in **Table 2** requires a FAT. FAT of the (b) (4) f(b) (4) will witnessed by Ology Bio engineers/RSOs remotely.

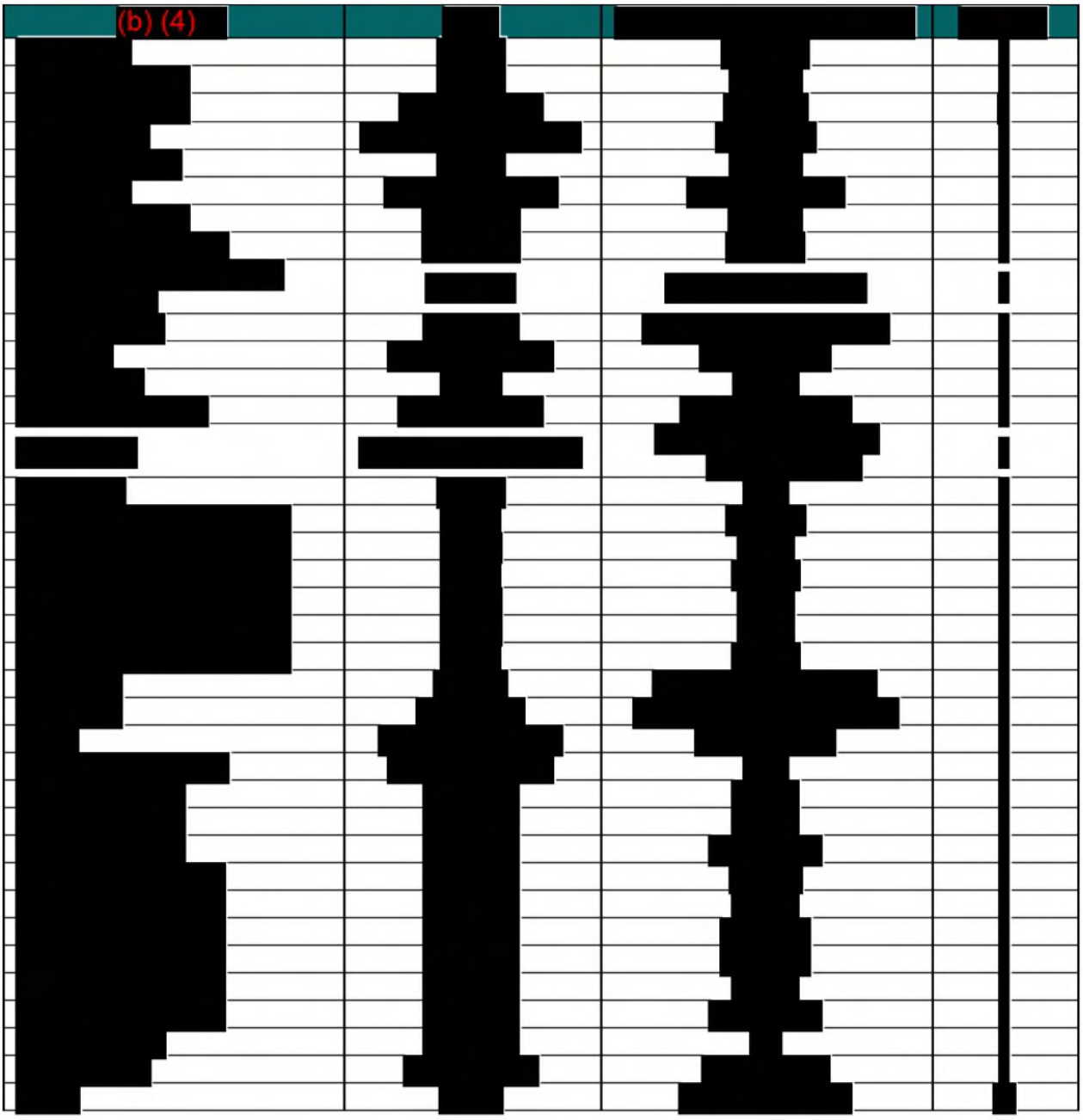
2.2.4 The Awardee shall install equipment at the DoD ADM Facility.

2.2.5 The Awardee shall perform CTP or IQ/OQ of the equipment based on the requirements identified in the SLIA.

2.2.6 The Awardee shall prepare a Qualification Report for each Direct Impact piece of equipment.

2.3 Task 3: Purchase, Installation and IQ/OQ of QC and SupportEquipment

Table 3. *QC and Support Equipment List*



2.3.1 The Awardee shall conduct an Engineering review, including generating a (b) (4) for each piece of equipment.

2.3.2 The Awardee shall purchase the equipment listed in **Table 3** in order to support QC testing activities resulting from continuous production at the specified scales and provide for baseline equipment such as cold storage units.

2.3.3 The Awardee shall install equipment at the DoD ADM Facility.

2.3.4 The Awardee shall perform (b) or IQ/OQ of the equipment based on the requirements identified in the (b).

2.3.5 The Awardee shall prepare a Qualification Report for each (b) (4) piece of equipment.

3.0 DELIVERABLES

3.1 Data Deliverables

(b) (4)					

**Category C=Data developed solely with USG funding allotted for this project.

3.2 Supply Deliverables

(b) (4)					

**Category C=Data developed solely with USG funding allotted for this project.

3.3 Acceptance of Deliverables

The U.S. Government (USG) will provide review of all data deliverables within 30 days of delivery. The USG will acknowledge receipt of all supply deliverables within 60 days of delivery.

[End of SOW]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 6

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00017	13-Oct-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: (b) (6)

The purpose of this amendment is to incorporate Appendix A-9 Rev 1, increase the value of Project 20-03 under CLIN 0003, increase the value of Project 20-09 under CLIN 0009, and incorporate incremental funding. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	(b) (6) TEL: (b) (6) EMAIL:

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B.	16C. DATE SIGNED
(b) (6)	October 7, 2020	(b) (6)	13 Oct 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00017

A. The purpose of this Amendment is as follows:
   a. Appendix A-9 Rev. 1 is hereby incorporated into the Agreement. This revision supersedes the previously incorporated Appendix A-9 in full.
   b. (b) (4) .
   c. The value of CLIN 0003 is hereby increased to reflect actual expenditures.
   d. The value of CLIN 0003 is hereby increased by (b) (4) from (b) (4) to (b) (4)
   e. (b) (4)
   g. SUBCLIN 000303 is hereby added to the Agreement to incorporate funding in the amount of (b) (4) under ACRN AM.
B. The total value of this Agreement is increased by (b) (4) from (b) (4) to (b) (4) .
C. Total funding for this agreement is increased by (b) (4) from (b) (4) to (b) (4)
D. The parties hereby agree that changes effected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this Agreement resulting from incorporation of Appendix A-9 Rev 1.
E. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003

The estimated/max cost has increased by (b) (4) from (b) (4) to (b) (4)

The total cost of this line item has increased by (b) (4) from (b) (4) to (b) (4)

(b) (4)

[redacted]

(b) (4)

[redacted]

SUBCLIN 000303 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000303					$0.00

Single Use Fermentors
FFP
Single Use Fermentors
PURCHASE REQUEST NUMBER: 0011505679-0002

NET AMT $0.00

ACRN AM (b) (4)
CIN: GFEBS001150567900003

SUBCLIN 000903 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000903					$0.00

SoloVPE Equipment
FFP
SoloVPE Equipment
PURCHASE REQUEST NUMBER: 0011505679-0002

NET AMT $0.00

ACRN AM (b) (6)
CIN: GFEBS001150567900002

SUBCLIN 000904 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000904					$0.00

Mixer Equipment
FFP
Mixer Equipment
PURCHASE REQUEST NUMBER: 0011505679-0002

NET AMT $0.00

ACRN AM (b) (4)
CIN: GFEBS001150567900004

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000303:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000903:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 000904:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 000303:
Funding on SUBCLIN 000303 is initiated as follows:

ACRN: AM

CIN: GFEBS001150567900003

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

SUBCLIN 000903:
Funding on SUBCLIN 000903 is initiated as follows:

ACRN: AM

CIN: GFEBS001150567900002

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

SUBCLIN 000904:
Funding on SUBCLIN 000904 is initiated as follows:

ACRN: AM

CIN: GFEBS001150567900004

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00023	21-Dec-2020	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 22-Feb-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to incorporate Appendix A-10, increase the agreement value, and incorporate incremental funding. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. (b) (6) TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	TEL: (b) (6) EMAIL:

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	21 Dec 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00023

A. The purpose of this Amendment is to incorporate Appendix A-10.
   a. The SOW for Project 21-01, Rapid Monoclonal Antibodies Manufacturing System using COVID mAbs, Appendix A-10, is hereby incorporated into the Agreement under CLIN 0010.
   b. New CPFF CLIN 0010 is hereby initiated with a value of (b) (4) .
   c. The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)
   d. SubCLIN 001001 is hereby added to the agreement ot incorporate incremental funding in the amount of (b) (4) under ACRN AP.
   e. Total funding for this agreement is increased by (b) (4) from (b) (4) to (b) (4)
B. The parties hereby agree that changes effected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this agreement resulting from incorporation of Appendix A-10.
C. All other terms and conditions remain the same and in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0010 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0010			Job		(b) (4)

PROJECT 21-01: Rapid mAb Manufacturing
CPFF
(b) (4), (b) (6)

[redacted]

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	(b) (4)

SUBCLIN 001001 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
001001					$0.00

MAB COVID-19 Optimization (b) (4)
FFP
MAB COVID-19 Optimization (b) (4)
PURCHASE REQUEST NUMBER: 0011588601

NET AMT	$0.00

ACRN AP (b) (4)
CIN: GFEBS001158860100010

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0010:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 001001:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY

N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0010 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-JAN-2022		JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)

SUBCLIN 001001:
Funding on SUBCLIN 001001 is initiated as follows:

ACRN: AP

CIN: GFEBS001158860100010

Acctng Data: 097202020210130000181705525202 52 S.0074658.1.1.17 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPDD

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
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2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00024	26-Jan-2021	SEE SCHEDULE	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
The purpose of this amendment is to provide notification to stop work on Project 20-04 and remove the DO rating from Projects 20-03, 20-04 and 20-05.. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6) Senior VP Government Contracts	(b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	January 25, 2020	BY (b) (6) (Signature of Contracting Officer)	25 Jan 2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00024

A. (b) (4)

B. The DO C-9 rating for Projects (b) (4) are hereby rescinded as follows:

a. (b) (4)

b.

C. All other terms and conditions remain the same and in full force and effect.

(End of Summary of Changes)

STATEMENT OF WORK

Title: Rapid Production of Monoclonal Antibodies as Medical Countermeasures Against COVID-19

NOTE: Unless otherwise stated in this SOW, the terms of the 2373 Agreement, dated 21 February 2020 shall govern performance of work under this SOW and are hereby incorporated by reference. This SOW shall be added as an Appendix to the 2373 Agreement.

1.0 SCOPE

The scope of this project includes the activities required to rapidly produce doses of monoclonal antibody (mAb) therapeutics against COVID-19 (the supply) suitable for use in future clinical trials to develop the best supplies, FDA-approved COVID-19 therapeutics, which are required by the Department of Defense (DoD). To facilitate manufacturing and release of the doses, the proposed effort includes technology transfer of the variable region sequences for (b) (4)(b) (4)

These will be down-selected to (b) (4)

(b) (4)

Background:

This SOW outlines the tasks required to produce (b) (4)

The "USG Performer" referenced throughout this SOW will be a contractor of the Defense Advanced Research Projects Agency (DARPA) Pandemic Prevention Program (P3). The Agreements Officer's Representative (AOR) will communicate with DARPA to coordinate the transfer of material and/or information from the USG Performer to the Awardee. All materials and information transferred to the Awardee shall be labelled as Government Furnished Property, subject to the conditions contained in Appendix C of the 2373 Agreement, and as such Awardee will have sufficient rights to use the materials and information in performance of the tasks required by this SOW.

20 REQUIREMENTS

21 Task 1: Project Initiation and Oversight

Notes:

- Labor for project oversight (Project Manager [PM], Principal Investigator [PI], contracts and finance) spans the lifecycle of the project.
- Data requirements span the lifecycle of the project through delivery of doses.

- The kick-off, (b) (4) meetings will be held virtually.
- If a due date for a deliverable is on a weekend or holiday, then the deliverable will be due on the next business day.
- Due date of Annual Reports will be based on award date and not the fiscal calendar year.

2.1.1 Planning

2.1.1.1 The Awardee shall host a project kick-off meeting (b) (4) following the (b) (4) award, provide an agenda (b) (4) prior to the meeting, and provide a meeting report (b) (4) .

2.1.1.2 The Awardee shall provide an Integrated Master Schedule (IMS) (b) (4) . The Awardee shall provide an updated IMS (b) (4) identifying task progress, percent completion and schedule slippage.

2.1.1.3 The Awardee shall provide a PMP that will contain, at a minimum, a Project Charter, Communication Plan, IMS, Work Breakdown Structure (WBS), Cost Management/Spend Plan and List of Deliverables.

2.1.2 Execution

2.1.2.1 Meetings

2.1.2.1.1 The Awardee shall conduct IPT meetings no less than twice per month. The Awardee shall provide the agendas and IPT slide decks within 24 hours in advance of the IPT. Finalized meeting minutes shall be submitted to the USG within five business days following each teleconference.

2.1.2.1.2 The Awardee shall conduct *ad hoc* meetings as necessary, upon team member or USG request, to discuss issues as they arise. Minutes from these meetings shall be provided to the USG within five business days following the meeting.

2.1.2.2 Reports

2.1.2.2.1 The Awardee shall deliver a Monthly IMS and spend plan for the life cycle of the project. The Awardee shall submit each Monthly IMS and spend plan within 20 calendar days after the end of each month of performance. The USG will have 10 calendar days to respond to the report with any comments, and the Awardee will have an additional five calendar days to revise the deliverable or respond to those comments.

2.1.2.2.2 The Awardee shall provide Quarterly and Annual Progress Reports. The reports shall provide a technical summary of progress over the associated time period, as well as a summary analysis of any risks, issues and/or opportunities.

2.1.2.2.3 The Awardee shall submit a Quarterly Financial Status Report no later than 20 calendar days after the end of each quarter of performance. The USG will have 30 calendar days to respond to the report with any comments, and the awardee will have an additional 10 calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three months for the duration of the period of performance.

2.1.2.2.4 The Awardee shall perform, record and report physical inventory results of all Contractor Acquired Property in the contractor's possession, if the Awardee purchases material or equipment using USG funds, as approved by the AOR during performance of the project.

2.1.2.2.5 Incident Reporting

2.1.2.2.5.1 The Awardee shall report any incident to the USG that could result in more than a one-month delay in schedule from the most recent IMS critical path delivered to the USG in an incident report. In addition, the Awardee shall provide advanced notice of critical path schedule changes resulting in more than a 15-day calendar shift that are not handled as Incident Reports. The Ology Bio PM will provide written notification (via email) to the AOR.

2.1.2.2.5.2 The Awardee shall telephonically contact the program manager for the USG no later than 24 hours after the incident is identified.

2.1.2.2.5.3 The Awardee shall submit a written summary report within three business days of an incident, to include what happened, the impact, the availability of any available corrective actions, and a timeline for any corrective actions to be in place. If additional time is required for the Root Cause Analysis, the Ology Bio PM will work with the AOR to agree on timing of the written summary report.

2.1.2.2.6 The Awardee shall provide the draft Quality Agreement within ten calendar days of project award. The draft Quality Agreement will be submitted via e-mail to the USG technical representatives. The USG shall respond with comments or acceptance ten calendar days following receipt of the draft Quality Agreement. The final agreement with incorporated changes shall be submitted five calendar days after receipt of USG comments. The USG will provide written acceptance.

2.1.2.2.7 The Awardee shall support USG quality audits of the Awardee's systems and procedures as outlined in the Quality Agreement, insofar as they relate to the service and control of the USG's product. These audits may be performed at times mutually agreed upon by the Awardee and the USG. The Awardee shall provide the USG with monthly follow-ups on the status of audit observation commitments found in the USG annual audit or regulatory inspection, as they apply to the USG's product.

2.2 Task 2: Technology Transfer and Plasmid Generation

Notes:

- The (b) (4) will be selected, will be provided by the USG Performer.

2.2.1 Task 2a: Information and Material Transfer

2.2.1.1 The Awardee shall coordinate with the USG Performer to obtain the (b) (4) (b) (4) There will initially be multiple sequences that will be provided by the USG provider. These will be analyzed (b) (4) for (b) (4) manufacturability analyses. Based on these analyses and the data (b) (4) (b) (4)

2.2.1.2 will be selected based o (b) (4)

2.2.2 Task 2b: Plasmid Generation

2.2.2.1 The Awardee shall (b) (4) (b) (4) These will include cloning of select antibody sequences with the (b) (4) (b) (4) .

2.2.2.2 (b) (4)

2.2.2.3 (b) (4)

2.2.2.4 (b) (4)

2.2.3 Task 2c: Gap and Risk Analyses

2.2.3.1 The Awardee shall complete and provide an initial Risk Assessment and Risk Mitigation program, including all tasks in the program.

2.2.3.2 The Awardee shall conduct and provide a Gap Analysis to identify any potential gaps or weaknesses associated with any of the tasks.

2.2.4 Task 2d: Animal Protocol Writing for ACURO

2.2.4.1 The Awardee shall write the (b) (4) that will be used for nonclinical studies in this project.

2.2.5 Task 2e: Computational Manufacturability Assessment

2.2.5.1 The Awardee shall perform a (b) (4) of

the [redacted]

2.2.5.1.1 [redacted] evaluation and rank order of [redacted]

2.2.5.1.2 Analysis of [redacted]

2.2.5.2 The Awardee shall provide a [redacted] Report.

2.3 Task 3: Pre-IND Consultation

Notes:

- Based on the urgent need for clinical evaluation of the product, the Pre-IND meeting will include an aggressive filing of the draft report (not in SEND format) if acceptable.
- Ology Bio will serve as the product Sponsor.

2.3.1 The Awardee, as Sponsor, shall consult FDA's Pre-IND Consultation program to support development of a novel mAb therapeutic to facilitate development of a RS with attached Target Product Profile (TPP) to expedite the IND filing.

2.3.2 The Awardee shall leverage regulatory experience from Awardee's previous [redacted] to support an expedited approach to an IND filing.

2.3.3 The RS will also include the use of the material generated from the stable pool transfections for toxicology, efficacy and Phase 1 clinical programs.

2.3.4 The Awardee shall support program objectives by developing risk assessment reports in areas where the Awardee's Regulatory Affairs (RA) team are developing high-risk strategies to include limiting stability timepoints to support Phase 1, limiting nonclinical safety data, and supporting [redacted] in the original IND application.

2.3.5 The Awardee shall develop a Phase 1 clinical synopsis to include in the Pre-IND briefing package. The Awardee shall provide the Pre-IND briefing package to the USG.

2.4 Task 4: Analytical Development and Qualification

Notes:

- Ology Bio will develop and qualify product-specific methods for QC lot release and stability testing including identity and potency methods.
- All other release methods are standardized methods and/or compendial methods.

2.4.1 [redacted]

2.4.2 The Awardee shall qualify analytical assays in a phase-appropriate manner.

2.4.3 The Awardee shall provide, for USG review onsite at the DoD ADM Facility or via a terminal in the Ology Bio MD office for remote review, an Analytical Method Qualification Report, with summary reports for each of the assays developed.

2.4.4 The Awardee shall develop, qualify and provide, for USG review onsite at the DoD

ADM Facility or via a terminal in the Ology Bio MD office for remote review, a Qualification Report for (b) (4) potency methods for the (b) (4) DS and (b) (4) DP.

2.5 Task 5: Stable Transfections

2.5.1 The Awardee shall develop stable pools of (b) (4) (b) (4) b) (4) .

2.5.2 The Awardee shall perform the stable transfections using Good Documentation Practices and document all source materials.

2.5.3 The Awardee shall expand the stable pools, use production assays to identify robust pools expressing the highest mAb levels, and select the top pool for initial scale-up and manufacturing.

2.5.4 The Awardee shall prepare and characterize cell banks like CGMP MCBs. The Awardee shall generate (b) (4) each stable pool Cell Bank.

2.5.5 (b) (4)

2.5.5.1 A comparison of overall titers will be made between the stable pools of the vendor and the Awardee.

2.5.5.2 A Go/No Go decision will be made based on a direct comparison of the titers and cell viability between the Awardee's and the vendor's stable pools (b) (4)

2.5.5.3 Based on the Go/No Go decision, (b) (4)

2.5.5.4 The Awardee shall receive stable pool materials from the vendor for (b) (4) evaluation.

2.5.5.5 The Awardee shall provide (b) (4) vials for each of the stable pools produced by the vendor.

2.5.5.6 The Awardee shall perform mycoplasma and sterility testing on (b) (4)

2.5.5.7 The Awardee shall prepare and characterize cell banks in a similar fashion as CGMP MCBs.

2.5.6 (b) (4)

2.5.7 (b) (4)

2.5.8 The Awardee will also perform limited (b) (4)

(b) (4) versions as well.

2.5.9 The Awardee shall down-select (b) (4) stable pools to be evaluated (b) (4) for their (b) (4).

2.5.10 The Awardee shall perform evaluation of the (b) (4)

2.5.11 The Awardee shall perform evaluation of the stable pool candidates using the (b) (4) (b) (4)

2.5.12 The Awardee shall provide materials from the down-selected candidate antibodies to be evaluated for (b) (4) confirmation of mAb efficacy (b) (4) in their (b) (4) of COVID-19.

2.5.13 The Awardee shall down-select to the best (b) (4) mAb candidates (b) (4) based on information (b) (4) and (b) (4) outlined in **Table 1**.

2.5.14 The Awardee shall provide a (b) (4) for each (b) (4) (b) (4) based on the generation of the stably transfected pools.

Table 1. Criteria for down-selection of the stable pools

(b) (4)	

2.6 Task 6: Process Development

Notes:

- Awardee will use the down-selected stably transfected cell pools generated during Task 5 as the starting materials in this task.
- Ology Bio will leverage an existing formulation (b) (4).
- Awardee will perform (b) (4) runs on a parallel path to the (b) (4) CGMP manufacturing, using data generated from (b) (4) to evaluate revised production parameters.

2.6.1 Media and Feed Optimization

2.6.1.1 The Awardee shall (b) (4) to evaluate (b) (4) the selected pools (b) (4) from Task 5 to investigate media optimization, culture feeds, time of feeds, and titer maximization.

2.6.1.2 Information from this (b) (4) may be considered in the down-selection to the (b) (4) (b) (4) that will be moved forward in this task. The down selection will be an IPT driven decision with input from JPEO and Ology Bio.

2.6.1.3 The Awardee will expand cells from (b) (4) stable pool through the (b) (4) to demonstrate successful seed train expansion and determine optimal expansion timing. Material will be utilized for downstream and analytical assay development.

2.6.1.4 The Awardee will perform (b) (4) on selected stable pools containing the (b) (4)

2.6.2 Process Development Runs (b) (4)

2.6.2.1 The Awardee shall perform (b) (4) Process Development Runs for (b) (4) selected pools from Task 5 (b) (4). The selection of which pools to use will be made in collaboration with the USG. Awardee will store DS frozen based on experience with previous mAb formulations.

2.6.2.2 Awardee will not perform adventitious agent testing on these (b) (4).

2.6.2.3 Awardee may use the materials from these runs for analytical method development (Task 4). Process Development Runs will include downstream purification steps through to final DS.

2.6.2.4 The Awardee shall execute (b) (4)

2.6.2.5 The Awardee shall use (b) (4) vials per lot in a mutually approved container/closure system (vial, stopper, seal) for the media fill validation runs. (b) (4)

2.6.2.6 The awarded shall comply with FDA Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice, Sept 2004.

2.6.2.7 The Awardee shall provide:

2.6.2.7.1 Process Development Report from (b) (4)

2.6.2.7.2 DS materials

2.6.2.7.3 Aseptic Media Qualification Report

2.7 Task 7: CGMP DS Runs with Stable Pools (b) (4)

Notes:

- Stably transfected cell pools generated during Task 5 and down-selected in Task 6 will be used in this task.

2.7.1 The Awardee shall perform (b) (4) CGMP DS Runs as required to generate sufficient (b) (4) (b) (4). Each CGMP DS run will also have a back up seed train that is maintained until the primary run of that (b) (4)

2.7.2 The Awardee shall conduct sampling and lot release testing that was successfully employed (b) (4) for CGMP materials.

2.7.3 The Awardee shall generate DS Reference Standards from materials generated during the (b) (4) Runs using the analytical methods described in Task 4.

2.7.4 The Awardee shall use in-process material generated in the (b) (4) runs in a viral clearance study for (b) (4) representative mAb.

2.7.5 The Awardee shall provide controlled and temperature-monitored transport of final released lots as directed by the AOR.

2.7.6 The Awardee shall complete (b) (4)

2.7.7 (b) (4)

2.7.8 The Awardee shall provide:

2.7.8.1 Reference standard materials for each (b) (4)

2.7.8.2 Viral Clearance Report

2.7.8.3 CGMP DS Campaign Summary Reports, raw material COA(s), analytical testing summaries and analytical reports, executed CGMP batch records, and COA and MSDS for CGMP DS for each of the mAbs.

2.7.8.4 CGMP DS for generation of CGMP DP (Task 8).

2.8 Task 8: CGMP DP Run (b) (4)

Notes:

- DP will be a combination of up to (b) (4), (b) (4)
- Initial DP (b) (4) will be performed for both (b) (4)
- No formulation development will be performed under this contract. Ology Bio will leverage a previously developed formulation (b) (4) for this effort.

2.8.1 The Awardee shall perform liquid fill operations using the CGMP DS of (b) (4) (b) (4)

2.8.2 The Awardee shall fill (b) (4) vials of (b) (4) CGMP DP lots suitable for use in a Phase 1 clinical trial at a concentration as directed by the AOR. This includes co-formulation, fill, inspection, labeling, packaging and QA review. (b) (4)

2.8.3 The Awardee shall fill the remainder of the (b) (4)

2.8.4 The Awardee shall conduct sampling and lot release testing that was developed under previous agreement (b) (4) for CGMP materials. A risk assessment will be performed to minimize the impact of sampling to the overall product yield.

2.8.5 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released DP lots as directed by the AOR.

2.8.6 The Awardee shall complete (b) (4) potency release testing of the CGMP DP lots.

2.8.7 The Awardee shall provide CGMP DP Campaign Summary Reports, raw material COA(s), analytical testing summary and analytical reports, and executed CGMP batch records, and COAs and MSDSs for CGMP DP lots.

2.9 Task 9: Regulatory Support

Notes:

- This effort does not include publishing via the FDA Gateway but will result in a regulatory application that is complete for future electronic publishing and submission. Please note IND complete does not include toxicology reports, as the plan is to engage with the FDA to determine the necessary toxicology for the original submission.
- The IND will be prepared without toxicology information to expedite review.

2.9.1 The Awardee shall conduct a kick-off meeting for the regulatory submission, followed by development and review of an IND application. The IND will be delivered as complete for submission (i.e., MS Word deliverables ready to go to the electronic publisher).

2.9.2 The Awardee shall develop and provide a RS to support the program through IND submission, including a TPP as an attachment to the RS.

2.9.3 The Awardee shall conduct Regulatory Risk Assessments.

2.9.4 The Awardee shall draft (b) (4) sections for Modules 1-5 (MS Word format) and provide an IND that is complete for filing, except for toxicology reports.

2.9.5 The Awardee shall support USG Emergency Use Authorization (EUA) requirements as needed to facilitate availability of the DP manufactured under this Agreement to the USG.

2.10 Task 10: Limiting Dilution Cloning

2.10.1 The Awardee shall conduct (b) (4) rounds of limiting dilution cloning from the (b) (4) lead stable pools (produced in Task 5) that were used above for the generation of clinical trial material for both the (b) (4) , with advanced (b) (4)

2.10.2 (b) (4)

2.10.3 The Awardee shall test the (b) (4)

2.10.4 The Awardee shall provide a (b) (4) for each of the (b) (4) (b) (4)

2.11 Task 11: Master Cell Banking

Notes:

- The (b) (4)(b) (4) (b) (4) will be available to USG for use in future efforts to produce additional clinical trial material.
- The MCB (b) (4) for the (b) (4) clone will be manufactured (b) (4) under a separate agreement with the DoD.

2.11.1 The Awardee shall produce a (b) (4)

and the (b) (4)

2.11.2 (b) (4)

2.11.3 The Awardee shall provide an MCB Report, including the MCB production batch record and a COA, for each of the mAbs.

2.12 Task 12: Process Confirmation Runs with MCBs (b) (4).

2.12.1 The Awardee shall perform (b) (4) Process Confirmation Run using the MCB produced in Task 11 for each of the (b) (4) mAbs.

2.12.2 The Awardee shall perform analytical characterization of the DS based on the reference standard for material from stable pools for each of the (b) (4) mAbs.

2.12.3 The Awardee shall provide an MCB Confirmation Run Report for each of the (b) (4) mAbs.

2.13 Task 13: CGMP DS Runs with MCBs (b) (4)

Notes:

- MCBs generated in Task 11 or WCB produced under separate agreement will be used in this task.
- As directed by the AOR, DS manufactured in this task may be filled as DP in Task 14 or may be stored frozen.
- The Task 13 runs will incorporate the downstream process aligning with the (b) (4) (b) (4). New resins and pre-packed columns will be purchased for this task and process.
- Ology Bio will store DS on-site prior to shipment to fill/finish (b) (4)

2.13.1 The Awardee shall perform (b) (4) DS Run for each of the (b) (4) mAbs (b) (4).

2.13.2 The Awardee shall conduct sampling and lot release testing that was developed under previous agreement (b) (4) for CGMP materials.

2.13.3 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released lot as directed by the AOR.

2.13.4 The Awardee shall provide CGMP DS Campaign Summary Reports, raw material COA(s), analytical testing summaries and analytical reports, and executed CGMP batch records, and COA and MSDS for CGMP DS for each of the (b) (4) (b) (4).

2.14 Task 14: CGMP DP Run

Notes:

- Stability of the CGMP DP lots will be included in a separate contract.

(b) (4)

2.14.2 The Awardee will (b) (4) fill CGMP DP lots suitable for use in Phase 1, 2, or 3 clinical trials in collaboration with the USG. This includes co-formulation, fill, inspection, labeling, packaging and QA review.

2.14.3 The Awardee will (b) (4) fill (b) (4) DP lots from Ology Bio clonal-derived material (Task 13) (b) (4) as outlined in the table below:

(b) (4)					

2.14.4 The Awardee shall conduct sampling and lot release testing that was successfully employed (b) (4) for CGMP materials. A risk assessment will be performed to minimize the impact of sampling to the overall product yield.

2.14.5 The Awardee shall provide controlled and temperature-monitored transport of analytical samples and final released DP lot as directed by the AOR.

2.14.6 The Awardee shall provide a CGMP DP Campaign Summary Report, raw material COA(s), analytical testing summary and analytical report, and executed CGMP batch records, and COA and MSDS for each CGMP DP lot.

2.14.7 The Awardee shall store released DP on-site at Ology Bio and at a 3rd party storage location pending direction from the DoD.

2.15 Task 15: Nonclinical Safety

Notes:

- Material generated in Task 6 will be used to support these assays.
- A dose-ranging study is not included based on toxicity risk assessment, which will be used to present a strategy in the Pre-IND interactions.

2.15.1 Task 15a: Develop and Perform (b) (4) Cell-Based Neutralization Assays or ELISA to Support (b) (4) Testing

2.15.1.1 (b) (4)

(b) (4)(b) (4)

(b) (4)

2.15.2 Task 15b: Tissue Cross-Reactivity Studies

2.15.2.1 The Awardee shall conduct tissue cross-reactivity using material generated from the stable transfections and provide a (b) (4) .

2.15.3 Task 15c: GLP Toxicology Study

2.15.3.1 The Awardee shall conduct a (b) (4)

2.15.3.2 The Awardee shall conduct (b) (4) for each of the (b) (4) .

2.15.3.3 The Awardee shall provide a Toxicology Study Report and (b) (4) data tables.

2.16 Task 16: Stability Studies (stable pool-produced material)

Notes:

- Material generated in Tasks 7 and 8 will be used in this task.

2.16.1 The Awardee shall conduct stability testing per an approved stability protocol on the CGMP DS and DP lots from the stable pools, including real-time and accelerated conditions for (b) (4) (b) (4) , along with reference standards. The Awardee will finalize stability testing as part of risk assessment to determine the minimum amount of material required.

2.16.2 The Awardee shall provide stability test results in annual reports.

2.17 Task 17: Stability Studies (MCB-produced material)

2.17.1 The Awardee shall conduct stability testing per approved stability protocol on the CGMP DS and DP lots from the MCB, including real-time and accelerated conditions for (b) (4) mAb DS and (b) (4) DP.

2.17.2 DS and DP stability studies will be matrixed to reduce testing load.

2.17.3 The Awardee shall provide stability test results in annual reports.

2.18 Task 18: Proof-of-Concept of mAb Production (b) (4)

Notes:

- The Awardee shall (b) (4) to perform Upstream Manufacturing only of the (b) (4) using their (b) (4) . Ology Bio will perform all downstream purification and release testing.
- The work was suspended following the completion of work in Task 18a.

(b) (4)

(b) (4)

(b) (4)

2.19 Task 19: Bioanalytical Development

2.19.1 The Awardee shall develop and validate (b) (4) bioanalytical assays at Ology Bio CA in preparation for the Phase 1 clinical trial to evaluate the (b) (4) (b) (4)

2.19.2 The Awardee shall develop and validate (b) (4) (b) (4)

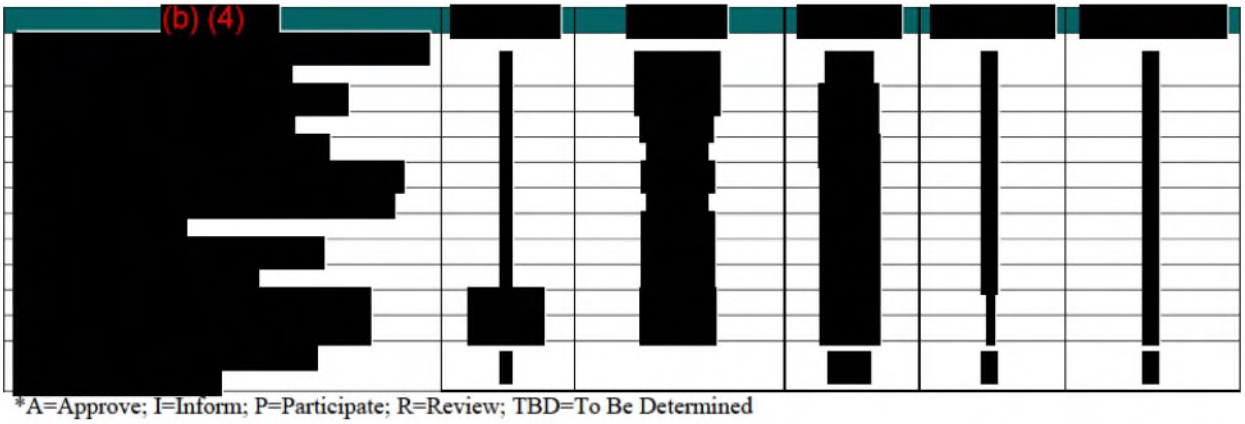
2.19.3 The Awardee shall perform the (b) (4) to support the Phase 1 trial. (b) (4) (b) (4) for (b) (4) in Phase 1 Part A, and (b) (4) and (b) (4) in Phase 1 Part B.

2.19.4 The Awardee shall perform (b) (4) in the Phase 1 clinical trial. (b) (4)

3.0 DELIVERABLES

3.1 Data Deliverables

(b) (4)

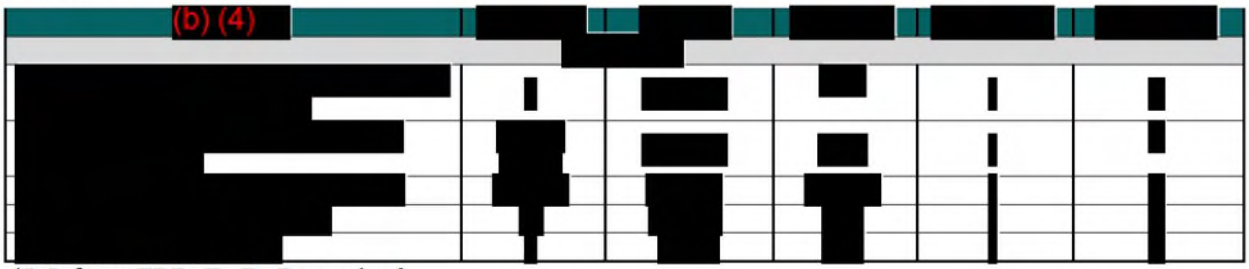


*A=Approve; I=Inform; P=Participate; R=Review; TBD=To Be Determined

1. Dates are subject to change

**Category A=Data developed with non-USG/private funding; Category B=Data developed partially with USG funding allotted for this project and partially with non-USG/private funding; Category C=Data developed solely with USG funding allotted for this project.

32 Supply Deliverables



*I=Inform; TBD=To Be Determined

33 Acceptance of Deliverables

The USG will provide review of all data deliverables within 30 days of delivery. The USG will acknowledge receipt of all supply deliverables within 60 days of delivery.

4.0 DATA RIGHTS

The USG shall have no rights to any preexisting technical data associated with Ology Bio's non-exclusive license (b) (4) that was not funded by the USG.

(b) (4)

5.0 BACKGROUND INTELLECTUAL PROPERTY AND MATERIALS

The following are Ology Bio's Background Intellectual Property (IP) and Materials, as defined in Article 9, Section A of the 2373 Agreement. (b) (4)

(b) (4)

(b) (4)

6.0 AOR AND ALTERNATE AOR CONTACT INFORMATION

AOR	Alternate AOR
[Name]	[Name]

7.0 AWARDEE KEY PERSONNEL

(b) (6)		

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00025	02-Mar-2021	SEE SCHEDULE	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003
	X	10B. DATED (SEE ITEM 13) 22-Feb-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the Agreement.

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)

The purpose of this Amendment is to incorporate Appendix A-2 Rev 4, decrease the value of Project 20-05 under CLIN 0002 accordingly, incorporate incremental funding for CLIN 0005, and update the AOR appointments for Projects 20-04 and 20-09. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		BY (b) (6) (Signature of Contracting Officer)	01-Mar-2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

P00025

A. The purpose of this Amendment is as follows:
   a. Appendix A-2 Rev 4 is hereby incorporated into this Agreement. This revision incorporates a number of programmatic changes including reduction in the subcontracted manufacturing effort (b) (4) and changes to the fill finish effort. This revision supesedes the previously incorporated Appendix A-2 Rev 3 in full.
      i. The value of CLIN 0002 is hereby reduced by (b) (4) from (b) (4) to (b) (4)
      ii. Funding on SLIN 000203, ACRN AL is hereby reduced by (b) (4) from (b) (4) to (b) (4)
   b. (b) (4)
   c. The AOR for Project 20-04, CLIN 0004 is hereby changed from Nicole Dorsey to Shannon Brooks and the CLIN description is updated accordingly.
   d. (b) (4)

B. The total value of this agreement is decreased by (b) (4) from (b) (4) to (b) (4)
C. Total funding for this agreement is decreased by (b) (4) from (b) (4) to (b) (4)
D. The parties hereby agree that changes affected by this Amendment constitute both the consideration and equitable adjustment due under any Article in this Agreement resulting from incorporation of Appendix A-2 Rev 4.
E. All other terms remain the same an in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002

The estimated/max cost has decreased by (b) (4) from (b) (4) to $46,381,910.00.
The fixed fee has decreased by (b) (4) from (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4)

(b) (4)

[redacted]

(b) (4)

[redacted]

SUBCLIN 000505 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000505					$0.00

Vero Cell Platform
(b) (4) [redacted]

[redacted]

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000505:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was decreased by (b) (4) from (b) (4) to (b) (4).

SUBCLIN 000203:

AL: 097202020210130000181705525202 52 S.0074658.1.1.6 6100.9000021001 AHPDD (CIN GFEBS001150679500001) was decreased by (b) (4) [redacted]

SUBCLIN 000505:
Funding on SUBCLIN 000505 is initiated as follows:

ACRN: AN

CIN: GFEBS001156573700003

Acctng Data: 097202120220400000260100060602 55 A.0011316.1.8.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

(b) (4)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P0001	10-Dec-2020	0011559735	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190002
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 20-Oct-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
The terms of this Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)

The purpose of this Amendment is to change the terms of the Agreement in the following manner:
1) Change the Government Program Manager and Assistant Program Manager
2) Adjust the language of the terms for future Government Furnished Property under Agreement section G.2.
3) Revise Agreement subsections under Article 7 to remove duplicate letter identifiers.
4) Add section H under Article 7 to address the cost principles that will govern this Agreement.

The changes are recorded in the fully amended and bi-laterally endorsed Agreement.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
(b) (6)	Lawrence E. Mize TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B.	16C. DATE SIGNED
(b) (6) (b) (6) (b) (6) (Signature of person authorized to sign)	December 11, 2020	BY (b) (6) (Signature of Contracting Officer)	11 Dec 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
	1 | 2

2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00002	15-Dec-2020	0011559735	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190002
CODE 3GQS9 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 20-Oct-2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
The Terms of This Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
See Continuation Page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
(b) (6)		(b) (6) TEL (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. (b) (6)	16C. DATE SIGNED
(b) (6) (b) (6) (Signature of person authorized to sign)	December 15, 2020	(Signature of Contracting Officer)	15 Dec 2020

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

AMENDMENT P00002

The purpose of this Amendment is to designate this Agreement as a Defense Priority and Allocation System (DPAS) rated order (15 CFR 700) as approved by the Department of Health and Human Services (HHS) Industrial Policy group. The changes are as follows:

a. Block 1 or the Agreement SF26 is hereby revised to incorporate a DPAS rating of DO-H5.
b. Article 14, Paragraph N is hereby incorporated into the Agreement to add the following: "This Agreement has been granted approval for a DO-H5 DPAS rating for national defense, emergency preparedness, and energy program use. The Awardee shall follow all requirements of the DPAS Regulation, 15 CFR 700. This rating can only be used on contracts and orders to support the expansion of production capacity."

The Awardee is hereby authorized to effect this rating on all vendors necessary to support the expansion of production capacity only at the DoD Advanced Development Manufacturing facility.

Additionally, the Government has added the AOR acronym to the Primary Program Manager listing in the Government Program Managers table listed in Article 3, Paragraph B.

All other Terms and Conditions remain in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-H5 has been added.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00004	15-Mar-2021	0011559735	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190002
	X	10B. DATED (SEE ITEM 13) 20-Oct-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) The terms and Conditions of This Agreement, Article 5, Section D.

E. IMPORTANT: Contractor [X] is not, [ ] is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6)
See Continuation Page.
All other Terms and conditions remain in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
	(b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ (Signature of person authorized to sign)		B (b) (6) (Signature of Contracting Officer)	15-Mar-2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

AMENDMENT P00004

The purpose of this Change Order is to incorporate the following:

A. Changes to the work performed under Project 21-01

1) Awardee proposed changes to the designs of project 21-01 are accepted in so far as they remain in scope of the original project to expand the manufacturing facility at the ADM.
2) Awardee proposed changes to the project schedule are accepted in so far as it represents an expedited path to completion.

B. The Awardee is hereby authorized to proceed with the redesign efforts at the expedited schedule project timeline at no increase in cost to the Agreement value. These efforts shall be performed in accordance with Article 1 Section E of the Agreement in terms of expending Government funds in advance of the completion of the real estate transaction.

C. The Awardee is hereby authorized to expend no more than (b) (4) of Government funds in advance of completion of the Real Estate Transaction for the purpose of making the deposit against the required fill/finish system. This shall not increase the total cost of project 21-01 and the Government shall have the ability to re-direct the delivery location of the instrument should this Agreement terminate prior to the system's delivery and installation.

D. Definitization of the final redesign, project timeline, cost for the fill/finish system deposit, Agreement Terms and total value to the Agreement shall occur within 10 days of this Amendment.

E. All other terms and conditions remain unchanged.

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1 CONTRACT ID CODE	PAGE OF PAGES
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2 AMENDMENT/MODIFICATION NO	3 EFFECTIVE DATE	4 REQUISITION/PURCHASE REQ NO	5 PROJECT NO (If applicable)
P00005	07-Apr-2021	0011559735	

6 ISSUED BY	CODE	7 ADMINISTERED BY (If other than item 6)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2190002
	X	10B. DATED (SEE ITEM 13) 20-Oct-2020
CODE 3GQS9	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
The Terms and Conditions of This Agreement

E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Modification Control Number: (b) (6)

See Continuation Page for Details.

All other terms and conditions remain in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Robert V. House, Ph.D. / Senior VP Government Contracts	(b) (6) TEL: (b) (6) (b) (6)

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. U (b) (6)	16C. DATE SIGNED
(b) (6) (b) (6) (Signature of person authorized to sign)	April 7, 2021	BY (Signature of Contracting Officer)	07 Apr 2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:
P00005
This Amendment makes the following changes:

1) Incorporates revised terms and conditions into the Agreement in the following:
   a. Article 1, Section E: Language to allow the Awardee to expend Government funds for the deposit of the fill/finish system in advance of the completion of the real estate transaction is hereby added.
   b. Article 7, Section E: The cost sharing and total project values are changed based on the negotiated total changes to the cost of project 21-01 and changes in the cost sharing arrangement.
   c. Article 7, Section H: Sub-Paragraphs 2) and 3) are hereby added into the Agreement:
      2) For all proposed projects, the Government and Awardee shall establish a budget based on current approved or submitted indirect rate calculations reviewed by the Defense Contract Audit Agency (DCAA) for such elements as fringe benefits, Overhead (OH), and General and Administrative (G&A) costs unless otherwise negotiated in the sub-sections below:
         a. The Government and Awardee agree to establish a (b) (4) on General and Administrative costs on subcontractor efforts performed under project 21-01.

      Should the results of a DCAA audit indicate that the rate(s) utilized in Agreement varies from the rate determined appropriate by the Government, the Agreement amount shall be adjusted downward or upward depending on final audit and review by DCAA.

      3) For all projects that include the acquisition of real property (buildings and immovable Government Property) for which the Government has agreed to fund as a direct cost associated with one or more projects issued under this Agreement, the Awardee agrees to remove these costs from future depreciation calculations and G&A valuations. The Awardee may include the costs of maintenance, upkeep and indirect costs to ensure the continued use of the property in the calculations of G&A, Fringe and Overhead in so far as they do not duplicate costs associated with other pools or direct cost elements.
   d. Article 14, Section O is hereby incorporated into the Agreement in its entirety:
      O. Project Timelines and Delivery Schedule of OTA Project 20-01, ADM Expansion Project.
      1) Awardee acknowledges that timely completion of the ADM Expansion Project is essential to meet the Government's stated objectives under this Agreement. Accordingly, Awardee represents that it will use its best efforts to adhere to the project timelines and delivery schedules incorporated into Appendix B.

      2) Awardee shall promptly notify the Government if, at any time during performance of the Agreement, it has a reasonable belief that any task listed within Appendix B will be completed seven (7) or more days after the date indicated in Appendix B ("Schedule Slip"). If Awardee identifies a Schedule Slip, it shall arrange a meeting

between the Government, Awardee, and its subcontractor Whiting-Turner within 24 hours. The meeting will focus on getting the schedule back on track and looking at future work and processes on the critical path that can be completed faster than scheduled. Any slip in schedule that is directly attributed to the fault of Awardee or its subcontractor(s) will be the financial responsibility of Awardee and its subcontractor(s); however, Awardee may seek Government reimbursement for Schedule Slips caused by force majeure events, natural disasters, and other events for which Awardee and its subcontractors have no control.

3) If there is a Schedule Slip and the schedule adjustment has not been approved by the Government and negotiated into Appendix B in accordance with paragraph (2) of this section, the Government may withhold milestone or expenditure payments for any individual task.

e. Appendix A, Item I, Project 21-01 Statement of Work: A revised statement of work for project 21-01 is hereby incorporated into Appendix A in its entirety.

f. Appendix B, Item I, OTA Project 21-01 ADM Expansion: A revised project timeline is hereby incorporated into Appendix B in its entirety.

g. Appendix C, Cost Sharing Arrangement: A revised cost sharing arrangement is hereby incorporated into the Agreement in its entirety.

2) The total cost of the project is hereby reduced to (b) (4) from (b) (4)

3) The total obligation amount of CLIN 0001, Project 21-01 is hereby reduced to $126,576,662.90 from (b) (4). As such, (b) (4) is hereby de-obligated from CLIN 0001.

All other terms and conditions remain in full force and effect.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was decreased by (b) (4) from (b) (4) to (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The estimated/max cost has decreased by (b) (4) from (b) (4) to (b) (4)
The total cost of this line item has decreased by (b) (4) from (b) (4) .43 to (b) (4)

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was decreased by (b) (4) from (b) (4) to (b) (4).

SUBCLIN 000101:

AA: 0972020202101300001817055252025 2 S.0074658.1.1.4 6100.9000021001 AHPDD (CIN GFEBS001155973500001) was decreased by (b) (4) from (b) (4) to (b) (4)

(End of Summary of Changes)