10 USC § 2373 AGREEMENT

BETWEEN

JUST - EVOTEC BIOLOGICS, INC. ("Awardee")
401 Terry Ave. N.
Seattle, WA 98109
DUNS: 079920868
CAGE Code: 7PFN4

And

NATICK CONTRACTING DIVISION ("Government")
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date:	**07 July 2020**
Agreement Number:	**W911QY-20-9-0015**
Total Amount of the Agreement:	(b) (4)

Awardee

(b) (6)

EVP Global Head Biotherapeutics, President US
Title

07/06/2020
Date

(b) (6)

Sr. VP Biotherapeutic Sciences
Title

07/06/2020
Date

Government

(b) (6)

Printed Name
Agreements Officer
Title

07 Jul 2020
Date

ARTICLE 1. SCOPE

1. 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. Each of the Awardee and the Government made be individually referenced herein as a "**Party**" and, collectively, as the "**Parties**".

2. 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).

3. 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.

4. The Parties agree that the ultimate purpose of this Agreement is for delivery of cGMP drug substance of two monoclonal antibodies (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).

5. The Government represents to Awardee that the Government has appropriate intellectual property rights to request the activities requested of Awardee under this Agreement.

ARTICLE 2. Term and Termination.

A. Term: The term ("**Term**") of this Agreement commences upon the Effective Date and extends through final payment hereunder, unless earlier terminated by a Party in accordance with this Agreement. This Agreement is anticipated to end eighteen (18) months after the Effective Date. A transaction for a supply underneath 10 USC 2373 is complete upon delivery of the final supply deliverable.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least thirty (30) 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. Such adjustment shall also include, but not be limited to, the following: If Government terminates this Agreement within thirty (30) business days of the scheduled initiation date of a Product supply run, then Government will fully reimburse Awardee for costs related to labor, materials, and non-cancellable commitments incurred by Awardee for such run. Also, Government will not receive a refund for raw materials ordered by and billed to Awardee for such run.

C. Termination for Cause: If the Awardee materially fails to comply with the material provisions of this Agreement, the Agreement Officer (AO), after issuance of a cure notice and failure of the Awardee to cure the defect within ten (10) business days 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,
   iv. withhold further funding, or
   v. take any other legally available remedies.

   The Awardee may terminate this Agreement if the Government materially breaches a material provision of this Agreement and fails to remedy or cure the same within thirty (30) calendar days following notification of such breach by Awardee to the Government.

D. Survival: In the event of termination or expiration of this Agreement, 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. Further, expiration or termination of this Agreement for any reason shall not relieve Government of its payment obligations under this Agreement for activities performed by Awardee prior to such expiration or termination.

ARTICLE 3. Project Management.

A. Program Governance: The Awardee is responsible for the overall management of the supply manufacture. The Government will have continuous interaction with the Awardee with respect to the work hereunder. The Awardee shall provide access to interim data in accordance with the Awardee's Project Timeline under the SOW.

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

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

Government Project Managers (GPM)

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

C. Key Personnel: The Awardee's organization shall be established with authority to effectively complete the Deliverables. This authority shall become effective upon execution of this Agreement and its integrity shall be maintained in accordance herewith until completion or acceptance of the effort by the Government. The key personnel listed in Appendix C 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. The AO has assigned an Agreements Officer's Representative (AOR) for this Agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the AO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the Agreement.

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 AO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the AO in accordance with Article 5.

Government Representatives:
Agreements Officer (AO)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Other Transaction Agreement Specialist (OTAS)
(b) (6)

ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Government Agreements Officer Representative:

(b) (6)
Assistant Program Manager
JPEO-CBRND Enabling Biotechnologies
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

Awardee Representative:

(b) (6)
SVP, Biotherapeutic Sciences
Just – Evotec Biologics, Inc.
401 Terry Avenue North
Seattle, WA 98109
(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 to achieve the objective.

B. Awardee shall use its Commercially Reasonable Efforts to perform its activities in compliance with this Agreement (including the Specifications as provided in the Statement of Work) and in conformity with cGMP (collectively, the "**Standards**"). "**Specifications**" shall mean a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. The Specifications establish the set of criteria to which a Deliverable should conform to be considered acceptable under this Agreement. Conformance to Specifications shall mean that a Deliverable, when tested according to the listed analytical procedures, will meet the listed acceptance criteria.

C. The Government acknowledges that certain Products are products which are unknown in terms of their product expression profiles and process and/or manufacturing characteristics and development activities for which the results of processing and other activities under this Agreement are uncertain and subject to variability and a chance of not meeting objectives, timelines and related Specifications. Therefore, provided that Awardee and its approved subcontractor perform the activities for such Products in accordance with the Standards, Awardee shall have no liability for the SOW activities not achieving the desired milestones, Specifications, or timelines.

"**Product**" shall mean any monoclonal antibody or other biologic processed by Awardee for delivery to Government pursuant to the Statement of Work.

D. Recommendations for Modifications: At any time during the Term, 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 a 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.

E. 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, the milestone payments, or other proposed changes to the terms and conditions of this Agreement.

F. Minor Modifications: The Government may make minor or administrative (non-substantive) Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, etc.).

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

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

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

J. 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 within sixty (60) calendar days. Thereafter, 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 by mutual consent to explore and establish an alternative dispute resolution procedure to resolve the dispute. The Awardee shall proceed diligently with performance under this Agreement pending resolution of the dispute.

ARTICLE 6. Inspection/Acceptance

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement,

to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government, or the Government's designee, may also inspect the premises of the Awardee or any sub-Awardee engaged in performance of work hereunder. The Government shall perform inspections and tests in a manner that will not unduly delay the work. If the Government performs any inspection or test on the premises of the Awardee or a sub-Awardee, the Awardee shall furnish and shall require sub-Awardees 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 sub-Awardee's premises.

B. The Government shall inspect/accept or reject the Deliverables as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the Deliverables shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming Deliverables. A Deliverable 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 Deliverables. Inspection and rejection of Deliverables will take place within ninety (90) days after provision of Deliverables to the Government.

ARTICLE 7. Financial Matters

A. This Agreement is a fixed milestone agreement. The Awardee shall be paid for each milestone executed and accomplished in accordance with the milestones ("**Payable Milestones**") set forth in the Project and Payment Schedule, Appendix B. The anticipated schedule for the Payable Milestones is identified by the Government's fiscal year, which ends on September 30 and begins on October 1 of the prior calendar year. The Payable Milestones set forth may be revised or modified only in accordance with the terms of this Agreement. The milestone payments provided under this Agreement are not intended to compensate the Awardee on a cost basis for performance under this Agreement. The nature of this payment structure and the Awardee's relationship with a sub-Awardee will not cause this Agreement to be deemed a cost-type agreement or provide the Government with any audit rights other than the access-to-records rights described herein.

B. Payments.

   a. The Government shall pay the Awardee, upon submission of proper invoices in accordance with the terms of this Agreement, the prices stipulated in this Agreement for Deliverables rendered and accepted.
   b. The Awardee shall be paid for each Payable Milestone executed and accomplished in accordance with each Payable Milestone required for delivery of the Deliverables as set forth in Appendix B. The Awardee's requests for payment will not be deemed to be requests for reimbursement or advance payment, but rather amounts identified in Appendix B due to the Awardee under this Agreement.
   c. The Awardee shall electronically submit a signed invoice to the Agreement Administrator for payment. Payments will be made via electronic funds transfer within thirty (30) calendar days of receipt of a request for payment. Payment under this Agreement will not be contingent on the Awardee first making payment to sub-Awardee(s).
   d. One copy of the payment/voucher shall be provided to each of the following persons:

Government Program Manager, Government Financial Manager, and Agreements Officer.

C. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth herein and in the supplemental PD2 version of this Agreement, and any subsequent modifications. The Government may incrementally fund this Agreement. 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 for this Agreement.

D. The Government shall pay the Awardee, upon submission of proper invoices, the costs 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 Deliverables delivered or rendered for which a price is separately stated in the Agreement. Payments for work will be made within thirty (30) calendar days of receipt by the Government of a request for payment under WAWF.

E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

a. Definitions. As used in this clause—
   i. Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.
   ii. Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).
   iii. 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 Agreement:

i. Document type. The Awardee shall use the following document type: Voucher
ii. Inspection/acceptance location. The Awardee shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.
iii. 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**

iv. 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 or other Deliverables delivered, costs, fee (if applicable), and all relevant back-up documentation in support of each payment request.
v. 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)

g. WAWF point of contact.

i. The Awardee may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.
ii. 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 Effective Date. 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 this Agreement more than three (3) years after the final payment is made by the United States under this Agreement.

ARTICLE 8. Report and Data Requirements

1. Weekly Teleconferences and Communication

Awardee shall conduct weekly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once the manufacturing tasks begin. Awardee shall provide agendas and read-ahead material as required two (2) days prior to the meetings and shall provide minutes of each meeting to the Government. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with JPEO EB.

2. Quarterly Progress Reports

The Awardee shall submit a Quarterly Progress report within twenty (20) calendar days after the end of each quarter of performance. The Quarterly Progress report shall contain the technical progress made during the previous quarter and the updated resource loaded Integrated Master Schedule (IMS) in Microsoft Project format. The schedule update shall include the explanation for any changes in the schedule, and drivers for the changes, as applicable. The report should also address any concerns that would impact the performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies. Note: Any identified changes require formal notification to the AO in accordance with the Agreement provisions.

In addition, the Quarterly Progress Report shall contain regular status updates of all relevant Intellectual Property license(s) necessary for the activities under the SOW to ensure that all necessary license(s) are in good standing as the project progress. In the event of any change in relevant license(s)' status or potentially imminent change in status, the Awardee shall immediately contact the OTA and GPM in writing.

The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional five (5) calendar days to revise the Deliverable or respond to those comments.

3. Expenditure Forecasts

The Awardee shall submit the first expenditure forecast within thirty (30) calendar days after receiving the project award. An updated forecast shall be submitted within fifteen (15) calendar days of any project modifications that modify the PoP or the cost. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

4. Ad Hoc Meetings

In addition to the monthly meetings and written quarterly program updates, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held.

5. Regulatory Documentation and Technical Data Packages

The Awardee shall work in consultation with the Government Regulatory and Quality Affairs staff for the development of regulatory submission packages to the FDA and include Government Regulatory and Quality Affairs staff in all formal discussions with the FDA including, if applicable, with respect to Products for which the Awardee is the sponsor. The Awardee shall provide the Government copies of all technical data generated by the Awardee prior to and during performance of the work, necessary to pursue FDA approval and notify the Government of FDA decisions as these take place.

If applicable, the Awardee shall prepare an IND/BLA in the Electronic Common Technical Document (eCTD) format for submission to the FDA and the Government. The Awardee shall submit all pre-IND, IND, pre-EUA, and/or BLA report submissions to the AOR for review. The Awardee will take into consideration the comments provided by the AOR and provide the final document being sent to FDA to the AOR. The Awardee shall provide all written communications to and/or from the FDA to the Government as it takes place. The Awardee shall courtesy copy the AOR on all email traffic to the FDA and will forward all emails received from the FDA to the AOR. The Awardee will allow a minimum of two (2) government representatives to any meeting with the FDA. Meeting minutes will be forwarded to the AOR within seven (7) calendar days of the meeting or teleconference.

All documentation submitted to the Government must have quality oversight from an independent quality group not reporting to the executing management group (for example, clinical trials group, data management group, etc.).

6. Miscellaneous Data Submissions

If applicable, the Awardee must submit to the Government all Point Papers, Briefings, Technical Performance Plans (TPP), Program Development Plans (PDP), Regulatory Strategy, Technology Transfer Report and Gap Analysis, Formulation Development, Feasibility and Optimization Reports, United States Army Medical Research and Material Command Animal Care and Use Review Office (USAMRMC ACURO) Approvals, Human Resources Operations Branch (HROB) Approvals, Technical Presentations and Publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: pharmaceutical development, manufacturing development, manufacturing validation, completed batch records, certificates of analysis, analytical development and validation, drug substance and product stability, nonclinical testing, and clinical testing. Examples include clinical performance and clinical quality documentation.

7. Work Breakdown Structure

Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. A Party (as applicable) shall provide changes to draft(s) within ten (10) calendar days of such request and provide the final document within ten (10) calendar days after approval of changes is received.

8. Integrated Master Schedule

The Awardee shall provide within fifteen (15) calendar days after project award an IMS in Microsoft Project format. Any updates to the IMS shall be included in the monthly progress reports.

Submission shall be fifteen (15) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional five (5) calendar days to revise the Deliverable or respond to those comments.

9. Incident Report.

The Awardee shall report any incident to the Government that could result in more than a one (1) week delay in schedule from the most recent IMS critical path delivered to the Government and telephonically contact the GPM within one (1) day of such incident. A written summary report shall be submitted within three (3) business days of an incident, to include, what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place.

10. Quality Agreement.

The Awardee shall submit a draft quality agreement ("**Quality Agreement**") within thirty (30) days following the Effective Date for Government review. Upon acceptance by the Parties and any required third parties, the Quality Agreement is to be executed by both Parties. This Quality Agreement must flow down to all subawards.

ARTICLE 9. Confidential Information

A. Definitions

i. "**Disclosing Party**" means the Party who discloses Confidential Information as contemplated by the subsequent Paragraphs.
ii. "**Receiving Party**" means the Party who receives Confidential Information disclosed by a Disclosing Party.
iii. "**Confidential Information**" or "**Proprietary Information**" means confidential and/or proprietary information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade

Secret (as defined below) if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. Confidential Information includes any information and materials considered a Trade Secret by the Awardee. "**Trade Secret**" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if –

a. The Disclosing Party thereof has taken reasonable measures to keep such information secret; and
b. The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

B. Exchange of Confidential Information: Neither Party shall be obligated to transfer Confidential Information independently developed by or on behalf of such Party absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

C. Authorized Disclosure: The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties (other than, in the case of Awardee, its and its Affiliate's employees, consultants, or other representatives who are bound by written obligations of confidentiality and non-use at least as stringent as such obligations set forth herein) or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article 11, Intellectual Property Rights, and Article 12, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

i. Are received or become available without restriction to the Receiving Party under a proper, separate agreement,
ii. Are not identified with a suitable notice or legend per Article 12 entitled "Confidential Information" herein,
iii. Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,
iv. Are or later become part of the public domain through no fault of the Receiving Party,
v. Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,
vi. Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,
vii. Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such

Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

D. Return of Proprietary Information: Upon the request of the Disclosing Party, the Receiving Party shall promptly return or destroy all copies and other tangible manifestations of the Confidential Information disclosed to Receiving Party. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media. Notwithstanding the foregoing, the Receiving Party (i) may retain one (1) copy of the Confidential Information, solely for evidentiary and/or auditory purposes and only to the extent such retention is required by internal procedures, professional standards or applicable law and (ii) shall not be obliged to delete automatically generated computer back-up copies of the Confidential Information generated in the ordinary course of information system procedures and stored securely by the Receiving Party, at all times subject to Receiving Party's ongoing obligations of confidentiality and non-use hereunder.

E. Term: A Receiving Party's obligations of confidentiality and non-use with respect to Confidential Information shall continue for a period of seven (7) years from expiration or termination of this Agreement; provided, however, that with respect to Confidential Information that constitutes a Trade Secret of the Disclosing Party, such obligations shall continue for so long as such Trade Secret is protected under applicable law.

F. The Government shall flow down the requirements of this Article 9 to their respective personnel, member entities, agents, and awardees (including employees) at all levels, receiving Confidential Information under this Agreement.

ARTICLE 10. Intellectual Property Rights

A. Background IP 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**")[1]. Except as expressly set forth in this Agreement or as the Parties may otherwise agree in writing, all right, title, and interest in and to any and all Intellectual Property conceived, reduced to practice, generated, or made by any Party, individually or jointly with another party arising from the performance of the activities under the Statement of Work that is specifically directed to a Deliverable and which does not require the use of Awardee's Background Intellectual Property or Improvement IP (defined below) shall belong solely to Government ("**Government IP**"). Awardee shall and hereby does assign all right, title, and interest in and to such Government IP to Government. Awardee shall promptly notify and disclose to Government in writing all such Government IP. Awardee shall, upon the reasonable request of Government, execute such documents, including any and all applications, assignments, or other instruments, give any testimony, and take such other reasonable actions as Government deems reasonably necessary to apply for, secure, and maintain patent or other proprietary

[1] Awardee owns or controls certain rights in Intellectual Property covering Awardee's platform technology including, but not limited to, antibody discovery, optimization, expression, processing, and manufacturing. Subject to confidentiality obligations, a listing of relevant patent applications claiming the foregoing will be provided to the Government upon written request.

protection in the United States or any other country with respect to such Government IP. "**Intellectual Property**" shall mean all intellectual property (whether or not patented or patentable), including patents, patent applications, trade secrets, copyrights, trademarks, designs, concepts, technical information, manuals, standard operating procedures, instructions, know-how, or specifications.

B. Improvement to Awardee's Background IP. If an improvement is made to Awardee's Background Intellectual Property in performance of the activities under the Statement of Work ("**Improvement IP**"), then Awardee shall solely own such Improvement IP. Government shall and hereby does assign all of its right, title, and interest in and to such Improvement IP to Awardee. Government shall, upon the reasonable request of Awardee, execute such documents, including any and all applications, assignments, or other instruments, and take such other reasonable actions as Awardee reasonably deems necessary to apply for, secure, and maintain patent or other proprietary protection in the United States or any other country with respect to Government's assignment of rights in such Improvement IP.

C. Deliverables; Ownership and Non-Exclusive License

(1) (a) As between the Parties and subject to Section 10.C(1)(b), the Government shall solely own all right, title, and interest in and to Product(s). (b) Awardee hereby grants to Government, a worldwide, perpetual, irrevocable, non-terminable, fully paid-up, royalty-free, non-exclusive license, with a right to sublicense, to use or exploit Awardee's Intellectual Property (including Awardee's Background IP and Improvement IP solely to the extent embodied in Product(s) and solely to the extent required to use or exploit such Product(s) provided, however, that except as otherwise expressly provided in this Agreement, (i) Awardee grants no license, express or implied or otherwise, to Government to use or exploit Awardee's Intellectual Property (including Awardee's Background Intellectual Property or Improvement IP) for any other purpose (including, but not limited to, development and/or manufacturing) of Products or for any other product(s).

(2) Patent Prosecution. The Party owning Intellectual Property arising from this Agreement is solely responsible for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications for such Intellectual Property.

(3) 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.

(4) Nothing in this Agreement prevents Awardee from carrying out activities for any other person or entity, including any activities that use products or processes that are similar to the Government Materials and the processes used to perform work under this Agreement, provided that such services will not use any of Government's Confidential Information, Government's Intellectual Property, or Government Property, and will not conflict with the performance of work for Government under this Agreement. "**Government Materials**" shall mean the materials to be provided to Awardee by Government for the performance of the work including, but not limited to, stable pools or other biological materials.

ARTICLE 11. Data Rights

A. (1) All Product-specific data ("**Product Data**") generated in connection with the performance of this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee's Confidential Information, whether generated by the Government or the Awardee, shall be solely owned by the Government and shall be regarded as the Confidential Information of the Government. Such Product Data will be provided by Awardee to the Government as Data Deliverables (defined below). (2) Notwithstanding anything to the contrary in this Agreement, the Government hereby expressly agrees that Awardee may use Product Data in a blinded format for Awardee's platform technology development and third party service provision purposes. Awardee agrees that such Product Data shall not be disclosed to third parties except as permitted by operation of Section 9.C of this Agreement.

B. The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this Agreement, all Product Data generated under this Agreement. Awardee agrees to deliver at no additional cost to the Government, copies of all Data Deliverables, in Awardee's possession and developed under this Agreement, necessary to deliver the supplies within sixty (60) calendar days from the date of the written request.

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

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911QY-20-9-0015 between the Government and the Awardee."

Any rights that the Awardee or the Government may have in Data Deliverables 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 11.

ARTICLE 12. Foreign Access to Data.

A. 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 Product Data derived from work executed under this Agreement. This publication plan will identify key new Product Data to be disclosed or presented and the target date for finalizing any related scientific abstract or manuscript. As part of its Quarterly Program Reviews, 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/gui delines-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 ten (10) business days for abstracts, or less than ten (10) business days if agreed by Project Managers and in order to meet publication submission deadlines. Review periods are twenty (20) 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 joint press releases related to the Product Data or entry into this Agreement. If both Parties agree that the Parties will issue such a joint press release(s), 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 work, will have review rights and will be appropriately accredited in the press release(s). 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. Government agrees that Awardee has the right to use and practice Intellectual Property owned or controlled by the Government solely as necessary for performance of the activities under the Statement of Work. Except as expressly set forth herein, nothing in this Agreement constitutes express or implied Government authorization and consent for Awardee to utilize, manufacture or practice Intellectual Property owned or controlled by the Government (whether or not 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 arising from this Agreement. When reasonably requested by a Party, all evidence and information in possession of the other Party pertaining to such claim or lawsuit will be provided to the requesting Party at no cost to the requesting Party.

C. Limitation of Liability. In each case to the extent permitted by applicable law, except for (1) breach of confidentiality obligations and (2) the Government's acknowledgement of and agreement to Awardee's immunity from liability arising from operation of Article 14(L) hereunder, 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 Article 10, 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 AO 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 (each, a "**Force Majeure Event**") provided that such performance shall be excused only to the extent of and during such disability and the affected Party shall use Commercially Reasonable Efforts to resume performance as soon as reasonably practicable and provided that such Force Majeure Event was not caused by such Party's negligence or willful misconduct. Any time specified for completion of performance in a Statement of Work and falling during or subsequent to the occurrence of any or all such Force Majeure Events shall be automatically extended for a commercially reasonable period of time to enable the non-performing Party to recover from such Force Majeure Event. Examples of Force Majeure Events are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, epidemic or pandemic, freight embargos, fire, flood, or strikes. The Party asserting the occurrence of a Force Majeure Event as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events. "Commercially Reasonable Efforts" means the performance of obligations or tasks by a Party in an active and sustained manner using a level of effort consistent with the exercise of good faith and prudent scientific and business judgment as commonly practiced in the pharmaceutical industry for the development of Products at a similar stage of development.

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. 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.

H. 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) the Articles of this Agreement, and the Appendices to the Agreement.

I. Integration. This Agreement reflects the entire understanding and agreement between the Parties with respect to the subject matter hereof and supersedes any or all prior or contemporaneous (oral or written) communications, understandings, representations, and agreements, express or implied, between the Parties with respect to the subject matter hereof. The Parties acknowledge that the existence or use of the PD2 version of this Agreement does not affect the foregoing.

J. Assignment. Awardee shall not assign its rights, or delegate its obligations, under this Agreement, in whole or in part, without the prior written consent of the Government, except to a successor-in-interest of Awardee's business unit or activities to which this Agreement is related or to an Affiliate. Any attempted assignment in violation hereof shall be void. "**Affiliate**" shall mean, with respect to Awardee, any corporation or other entity that controls, is controlled by, or is under common control with Awardee. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or controls, directly or indirectly, fifty percent (50%) or more of the voting power of the other corporation or entity or otherwise has the power to control its general activities.

K. DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY DISCLAIMS ALL REPRESENTATIONS, AND WARRANTIES, WHETHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

L. Immunity From Liability. In accordance with the Public Readiness and Emergency Preparedness Act ("**PREP Act**"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 USC 247d-6e), as well as the Secretary of HHS' Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (the "**PREP Act Declaration**"), 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), (i) this Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration; (ii) Awardee's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and (iii) Awardee is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration. Therefore, in accordance with Section IV and VII of the PREP Act Declaration as well as the PREP Act (42 USC 247d-6d), the Government expressly acknowledges and agrees that Awardee shall be immune from suit and liability to the extent and as long as Awardee's activities under this Agreement fall within the terms and conditions of the PREP Act and PREP Act Declaration. In accordance with the PREP Act, such immunity extends to all claims for loss caused by, arising out of, relating to, or resuming from the administration to or the use by an individual of a Covered Countermeasure. "**Loss**" means any type of loss including – death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or damage to property, including business interruption loss. Under the PREP Act, a manufacturer (e.g., Awardee) as a Covered Person includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a covered countermeasure; and any or all of the parents, subsidiaries, Affiliates, successors, and assigns of a manufacturer.

Appendix A
Statement of Work

1. Statement of Work: Production of Monoclonal Antibody Product Countermeasures Against the Threat COVID-19

1.1. Task 1- Cell Line Development

Objective
A highly productive clonal cell line with sufficient expression to meet clinical mass demands will be generated for each antibody. These clonal lines will be used for the creation of MCBs and associated rigorous testing to meet cGMP requirements.

Activities
Government will transfer Stable Pools to Awardee (b) (4)

Deliverables
1. Cell Line Development Report: Includes vector, cell line development and bioreactor run summary
2. Research Cell Bank Testing Report

Go/No-Go decision point
1. Greater than 1 g/L in 10 day fed-batch plate assay
2. Amino acid sequence verification of selected clones

1.2 Task 2 - Upstream Process Development

Objective
The upstream process development activities define the process conditions suitable for scale-up and clinical manufacturing. If necessary, the platform process conditions will be modified to maximize titer and

optimize product quality.

Activities

(b) (4) [redacted]

Deliverables
1. Bioreactor run summaries included in a Cell Line Development report to be provided.
2. Upstream Process Transfer Document (PTD): Supports cGMP run
3. Team supply from 2L bioreactor

Go/No-Go decision point
1. Expression of greater than 6 g/L in 2L IFB bioreactors
2. Product quality to meet acceptance criteria

1.3 Task 3 - Cell Bank Creation and Testing

Objective
To generate a master cell bank suitable for cGMP production.

Activities

(b) (4) [redacted]

This will ensure that subsequent bioreactor development and ultimately GMP DS manufacturing will be successful.

Awardee creates MCB

An MCB o (b) (4) vials for each mAb will be created and frozen at Awardee, (b) (4)

Table 1 Assays Used for Master Cell Bank Testing

Sterility
Bacteriostasis & Fungistasis
Mycoplasma by PCR, USP, EP, PTC
(b) (4)

Deliverables

1. MCB Production Batch Record
2. Certificate of Analysis for MCB
3. Certificate of Conformance for MCB
4. MCB vials remaining upon release of MCB will be shipped to the Government's designated storage facility within 1 month.

Go/No-Go decision point

1. Passed all testing for MCB

1.4 Task 4 - Downstream Process Development

Objective

To develop a purification process for each antibody that meets final DS platform specifications and viral clearance targets to support a phase 1/2 clinical trial.

Activities

(b) (4)

(b) (4)

Table 2 Outline of Viral Clearance Testing Strategy

Step	Virus	Mechanism of Clearance
(b) (4)		

Deliverables

1. Downstream Process Development Report
2. Downstream Process Transfer Document (PTD): Supports cGMP Run
3. Scaled-down Model Qualification Report: Supports viral clearance study
4. Viral Clearance Summary Report: Includes retroviral-like particle (RVLP) clearance calculations based on RVLP quantitation of the cGMP production culture.

Go/No-Go decision point

1. Overall process yield > 60%
2. Purity level > 95% by SEC
3. HCP level < 200 ppm

1.5 Task 5 - Analytical Method Development/Qualification and Extended Characterization

Objective

Phase 1/2 IND fit-for-purpose method qualification for each antibody will be performed according to ICH Q2R1. In-process samples will be evaluated during development to support the downstream scaled down models used for viral clearance and intermediate hold stability assessment. The purified development material generated from the bioreactor experiments will be used as an interim reference standard (iRS) and will be used to establish methods that are fit-for-purpose. DS and DP are proposed to have the same formulation and protein concentration to eliminate additional DP sample qualification activities. Extended characterization will be performed to verify sequence, confirm disulfides, and assess levels of post-translational modifications using the multi-attribute method.

Activities

Method Development (b) (4)

(b) (4)

Methods Robustness (b) (4)

Method Qualification: (b) (4)

Compendial Assays (b) (4)

Extended Characterization (b) (4) will be characterized using (b) (4) to verify (b) (4) as indicated in Table 3.

Table 3 Product Characterization Testing

Attribute	Release or Characterization Method	iRS	RS	GMP DS
Appearance	(b) (4)			
Purity				
Charge Variants				
Glycans				
Process Impurities				
Potency				
Identity				
Adventitious Agents				
General				
Quantity				
Sequence Confirmation				
Disulfide Confirmation				
Isoelectric Point				
Post-translational modifications				

This is a platform assay list and may be adjusted for specific program needs or CQAs.

Deliverables
1. Qualification Summary Reports for each analytical method containing description of method and tables of the fit for purpose results
2. Quality Control Analytical Methods (test method SOPs)
3. Extended characterization report (for cGMP material)

Go/No-Go decision point
1. mAbs pass neutralization activity assay (provided by Government, or pseudovirus assay from Evotec)

1.6 Task 6 - Formulation Verification

Objective
Phase 1 IND fit-for-purpose formulation development to support long-term storage of DS and DP will be performed for each antibody. It is assumed that frozen liquid DS and DP formulations are acceptable. The DS will be formulated the same as the DP and stored frozen. The DP will be filled up to a volume of 1.4 mL in Schott RTU Fiolax clear glass vials, ISO2R, with a fluoropolymer coated grey butyl rubber stopper and aluminum crimp seal. The platform formulation of 10mM acetate, 9% sucrose, and pH 5.2 with 0.01% PS80 up to 100 mg/mL will be used. The assays used for the formulation verification studies are described in Table 4.

Activities
DS Formulation verification studies (b) (4) [redacted]

DP Formulation Verification Study: (b) (4) [redacted]

IV and / or Syringe Stability (b) (4) [redacted]

The intent of the IV bag study is to demonstrate the DP in IND development will not show excessive physical degradation when infused through IV bags and infusion lines. (b) (4) [redacted]

The intent of the syringe hold study is to demonstrate the DP in IND development will not show excessive physical degradation when prepared and held in a syringe as prepared for subcutaneous administration. (b) (4) [redacted]

Transcription Study: (b) (4)

Deliverables

1. Formulation Development Report: Summarizes stability data in support of formulation recommendation and syringe and/or IV bag compatibility to support clinical studies.

Table 4 Formulation and Toxicology/Lead Lot Verification

Attribute	Method	Method Purpose	DP and DS	Freeze/Thaw, Transport, IV and/or Syringe
Appearance	(b) (4)			
Purity				
Charge Variants				
Potency				
General				
Quantity				
Particles				
Post-translational modifications				

(b) (4)

Go/No-Go decision point

1. Accelerated testing (30°C) < 3%/month aggregates and <3%/month clipping by SEC.

1.7 Task 7 - Toxicology Supply and Lead Lot Stability

Objective

For each antibody, non-cGMP drug substance for IND-enabling preclinical and toxicology studies will be produced and filled into containers suitable for the nonclinical studies.

Activities

(b) (4)

(b) (4) [redacted]

Deliverables
1. Toxicology Campaign Report
2. Certificate of Testing
3. A mutually agreed-upon amount of Toxicology DS and diluent.
4. Reference Standard (300 vials, 100 µl each)
5. Toxicology DP Stability testing results

1.8 Task 8 - cGMP Manufacturing of Clinical Drug Substance

Objective
Awardee will perform up to 6 total 500L cGMP runs to provide drug substance for Phase 1/2 clinical trials, cGMP stability studies, and viral clearance assessment. An early read on the productivity of the stable cell line pools will inform the likelihood of obtaining desired mass from such runs.

Activities
Awardee will prepare all necessary documents for process transfer and production of each cGMP drug substance (b) (4) [redacted]

Deliverables
1. Bill of Materials (BOM)
2. Manufacturing Batch Records (MBRs)
3. Sampling and In-process Testing Plan
4. Campaign Summary: Includes the manufacturing process summary, run data, and in-process assay results
5. Filled DS for Phase 1 clinical studies
6. Placebo if requested

1.9 Task 9- Reference Standard Characterization

Objective
To characterize an interim reference standard created from the 2L clone selection bioreactor experiment and a reference standard (RS) created from the Toxicology run for each antibody. These standards will be used as method suitability controls during cGMP DS and DP release and stability testing.

Activities

Interim Reference Standard (b) (4) [redacted]

(b) (4) [redacted]

Reference Standard: (b) (4) [redacted]

Deliverables
1. Interim Reference Standard
2. Reference Standard
3. Reference Standard CoA
4. Reference Standard Characterization Protocol
5. Reference Standard Characterization Report

1.10 Task 10 - GMP DS Release Testing and Stability

Objective
To perform drug substance lot release and stability testing of cGMP-produced material. DS stability data (12-month duration) will be used in the DS stability section of the IND to demonstrate product stability at the ≤ -70°C storage condition.

Activities
(b) (4) [redacted]

Table 5 GMP DS Stability Testing

Stability Condition	Test Interval – Time point (months)
(b) (4) [redacted]	

Specification Generation (b) (4) [redacted]

cGMP Drug Substance Release and Stability Testing (b) (4) [redacted]

(b) (4)

[redacted]

Deliverables

1. cGMP DS CoA and CoC
2. DS Stability Summary Tables
3. Approved specification
4. Reagent clearance report

Table 6 GMP DS Release Assays

Attribute	Release Method	Stability Method	Method Purpose	Method Type	Proposed Product Quality Targets
Appearance	(b) (4)				
Purity					
Charge Variants					
Process Impurities					
Potency					
Identity					
Adventitious Agents					
General					
Quantity					

1.11 Option for Comparability Studies (Ology Fed-Batch and Awardee iFB)

Given the early stage of development of the two COVID-19 antibody projects, thoroughly defined product quality profiles and critical quality attributes have not yet been established for either molecule. However,

given that both are fully human monoclonal antibodies directed against SARS-CoV2, some aspects of a likely comparability exercise can be described. First, as development proceeds, product quality information from both the fed-batch process and IFB process should be shared to maintain alignment between the process formats if possible. Second, criteria around known CQA, such as potency by binding ELISA, or pseudovirus testing, process related impurities (such as host cell protein level) and product related impurities (such as high molecular weight) should meet proposed (and shared) specification requirements for release and stability (refer to Table 4 for proposed release and stability tests and specifications). If, during development, specific product quality attributes are deemed critical, or speculated to be critical in addition to those listed above as specification release/stability tests, they should be added to a comparability protocol, have tests rigorously developed and qualified, and have pre-defined acceptance ranges established.

The general approach listed above should only serve as a starting point for defining comparability between product produced at Ology Bioservices, Inc. using a fed-batch process, and that from Awardee using an IFB process. As information is gained from clinical design, including the number of study arms, the desire to separate or blend the two products in the same or similar trials, and the evolving understanding of the critical quality attributes of the two products, the protocol and underlying comparability acceptance criteria should be updated to ensure the highest probability of equivalent safety and efficacy between the products.

1.12 Quality Oversight and Regulatory Support

Awardee will provide stage-appropriate quality assurance and a quality management system for drug substance manufacturing with the ability to (a) ensure drug substance readiness for drug product(s) fill finish and subsequent entry into Phase 2 clinical trials; (b) support the Sponsor of the drug product in writing all of the required regulatory filings in particular the CMC section; and (c) support drug products slated for EUA or licensure within 12-18 months. Awardee's quality systems are designed to ensure compliance with all phase appropriate regulatory standards and guidance documents. Awardee will ensure appropriate raw materials and standards are used in manufacturing and quality control. cGMP operations will meet phase appropriate compliance and produce high quality products. Awardee will host a quality systems audit and prepare for a successful production campaign. A Quality Agreement between Awardee and the Sponsor will be prepared in order to outline the roles and responsibilities of each Awardee and the Sponsor as they apply to GMP and Quality Systems requirements. The Quality Agreement should be in place prior to the initiation of a GMP run. Through timely and frequent communication, the Government will be informed of the compliance status of the project. Awardee will collaborate and ensure timely reporting of incidents to facilitate an on-time disposition of product. Awardee will also provide an electronic disposition documentation package suitable for regulatory filings.

1.13 Estimated Project Timelines

Figure 2 and Figure 3 present estimated project timelines for the two antibody manufacturing programs described in this SOW (Section B.1). The timeline shown in Figure 1 details project activities beginning with the transfer of a sequence to Awardee on June 15, 2020. The timeline shown in Figure 2 details project activities beginning with the transfer to Awardee of either a RCB or an MCB on September 1, 2020. Both timelines assume that no additional process development work outside of this SOW will be required prior to GMP manufacturing. In addition, the GMP manufacturing run slots shown in the timelines are estimated dates. We currently have other projects competing for the Q1 run dates; however, we recognize the expediency needed for this project and we will work together to secure the fastest manufacturing run

schedule.

Note: A revised timeline will be created upon receipt of cell lines at the end of June, 2020. We are assuming a manufacturing start date for Run #1 in early September 2020 and start date for Run #2 in late September. The additional 4 runs will be initiated in H1 2021 with further resolution with respect to timing to be provided in the IMS.

(b) (4)

(b) (4)

2.0 Deliverables

2.1 Data Deliverables

Deliverable*	**Frequency**	**Schedule***	**SOW Ref**	**Data Rights****
Cell Line Development Report	Once	Month 4	Task 1	Bioreactor Run data provided in summary format
Research Cell Bank Testing Report	Once	Month 4	Task 1	Supporting data
Bioreactor run summaries	Once	Month 4	Task 2	Supporting data
Upstream Process Transfer Document	Once	Month 3	Task 2	Supporting data
MCB Production Batch Record	Once	Month 4	Task 3	Supporting data
Certificate of Analysis for MCB	Once	Month 6	Task 3	Supporting data
Certificate of Conformance for MCB	Once	Month 6	Task 3	Supporting data
Downstream Process Development Report	Once	Month 5	Task 4	Supporting data
Downstream Process Transfer Document	Once	Month 3	Task 4	Supporting data

Scaled-down Model Qualification Report	Once	Month 5	Task 4	Supporting data
Viral Clearance Summary Report	Once	Month 5	Task 4	Supporting data
Qualification Summary Reports for each analytical method	Once	Month 6	Task 5	Supporting data
Quality Control Analytical Methods	Once	Month 4	Task 5	N/A
Extended characterization report (GMP DS)	Once	Month 6	Task 5	Supporting data
Formulation Development Report	Once	Month 5	Task 6	Supporting data
Toxicology Campaign Report	Once	TBD	Task 7	Supporting data
Tox Certificate of Testing	Once	TBD	Task 7	Supporting data
Bill of Materials (BOM)	Once	Month 1	Task 8	N/A
Manufacturing Batch Records	Once	Month 1	Task 8	Supporting data
Sampling and In-process Testing Plan	Once	Month 2	Task 8	Supporting data
Campaign Summary	Once	Month 5	Task 8	Supporting data
Reference Standard CoA	Once	Month 5	Task 9	Supporting data
Reference Standard Characterization Protocol	Once	Month 4	Task 9	Supporting data
Reference Standard Characterization Report	Once	Month 6	Task 9	Supporting data
cGMP DS CoA and CoC	Once	Month 5	Task 10	Supporting data
DS Stability Summary Tables	1, 3, 6, 9, 12m	Month 5, 7, 10, 13, 15	Task 10	Supporting data
Reagent clearance report	Once	Month 5	Task 10	Supporting data
Approved specifications	Once	Month 5	Task 10	N/A
Progress and Financial reports	Quarterly	Month 4, 7, 10, 13, 16	N/A	N/A
Integrated Master schedule/timeline	Quarterly	Month 4, 7, 10, 13, 16	Section 1.13	N/A
Final Project Report	Once	Month 18	N/A	N/A
Regulatory documentation	As required	As required	Section 1.12	N/A

*Deliverables and schedule are listed for the first mAb candidate, the same deliverables will be generated for the 2nd mAb; however, the schedule will be shifted by 1 month.

****Data Rights:** Subject only to Awardee's limited right to use Product Data by operation of Section 11.A.(2), the Government owns all right, title, and interest in and to and Product-specific deliverables-associated data ("**Data Deliverables**") for continuing Product development, manufacture, and commercialization. Awardee will enable the Government with all relevant Product Data supporting a specific deliverable.

2.2 Supply Deliverables

mAb No. 1:

Deliverable	Frequency	Schedule	SOW Ref	Data Rights*
Team supply from 2L bioreactor	Once	Month 1	Task 2	Standard characterization data
Research Cell Bank	Once	Month 3	Task 2	N/A
Interim Reference Standard	Once	Month 1	Task 9	Supporting data
Any MCB vials remaining upon release of MCB (shipped to the Government's designated storage facility within 1 month)	Once	Month 6	Task 3	N/A
Mutually agreed-upon amount of Toxicology DS and diluent	Once	Month 5	Task 7	N/A
Reference Standard (300 vials, 100 µl each)	Once	Month 4	Task 7	Supporting data
Filled DS for clinical studies	Up to 5 runs for a maximum total of 6 runs inclusive of mAb 2	Initial Run: Month 5; Additional estimated in H1 2021	Task 8	Supporting data
Placebo (if requested)	Once	Month 4	Task 8	Supporting data

mAb No. 2:

Deliverable	Frequency	Schedule	SOW Ref	Data Rights*
Team supply from 2L bioreactor	Once	Month 2	Task 2	Standard characterization data
Research Cell Bank	Once	Month 4	Task 2	N/A
Interim Reference Standard	Once	Month 2	Task 9	Supporting data
Any MCB vials remaining upon release of MCB (shipped to the Government's designated storage facility within 1 month)	Once	Month 7	Task 3	N/A
Mutually agreed-upon amount of Toxicology DS and diluent	Once	Month 6	Task 7	N/A
Reference Standard (300 vials, 100 µl each)	Once	Month 5	Task 7	Supporting data

Deliverable	Frequency	Schedule	SOW Ref	Data Rights*
Filled DS for clinical studies	Up to 5 runs for a maximum total of 6 runs inclusive of mAb 1	Initial Run: Month 6; Additional estimated in H1 2021	Task 8	Supporting data
Placebo (if requested)	Once	Month 5	Task 8	Supporting data

***Data Rights:** Subject only to Awardee's limited right to use Product Data by operation of Section 11.A.(2), the Government owns all right, title, and interest in and to and Product-specific deliverables-associated data ("**Data Deliverables**") for continuing Product development, manufacture, and commercialization. Awardee will enable the Government with all relevant Product Data supporting a specific deliverable.

Appendix B
Project and Payment Schedule

The below payment schedule is traceable to applicable task(s)/deliverable(s) identified within the Statement of Work. Payments are due upon completion and acceptance of all deliverables within each phase. An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements within ten (10) days of the Deliverable being submitted.
IAW with F.1 "Financial Matters", the type of payments made under this PPO are Fixed Amount and Cost Based as proscribed below.

(b) (4)

(b) (4)

(b) (4)

The Awardee shall proceed with the performance of the above tasks in accordance with the terms and conditions of this Agreement and its Appendices.

Appendix C
Key Personnel

1. Awardee's Organization and Key Personnel.

The Awardee's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the effort.

The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the AO. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the AO not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No reassignment shall be made by the Awardee without written consent of the AO. The "Key Personnel" list presented in Table 1 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

Table 1. Key Personnel

(b) (6)

Appendix D
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 under fixed price terms of this Agreement (FP-GP) if 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]:

N/A

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, reasonable 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.

(b) (6)

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)
P00001	17-Nov-2020	0011519490-0001	

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)		
JUST-EVOTEC BIOLOGICS, INC. 401 TERRY AVE N 2ND FL SEATTLE WA 98109-5263		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090015
	X	10B. DATED (SEE ITEM 13) 07-Jul-2020
CODE 7PFN4	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 _____ 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 correct the CLIN structure to include multiple deliveries on CLINs 0003, 0004, 0005, and 0006 and reduce the unit prices accordingly. 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) (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)	13-Nov-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:

P00001

A. The purpose of this amendment is to correct the CLIN structure to include multiple deliveries as follows.
   a. CLIN 0003 delivery quantity is hereby increased from (b) (4) CLIN 0003 unit price is reduced by $(b) (4) from $(b) (4) to $(b) (4) The total cost of CLIN 0003 is unchanged.
   b. CLIN 0004 delivery quantity is hereby increased from (b) (4) CLIN 0004 unit price is reduced by $1(b) (4) from (b) (4) to (b) (4). The total cost of CLIN 0004 is unchanged.
   c. CLIN 0005 delivery quantity is hereby increased from (b) (4) CLIN 0005 unit price is reduced by (b) (4) from (b) (4) to (b) (4) The total cost of CLIN 0005 is unchanged.
   d. CLIN 0006 delivery quantity is hereby increased from (b) (4) CLIN 0006 unit price is reduced by $(b) (4) from $(b) (4) to (b) (4). The total cost of CLIN 0006 is unchanged.
B. All other terms and conditions remain the same and in full force and effect.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0003

The pricing detail quantity has increased by (b) (4)
The unit price amount has decreased by $(b) (4).

CLIN 0004

The pricing detail quantity has increased by (b) (4)
The unit price amount has decreased by $(b) (4).

CLIN 0005

The pricing detail quantity has increased by (b) (4)
The unit price amount has decreased by (b) (4).

CLIN 0006

The pricing detail quantity has increased by (b) (4)
The unit price amount has decreased by $(b) (4)

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0003 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
06-OCT-2020	1	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
06-OCT-2020	3	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0004 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
06-NOV-2020	1	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

06-NOV-2020	5	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0005 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
06-DEC-2020	1	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
06-DEC-2020	9	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0006 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
06-JAN-2021	1	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

06-JAN-2021	6	JPL CBRND ENABLING BIOTECHNOLOGIES . 110 THOMAS JOHNSON DR FREDERICK MD 21702 FOB: Destination	W56XNH

(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)
P00002	08-Jan-2021	0011519490-0001	

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.
JUST-EVOTEC BIOLOGICS, INC. 401 TERRY AVE N 2ND FL SEATTLE WA 98109-5263		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090015
CODE 7PFN4 FACILITY CODE	X	10B. DATED (SEE ITEM 13) 07-Jul-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 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 designate this agreement as an HRPAS rated order DO-C9 (DO-HR), by incorporating a DPAS rating in SF 26 Block 1 and revising section G accordingly, and to update the GPM and AOR. 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) EMAIL:

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
(b) (6) (Signature of person authorized to sign)	Jan, 8, 2021	BY (b) (6) (Signature of Contracting Officer)	08 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:

P00002

A. The purpose of this Amendment is to designate this Agreement as a Health Resources Priority and Allocations System (HRPAS) rated order in accordance with 45 CFR 101 as approved by the Secretary of Health and Human Services on 22 December 2020.
B. Block 1 of the Agreement SF 26 is hereby revised to reflect a DPAS rating of DO-C9.
C. Section G of the PD2 version of the agreement is hereby revised to incorporate additional detail relating to the order rating.
D. Article 3B is revised to remove (b) (6) as the GPM. The GPM for this agreement is hereby changed to:

(b) (6)

E. Article 4 is revised to remove Candace Rock as the AOR. The AOR for this agreement is hereby changed to:

(b) (6)
Assistant Product Manager
JPL-CBRND Enabling Biotechnologies (JPL-CBRND-EB)
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)

F. Article 7E, Paragraph f.v. is hereby superceded in whole as follows:

v. 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)

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

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-C9 has been added.

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

AGREEMENT ADMINISTRATION

A. In no event shall any understanding of agreement, modification, change order, or other mater in deviation from the terms and conditions 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 agreement document executed by the Agreement Officer.

B. The telephone number and e-mail addresses of the Agreement Officer and Agreement Specialist are:

(b) (6)

(b) (6)

C. The telephone number and e-mail address of the Government Program Manager is:

(b) (6)

D. Order Rating

This is a **DO rated order** for the purpose of emergency preparedness and the Awardee shall follow all the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR Part 101). If the awardee needs to utilize industrial resources to fulfill this rated order for a health resource, it is authorized pursuant to 45 CFR §101.36(b) to place the same priority rating and program identification symbol for health resources on its orders for industrial resources with its suppliers.

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.

(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.

(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.

(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

(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.

(b) (6)

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

(End of clause)

(End of Summary of Changes)

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)
P00003	09-Mar-2021	0011519490-0001	

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)		
JUST-EVOTEC BIOLOGICS, INC. 401 TERRY AVE N 2ND FL SEATTLE WA 98109-5263		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY2090015
	X	10B. DATED (SEE ITEM 13) 07-Jul-2020
CODE 7PFN4	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 changes to Appendices A and B dated 04 March 2021 at no additional cost to the Government. 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 (b) (6) (Signature of person authorized to sign)	15C. DATE SIGNED March 9, 2021	16B. BY (b) (6) (Signature of Contracting Officer)	16C. DATE SIGNED

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 to incorporate changes to the Statement of Work and Payment Schedule, Appendices A and B, dated 04 March 2021. The revised Appendices supercede the previously incorporated versions in full.
B. The total value of this Agreement remains $(b) (4)
C. The total funding for this Agreement remains $(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 the revised Appendices A and B.
E. All other terms and conditions remain the same and in full force and effect.

(End of Summary of Changes)