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

REPLY TO
ATTENTION OF

16 September 2020

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

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-06, Objective Area TRE-PRE-20-06, entitled "Wearable Focused Ultrasound Phased Array Device to Treat COVID-19-Induced Inflammation and Acute Respiratory Distress Syndrome (ARDS)" (The Ultran Group, Inc.)

REF: Request for Updated Proposal Submitted in Response to RPP 20-06 under OTA W15QKN-16-9-1002 for Objective TRE-PRE-20-06, dated 13 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-06 on 04 May 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting The Ultran Group, Inc. as the awardee. The Government requests that a Firm-Fixed-Price Agreement be issued to The Ultran Group to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of The Ultran Group's proposal for "Wearable Focused Ultrasound Phased Array Device to Treat COVID-19-Induced Inflammation and Acute Respiratory Distress Syndrome (ARDS)" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The Cost Proposal that has been analyzed and negotiated final by the Government, you are hereby directed to issue a Project Agreement to The Ultran Group for the subject project. The total project value has been determined fair and reasonable and The Ultran Group's proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed (b) (4). The break-out of the costs is as follows: $1,023,776.00 to perform project efforts included in the SOW

and (b) (4) for the Consortium Management Firm (CMF) Administrative Cost. The effort is fully funded.

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

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

In addition, ATI is advised of the implementation guidance for Section § 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year 2019 (Pub. L. 115–232), which prohibits executive agencies from entering into, extending, or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. While the interim rule and Defense Pricing and Contracting (DPC) implementation memorandum are directed to FAR-based contracts, the § 889(a)(1)(B) prohibition went into effect August 13, 2020, and applies to Other Transactions (OTs) for Prototype Projects under § 2371b of title 10, United States Code (U.S.C.). Any OT for Prototype Project agreement on or after August 13, 2020 must contain an article for the Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment that requires the offeror to represent if it uses any equipment, system, or service that uses covered telecommunications equipment or services.

ATI must receive § 889(a)(1)(B) Certification from the MCDC member prior to executing any new project agreements or modification to an existing project agreement. A copy of the certification should be provided to the undersigned.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail (b) (6)
Phone: (b) (6)

Regards,

(b) (6)

Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: Encl 3_MCDC2006-004 SOW_Rev2

Statement of Work
for
Wearable Focused Ultrasound Phased Array Device to Treat COVID-19-Induced Inflammation and Acute Respiratory Distress Syndrome (ARDS)

RPP #: 20-06
Project Identifier: MCDC2006-004
Consortium Member: The Ultran Group, Inc.
Title of Proposal: Wearable Focused Ultrasound Phased Array Device to Treat COVID-19-induced Inflammation and Acute Respiratory Distress Syndrome (ARDS)
Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) Joint Program Manager-Medical (JPM-Medical)

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

The Ultran Group, Inc. (Ultran) and its subsidiary, SecondWave Systems, Inc. (SecondWave), have developed a wearable medical device to treat inflammation disorders, which occur in high prevalence and have limited treatment options. The method of treatment with this device involves non-invasive low intensity focused ultrasound energy delivery to the spleen to suppress the production of inflammatory cytokines. This device and its therapeutic administration have the potential ability to treat extreme cases of the Coronavirus Disease 2019 (COVID-19), whereby the virus induces the body to produce a 'cytokine storm' that leads to respiratory failure, known as Acute Respiratory Distress Syndrome (ARDS; Mehta et al., 2020).[1] The proposed prototype project and therapy will not only be beneficial to the US civilian population, but also the military.

As there is currently no existing treatment for ARDS in COVID-19 patients, Ultran has repurposed its Miniature Immunotherapy Neuromodulation Instrument (MINI) as a Medical Countermeasure (MCM) for COVID-19 treatment. This enhances Department of Defense (DoD) mission effectiveness, by improving the ability to treat military personnel who contract the disease. The project will potentially allow the US DoD to perform its operations more freely and with less restriction than the currently imposed measures required to deal with COVID-19, reduce negative symptoms of patients, and decrease the death rate within military and civilian populations. This project includes conducting clinical trial(s) and obtaining Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) within approximately (b) months, followed by delivery of a large volume (b) (4) of devices for widespread distribution. The project will deliver monthly, quarterly, and interim reports detailing progress with respect to its objectives, financial performance, and intellectual property generation. A Clinical Study Team (CST) will be formed to meet with the Government on a regular basis (i.e. bi-weekly) to inform status regarding clinical trial design and administration. Ultran will also execute intellectual property, such as patent application submissions, and obtain Institutional Review Board (IRB) and US Army Medical Research and Development Command (as needed) approval for planned preclinical and clinical

[1]Mehta, P., McAuley, D. F., Brown, M., Sanchez, E., Tattersall, R. S., Manson, J. J., & Hlh Across Specialty Collaboration, U. K. (2020). COVID-19: consider cytokine storm syndromes and immunosuppression. Lancet, 395(10229), 1033-1034. doi:10.1016/S0140-6736(20)30628-0

trials (IAW Article XXI, Sections J. and K. of the Other Transaction Agreement, number W15QKN-16-9-1002). Clinical trials will be completed per Good Clinical Practice (GCP) requirements and written to Electronic Common Technical Document (eCTD) standards for FDA submission. The proposed effort will result in a novel state-of-the-art medical device therapy solution for COVID-19 treatment, as well as additional inflammation disorders, to potentially treat rheumatoid arthritis, sepsis, acute kidney injury, Crohn's disease, and inflammatory bowel disease. This treatment provides a heavily desired alternative to expensive anti-inflammatory drugs and biologics, which often include extreme side-effects.

(b) (4) [redacted]

1.2 Scope

This project plan includes the manufacturing of an initial set of devices, as well as facilitation of an animal study and clinical trial for COVID-19 anti-inflammation treatment for ARDS. The output of the clinical trial will include a detailed report with findings regarding administration of therapy, patient response, and recommendations for future treatments using this method. Upon completion of the clinical trial, EUA will be obtained from the FDA, followed by manufacturing of a large volume of units to be distributed for widespread deployment to a larger number of sites.

In addition to the core plan, this effort includes an additional trial site whereby partners at the (b) (4) [redacted] will implement the SecondWave MINI device through their existing collaborations with military units in (b) (4) [redacted], with the ultimate goal to expand to multiple US Service member clinical trial sites. (b) (4) [redacted] will foster and coordinate Service member clinical trials through leveraging of existing (b) (4) [redacted] collaboration, and rapidly reach out to national naval medical centers, (b) (4), (b) (6) [redacted] for eventual multi-site trials. Additional contacts within (b) (4) [redacted] (b) (4), (b) [redacted]) will be activated to synergize additional multi-site Service member clinical trials.

1.3 Objective

The objective of this project is to apply and establish the SecondWave MINI device as a new therapeutic treatment for extreme cases of COVID-19-induced ARDS. This will be achieved by manufacturing initial devices for a clinical trial, facilitation of the clinical trial, and obtaining FDA EUA for the device and therapy. The prototype device is specifically designed for non-invasive treatment for inflammation, deliverable upon a small form factor which can be produced at low cost and in high volume. This positions the MINI system to potentially address the issue of extreme cases of COVID-19, with the possibility of reducing the current death rate. The project

will occur over a 6-month period, and result in the manufacturing and distribution of (b) (4) devices for widespread deployment.

This is a prototype project because the contractor will further develop an ultrasound MINI device to evaluate the technical feasibility of using the device as a therapeutic treatment for extreme cases of COVID-19-induced ARDS.

In accordance with 10 U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures. If follow-on production is desired by the Government, production would need to support approximately (b) (4) advanced prototypes for testing and evaluation, and up to (b) (4) to (b) (4) final units for procurement over a (b) (4) period. This prototype project will be successfully completed if the contractor meets the key technical goals of the project, as listed within this document, meets the success metrics established by this agreement or, at the accomplishment of particularly favorable or unexpected results that justifies transition to production.

If there is a conflict between the Project Agreement and the Base Agreement, the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

This scope of work includes the effort necessary to bring this solution to patients: Support for additional preclinical and clinical studies, device fabrication and volume manufacturing, and regulatory/quality management activities. The detailed work plan is described below.

Stage I: Device Fabrication, Verification, and Clinical Study

Task 1: Complete MINI Wearable System (b) (4) units)

Building upon Ultran's already designed and tested wearable solution, Ultran shall incorporate the latest improvements and fabricate (b) (4) units of the next-generation MINI wearable system. For this effort, Ultran shall continue to leverage its prototype development partners and its own manufacturing site located in State College, PA.

Task 1.1: Fabricate Pulser and Power Boards

The pulser and power boards are the two key components of the MINI system. Ultran has optimized their circuit designs, over the last several years, with aid from its prototype development partner. This sub-task includes incorporating the latest improvements (if necessary) and fabricating PCBs (Printed Circuit Board) of both pulser and power boards.

Milestone(s): Completion of pulser and power bord assembly.

Deliverable(s): Electrical schematics, Bill of Materials (BOM) and PCB layouts (Gerber files) of both pulser and power boards; Fabricated and fully assembled pulser and power PCBs.

Task 1.2: Fabricate Transducer Arrays

Ultran has designed and developed a suite of patented multi-channel ultrasound transducer arrays for the MINI wearable system. This work shall continue to take place at Ultran's manufacturing plant located in State College, PA. Ultran shall produce its next generation transducer arrays for the MINI wearable system, which includes fabrication of GMP™ (Ultran's patented Gas-Matrix Piezoelectric), assembly and testing.

Milestone(s): Manufacture of transducer arrays.

Deliverable(s): Fabricated and fully assembled transducer arrays.

Task 1.3: Fabricate Mechanical Enclosures

Ultran shall finalize mechanical drawings and fabricate enclosures to house the pulser, power and transducer assemblies manufactured in Tasks 1.1 and 1.2. There are two enclosure modules – System Module (houses pulser board and transducer array) and Power Module (houses power board). For this task, Ultran shall continue to utilize its in-house CAD (Computer Aided Design) engineering capabilities and 3rd party machine shops for fabricating enclosures.

Milestone(s): Fabrication of system and power module enclosures.

Deliverable(s): CAD mechanical drawings of system and power module enclosures; Fabricated system and power module enclosures.

Task 1.4: Assemble Patient Coupling Kit

Ultran shall evaluate and identify the optimum coupling mechanism for the MINI wearable system. For this task, Ultran has partnered with (b) (4) a leading manufacturer of class 1 medical devices. Ultran shall continue to work with (b) (4) to design and procure components of a patent coupling kit and assemble the kit at its State College facility.

Milestone(s): Completion of patient coupling kit assembly.

Deliverable(s): BOM; IFU (instructions of use); coupling kits.

Task 1.5: Assemble Device Cleaning and Disinfection Kit (for device reuse)

In order to support proper cleaning and disinfection of the MINI system between uses, Ultran shall develop and furnish a kit containing appropriate commercially available off-the-shelf disinfectants to achieve intermediate-level disinfection in accordance with applicable guidelines (e.g. isopropyl alcohol wipes).

Milestone(s): Procurement and assembly of disinfectants.

Deliverable(s): Assembled disinfection kits.

Task 1.6: Procure Key Accessories/Assemblies (e.g., cabling, power adapter)

(b) (4)

(b) (4) [redacted]

Milestone(s): Purchase and receive AC power adapters and multi-conductor cables.

Deliverable(s): AC power adapters; multi-conductor cables.

Task 1.7: Conduct Final System Integration and Assembly

This task includes the assembly of the system module and power module, followed by full integration of the MINI system by incorporating auxiliary components, such as high-voltage cables and AC power adapters. This work shall take place at Ultran's State College, PA plant. For this effort, Ultran shall use the components manufactured in Tasks 1.1, 1.2 and 1.3, as well as assembled system and power modules with adequate Ingress Protection (IP) rating (IP64 or better).

Milestone(s): Fully assembled standalone, MINI wearable system.

Deliverable(s): Assembled system modules and power modules; Assembled standalone, MINI wearable devices by integrating system modules, power modules, high-voltage cable, and AC power adapter.

Task 1.8: Complete Device Programming (software, firmware)

Ultran has produced firmware capable of operating the MINI wearable system in semi-autonomous mode. Ultran shall provide firmware programming support, which consists of a set of user input variables that provides adequate customization for targeted ultrasound therapy based on the patient profile. Ultran shall determine the appropriate values for user inputs and pre-program the MINI wearable systems that deliver the intended ultrasound therapy.

Milestone(s): Completion of MINI wearable system programming.

Deliverable(s): Pre-programmed MINI wearable systems to deliver the intended ultrasound therapy.

Task 2: Design Verification & Validation (V&V)

Verification and validation of the system shall be conducted under Ultran's Quality Management System (QMS) in accordance with applicable FDA guidance (e.g., Quality System Regulation, Ultrasound guidance) and recognized consensus standards (e.g., IEC 60601-1 for basic safety and essential performance, ISO 14971 for application of risk management). This V&V protocol is designed to (1) establish safety and efficacy of the SecondWave MINI device, and (2) establish a risk-benefit profile consistent with Institutional Review Board (IRB) approval and subsequent FDA EUA.

Task 2.1: Performance Testing for Inflammatory Reduction Therapy Parameter Set

Building on successful benchtop performance and preclinical small animal data from (b) (4) [redacted], Ultran shall conduct similar tests with the MINI system to fully characterize its energy delivery capabilities and establish efficacy in a small animal model.

Task 2.1.1: Ultrasound Stimulation Output Characterization (benchtop)

Ultran shall fully characterize the MINI system's stimulation output to the specifications outlined in the system's Design Inputs documentation. The test protocol shall include measurement of ultrasound pressure output at various points under normal operating conditions and treatment duration/schedule.

Milestone(s): Verification of delivered energy per specification (e.g., depth, treatment duration, etc.).

Deliverable(s): Test report documenting stimulation output characteristics.

Task 2.1.2: Preclinical Small Animal Study with MINI Device

(b) (4) shall complete a small animal study in an inflammation/sepsis rodent model ((b) (4) animals) to confirm that the MINI system can reliably reduce the relevant cytokines and markers (e.g., IL-6, IL-1b, TNF-alpha, IL-10, IL-8, IFN-gamma) that have been described for COVID-19, and leverage the stimulation protocols that shall be used to treat patients. (b) (4) The spleen and lungs shall also be extracted to measure biomarker levels in those tissues. Any animal use shall be reviewed and approved in accordance with Department of Defense Instruction (DoDI) 3216.01, Use of Animals in DoD Programs, by a DoD Component Headquarters Oversight Office. Ultran shall furnish evidence of such registration and approval to the Agreements Officer (AO) and Agreements Officer's Representative (AOR) before beginning work under this contract.

Milestone(s): Validation of MINI function and efficacy through animal study.

Deliverable(s): Report documenting performance of MINI system and preclinical animal outcomes.

Task 2.2: Design Verification and Safety Testing

Ultran shall complete a suite of design verification and safety tests to confirm that the MINI system operates to specification and is safe to use on human patients. These tests consist of: system/hardware and software verification testing per FDA Design Controls guidance, electrical, mechanical, and thermal safety testing (device surface) per IEC 60601-1, thermal safety testing (internal tissues), electromagnetic compatibility per IEC 60601-1-2, and biocompatibility of patient coupling materials per ISO 10993.

Milestone(s): Completion of verification and safety testing.

Deliverable(s): Test reports documenting passing of all verification and safety test criteria.

Task 2.3: Design Validation

Ultran shall complete relevant design validation tests that confirm suitability of the MINI system for its intended use. These tests consist of: patient coupling testing and simulated

use case testing for patient comfort and device usability.

Milestone(s): Completion of design validation testing.

Deliverable(s): Test reports documenting passing of validation test criteria.

Task 3: Human Clinical Study for COVID-19 with MINI System

The safety and feasibility of the MINI device in COVID-19 patients shall be evaluated in a 2-part clinical study performed with partners at (b) (4), where COVID-19 patients will be cared for. In the first part, (b) (4) patients with worsening symptoms who have not yet been admitted into the Intensive Care Unit (ICU) or placed on ventilators, shall be enrolled in the study. Their spleen will be stimulated daily ((b) (4) for up to (b) (4) or until they need to be put onto a ventilator (if necessary). Blood samples shall be taken before ultrasound stimulation and daily, which is important to closely monitor cytokines ((b) (4) for efficacy, as well as to ensure the safety of patients, and that stimulation does not cause unexpected pro-inflammatory or other adverse effects. Success in significantly reducing relevant inflammatory cytokines in at least (b) (4) of the patients without any major safety issues, will enable initiation of the second part of the clinical study. In the second part, there will be (b) (4): a stimulated group and a sham group (b) (4) including during the period when patients are put onto ventilators. Primary outcome measures include reduced days of hospitalization and reduced death rate. Secondary outcome measures include significant reduction in levels of relevant biomarkers, reduction in duration/need of ventilator and enhanced oxygen usage, and reduced number of other organ failures. Any human research shall be reviewed and approved in accordance with Department of Defense Instruction (DoDI) 3216.02, The Protection of Human Subjects and Adherence to Ethical Standards in DoD Conducted and Supported Research. Ultran shall furnish evidence of such registration and approval to the AO and AOR before beginning work under this contract.

Task 3.1: IRB and HRPO Approval

The clinical trial protocol for both parts shall be developed and prepared for treating COVID-19 patients with the MINI device. Based on detailed discussions with the frontline clinicians working daily with COVID-19 patients, and by leveraging the continuously updated findings available in the scientific/clinical field on this topic, the appropriate design and types of patients needed for this clinical trial shall be determined. (b) (4) Following IRB approval, device and study information will be submitted to the U.S. Army Medical Research and Development Command (USAMRDC), Human Research Protection Office (HRPO) for review and approval.

Milestone(s): Submit package to IRB and HRPO; Obtain IRB approval at (b) (4) and USAMRDC HRPO approval to perform the human study.

Deliverable(s): IRB and HRPO submission packages; IRB and HRPO approval letters.

Task 3.2: Trial Part 1

(b) (4) patients shall be initially tested with the MINI device for approximately (b) (4), in order to confirm that relevant biomarkers can be significantly suppressed in response to ultrasound stimulation of the spleen.

Milestone(s): Completion of the human clinical study Part 1.

Deliverable(s): Report summarizing clinical findings from Part 1 of the study.

Task 3.3: Trial Part 2

(b) (4) shall be recruited into a randomized controlled trial, in which (b) (4) shall receive ultrasound stimulation of the spleen for up to (b) (4), while (b) (4) shall receive sham stimulation. Several primary and secondary outcome measures shall be evaluated, including safety of treatment.

Milestone(s): Completion of interim analysis; Completion of the human clinical study Part 2.

Deliverable(s): Interim report and final reports summarizing the clinical findings from Part 2 of the study.

Stage II: FDA Emergency Use Authorization & Volume Manufacturing

Task 4: Regulatory (FDA) Emergency Use Authorization

Ultran shall conduct all activities required to apply for and receive EUA from the FDA, supported by a Regulatory consultancy, (b) (4) by UL. As Sponsor, Ultran shall submit a letter to the FDA, indicating the Senior Director Medical Regulatory (SDMR) as a co-contact and that the FDA is authorized to contact the SDMR for DoD regulatory/policy input as needed for the Ultran development effort. To the maximum extent practicable, the Government will include Ultran in any and all meetings and correspondence with the FDA. If it is not practicable to include Ultran in any interaction with the FDA, the Government will provide a summary of the interaction to Ultran within ten (10) business days. This task includes all FDA engagement as defined in the FDA's EUA guidance, and as directed by the FDA in previous communications with the agency. In addition, this task includes improvements to Ultran's Quality Management System and associated quality processes necessary to achieve EUA and distribute final product. As regulatory planning is largely complete, this task focuses primarily on execution and implementation of this strategy, as defined in the sub-tasks below.

Task 4.1: Product Labeling

Ultran shall develop proposed product labeling (e.g., intended use, indications for use, warnings and contraindications, etc.) for the MINI system, which shall be drafted and negotiated with the FDA during pre-EUA communications, and finalized as part of the final submission.

Task 4.2: Product Materials

Ultran shall develop product documentation to accompany the deployed system. Required documentation for EUA consists of an Instructions for Use (i.e., operator's manual), Fact Sheet for Healthcare Professionals, and Fact Sheet for Patients. Additional user documentation shall be developed as needed, based on user feedback during the clinical studies.

Task 4.3: Compiled Safety and Effectiveness Data

Ultran shall synthesize all data supporting safety and effectiveness of the MINI system. This shall include benchtop (safety and performance), preclinical, and clinical study, as well as previously published data on focused ultrasound in other applications.

Task 4.4: Risk-Benefit Analysis

Ultran shall prepare a risk-benefit analysis following the methodology outlined in the FDA's 2019 guidance on benefit-risk determination.

Task 4.5: Manufacturing Documentation

Ultran shall prepare documentation outlining the MINI system's manufacturing processes, controls, sites, and production capabilities.

Task 4.6: Quality System Summary

Ultran shall summarize and compile artifacts of its Quality Management System and quality processes.

Milestone(s): Submission of pre-EUA package to the FDA; Submission and approval of final EUA package to the FDA.

Deliverable(s): Regulatory Strategy to achieve EUA, pre-EUA and final-EUA packages; MINI system authorized for distribution through EUA pathway.

Task 5: Quality Management System Enhancement

Ultran shall enhance its Quality Management System (QMS) to ensure all components relevant to EUA are in place. This includes formalizing existing Risk Management, Document Control, and Design Control processes (e.g., formal release of Standard Operating Procedures [SOPs], release of key requirements and test protocol documentation), and implementation of additional processes covering production and distribution (e.g., Records Requirements, Distribution Controls, and Medical Device Reporting). Note that the FDA has waived some requirements of its Quality System Regulation for EUA devices; however, Ultran expects that a thorough, documented discussion of its system supports a positive risk-benefit determination, and will enhance pre-EUA engagement with the FDA. In the event there are audits/site visits, One Network of Excellence for Regulatory Affairs and Quality Assurance (ONE-RAQA) SDMR or SME delegated by SDMR, will be invited.

Milestone(s): Completion of QMS enhancement activities.

Deliverable(s): Quality Agreement (if applicable with respect to potential suppliers), Relevant SOPs and Design Control / QMS documentation.

Task 6: Volume Device Manufacturing ((b) (4) MINI units)

This task includes fabrication, assembly, testing, packaging and shipping of (b) (4) units of the MINI wearable device. For this work, Ultran has partnered with (b) (4) a full-service medical device Contract Manufacturer (CM). Ultran first made contact with (b) (4) and since then, both companies have had several meetings, including Ultran's visit to (b) (4) . With (b) (4) sites and an FDA registered QMS, (b) (4) is essentially an extension of Ultran to support its ramp-up

manufacturing needs in Stage 2 and beyond. This task is divided in two parts – manufacturing planning, and manufacturing and shipment of (b) (4) units. Sub-task 6.1 (manufacturing planning) shall be conducted concurrently with Task 1. Sub-task 6.2 (manufacturing and shipment) is aligned with completion of EUA (Task 4). This approach allows Ultran to efficiently manage the manufacturing schedule, while ensuring that the necessary FDA approvals are in place before shipping its first batch of (b) (4) MINI wearable devices.

Task 6.1: Manufacturing Planning

This sub-task of manufacturing planning is crucial for successful transition from prototype to mass production of MINI wearable devices, thereby enabling the fastest time to market on a robust schedule. Ultran shall leverage its commercial partner, (b) (4) for successful completion of Task 6. Ultran recognizes that the process of onboarding the new project, New Product Introduction (NPI), to its CM, is critical and hence shall initiate and execute the following tasks in parallel to Task 1.

Task 6.1.1: Contract Manufacturer Onboarding

Ultran shall review and translate electrical schematics, mechanical designs, PCB layouts and other supporting design documents of MINI wearable devices to be in compliance with (b) (4) .

Task 6.1.2: BOMs Component Lifecycle Analysis

Ultran shall conduct a review of the BOM for technology selection and long-tern component availability, BOM lifecycle analysis, and smaller components, where possible.

Task 6.1.3: Design Alignment to CM NPI Process

Ultran shall test the power supply (b) (4) measure total power used, measure noise, investigate reasonable safety margins, measure efficiency and implement improvements (if necessary). Ultran shall evaluate PCB layouts (for adequate number of layers, trace thickness, ground, supply and signal layers configuration, and copper density) and optimize (if necessary).

Task 6.1.4: Material Vendor Onboarding and Procurement

Ultran shall identify key vendors and set up sourcing channels for specialized components. Ultran shall implement purchase orders and secure necessary components, such as the chipset, enclosures, cables and ultrasound transducer arrays.

Task 6.1.5: Small Prototype Run of 10 Units

This is vital for a smooth NPI process, and allows the CM to familiarize with the assembly of MINI wearable devices. Processes like oven profile creation, cell workstation creation for optimal workflow, tooling verification, and tester troubleshooting, shall be worked out in this small initial run. As a result, (b) (4) shall have a preconfigured manufacturing process for Task 6.2.

Task 6.1.6: Device-Level Test Fixture and Setup

Ultran shall work closely with (b) (4) test engineers and deploy a test fixture at the (b) (4) manufacturing plant at (b) (4). This will allow for robust testing and validation of MINI wearable devices before they are shipped.

Milestone(s): Transition to mass manufacturing of MINI devices.

Deliverable(s): Component lifecycle report; Altium schematics and PCB files, PCB assembly drawings, and Gerber files; Altium BOMs; Test fixture.

Task 6.2: Manufacturing and Shipment

This sub-task shall initiate after successful completion of sub-task 6.1. This work shall take place entirely at (b) (4) manufacturing site in (b) (4)

Task 6.2.1: Fabrication and Assembly of PCBs

Ultran and (b) (4) shall fabricate and assemble multi-layer PCBs of the pulser and power board for MINI wearable devices.

Task 6.2.2: Assembly of System and Power Modules

Using the components procured in Task 6.1.5 and assemblies manufactured in Task 6.2.1, Ultran and (b) (4) shall assemble the System Module and Power Module. Each MINI device set is comprised of both a system and power module connected by a cable.

Task 6.2.3: Device Programming, Testing and Quality Control

Fully assembled MINI devices shall be programmed based on pre-determined ultrasound therapy. Ultran and (b) (4) shall follow programming instructions and test each MINI device in compliance with its QMS. In addition, (b) (4) documentations shall be prepared as required, and shall follow (b) (4) internal (b) (4) process for medical devices, which is written with respect to 21CFR80 design controls.

Task 6.2.4: Labeling and Packaging

(b) (4) shall incorporate elements related to MINI labeling into their QMS, as well as relevant leveling specifications in the design history file. For this work, Ultran will establish labeling procedures, highlighting procurement, storage, attachment, and inspection of the MINI device label. (b) (4) shall follow these labeling guidelines and package the MINI systems before shipping.

Task 6.2.5: Manufacturing of (b) (4) Units Per Week

This task includes manufacturing (b) (4) MINI devices per week, for a total of (b) (4) units. These units are intended for use to support any additional clinical trials and general post-EUA deployment, based on the MINI deployment schedules described in Task 7. (b) (4) is expected to generate and retain necessary batch manufacturing records under its QMS that shows conformance as defined in 21CFR 820.3(i) and 21CFR 820.86.

Task 6.2.6: Shipment of All Remaining Units

Following Emergency Use Authorization, all units not already deployed to clinical trial sites, will be rapidly deployed to targeted general deployment sites.

Milestone(s): Mass manufacturing of MINI devices ((b) (4) devices per week); Shipment of devices to targeted trial sites and general deployment sites.

Deliverable(s): Manufacturing of (b) (4) MINI devices and associated test reports, for a total of (b) (4) units; Shipment of (b) (4) units to trial and general deployment sites.

Task 7: MINI System Deployment

Following EUA, Ultran shall deploy the (b) (4) MINI systems to a pre-identified set of hospitals to benefit their COVID-19 patient populations.

Task 7.1: Site Identification

Ultran shall leverage a strong network of clinicians to identify appropriate sites for the deployment of systems. Criteria shall be established to determine best use of the devices, taking into account the current disease burden in different geographies at the time of deployment, and the ability of each target site to rapidly train clinical staff and deploy into patient care.

Milestone(s): All sites identified for deployment of the (b) (4) systems.

Deliverable(s): List of sites with quantity and timing of device shipments.

Task 7.2: Physician Education

To facilitate adoption, Ultran shall develop materials to educate physicians at each target site on the MINI system attributes and clinical evidence supporting its use. Materials shall be distributed as needed, and may be accompanied by in-person or remote physician meetings for further education in advance of system deployment at the site.

Milestone(s): Completion of physician education materials; Distribution of materials and/or participation in physician meetings.

Deliverable(s): Physician education materials covering product and clinical evidence.

Task 7.3: System Deployment

Ultran shall coordinate shipments to each identified site according to the agreed upon delivery schedule.

Milestone(s): Completion of site shipments.

Deliverable(s): MINI systems delivered to sites.

Task 7.4: Site Training and Implementation

Ultran shall develop and execute a training program to coincide with device delivery. This program shall employ in-person site initiation training, as well as recorded training modules for asynchronous training (e.g., new staff, refresher training). The program shall also utilize a "train the trainer" approach to establish a site champion / super-user and to simplify ongoing site communications and support.

Milestone(s): Completion of training program development; Execution of the training program for each site.

Deliverable(s): Training program description and materials.

Task 7.5: Site Support Planning

Ultran shall develop and implement support processes to provide ongoing technical and use-related assistance to sites using the MINI system.

Milestone(s): Implementation of site support processes.

Deliverable(s): Description of support processes.

Task 8: Additional Trial Sites for Civilian and/or Military Patients ([redacted]

Clinical partners at [redacted] shall perform a clinical study in [redacted] A similar study, as described above for Part 2 of the clinical study at the [redacted] shall be performed with up to [redacted] patients from the surrounding infected SARS-CoV-2 population. Given continual changes in the quantities of COVID-19 patients presenting at different hospitals, final site selection will be based on availability of patients meeting the inclusion criteria at the time of the study, and may include [redacted]

Task 8.1: IRB and HRPO Approvals

The same work shall be executed in accordance with Task 3.1.

Milestone(s): Submit package to IRB and HRPO; Obtain IRB approval at final study site(s) (e.g., [redacted]) and HRPO approval to perform the human study.

Deliverable(s): IRB and HRPO submission packages; IRB and HRPO approval letters.

Task 8.2: Clinical Trial Part 2

The same work shall be executed in accordance with Task 3.3.

Milestone(s): Completion of interim analysis; Completion of the human clinical study.

Deliverable(s): Interim and final reports summarizing clinical findings from the study.

Task 9: Program Management and Reporting

Ultran shall provide regular reports regarding project status and performance, to include the following: Quarterly Technical and Business Reports, Annual Technical and Business Reports, Final Technical and Business Report, and Interim and Final Patent Reports.

Task 9.1: Project Kick-off Meeting and Report

Commencement of project with kick-off meeting and delivered report.

Milestone(s): Project commencement.

Deliverable(s): Kick-off report and meeting.

Task 9.2: Monthly Financial Status and Expenditure Forecast Report

Financial report following monthly periods.

Milestone(s): Completion of monthly periods.

Deliverable(s): Monthly financial status and expenditure forecast reports.

Task 9.3: Monthly Progress Reports

Progress reports following monthly periods.

Milestone(s): Completion of monthly period.

Deliverable(s): Monthly progress reports.

Task 9.4: Quarterly Technical and Business Reports

Report following completion of each quarterly performance period.

Milestone(s): Completion of quarterly period.

Deliverable(s): Quarterly technical and business reports.

Task 9.5: Final Technical and Business Report

Final technical and business report following project completion.

Milestone(s): Project completion.

Deliverable(s): Final technical and business report.

Task 9.6: Interim and Final Patent Reports

Interim and final reports detailing patent filings and applications as related to this effort.

Milestone(s): Preparation and Filing of patents related to this project.

Deliverable(s): Interim and final patent reports.

Task 9.7: Work Breakdown Structure (WBS)

Milestone(s): Completion of project planning.

Deliverable(s): Work Breakdown Structure.

Task 9.8: Integrated Master Schedule (IMS)

Milestone(s): Completion of project planning.

Deliverable(s): Integrated Master Schedule.

Task 9.9: Draft and Final Meeting Minutes

Milestone(s): Completion of various meetings.

Deliverable(s): Draft minutes to be submitted to the Government five (5) business days following each meeting, and final minutes within three (3) days of Government comment.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Rights
4.1	Electrical schematics, BOM and PCB layouts (Gerber files) of both pulser and power boards; Fabricated and fully assembled pulser and power PCBs.	(b) (4)	5.4	Task 1.1	Partially funded at gov. expense	Gov. Purpose
4.2	Fabricated and fully assembled transducer arrays.		5.4	Task 1.2:	Partially funded at gov. expense	Gov. Purpose
4.3	CAD mechanical drawings of system and power module enclosures; Fabricated system and power module enclosures.		5.4	Task 1.3	Funded at gov. expense	Gov. Purpose
4.4	BOM; IFU (instructions of use); coupling kits.		5.4	Task 1.4	Funded at gov. expense	Gov. Purpose
4.5	Procurement and assembly of disinfectants.		5.4	Task 1.5	Funded at gov. expense	Gov. Purpose
4.6	AC power adapters; multi-conductor cables.		5.4	Task 1.6	Funded at gov. expense	Gov. Purpose
4.7	Assembled system modules and power modules; Assembled standalone, MINI wearable devices by integrating system modules, power modules, high-voltage cable, AC power adapter.		5.4	Task 1.7	Funded at gov. expense	Gov. Purpose
4.8	Pre-programmed MINI wearable systems to deliver intended ultrasound therapy.		5.4	Task 1.8	Partially funded at gov. expense	Gov. Purpose
4.9	Test report documenting stimulation output characteristics.		5.6	Task 2.1.1	Funded at gov. expense	Gov. Purpose
4.10	Report documenting performance of MINI system and preclinical animal outcomes.		5.6	Task 2.1.2	Funded at gov. expense	Gov. Purpose
4.11	Test reports documenting passing of all verification and safety test criteria.		5.6	Task 2.2	Funded at gov. expense	Gov. Purpose
4.12	Test reports documenting passing of validation test criteria.		5.6	Task 2.3	Funded at gov. expense	Gov. Purpose

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Rights
4.13	IRB ((b) (4) submission package.	(b) (4)	5.7	Task 3.1	Partially funded at gov. expense	Gov. Purpose
4.14	HRPO submission; IRB ((b) (4) /HRPO approval letters.		5.10	Task 3.1	Partially funded at gov. expense	Gov. Purpose
4.15	Report summarizing (b) (4) clinical findings from Part 1 of study.		5.14	Task 3.2	Partially funded at gov. expense	Gov. Purpose
4.16	Interim report summarizing (b) (4) clinical findings from Part 2 of study.		5.16	Task 3.3	Partially funded at gov. expense	Gov. Purpose
4.17	Final report summarizing (b) (4) clinical findings from Part 2 of study.		5.18	Task 3.3	Partially funded at gov. expense	Gov. Purpose
4.18.1	Pre-EUA package and regulatory strategy.		5.2	Task 4	Partially funded at gov. expense	Gov. Purpose
4.18.2	Final EUA package; MINI system authorized for distribution through EUA pathway.		5.20	Task 4	Partially funded at gov. expense	Gov. Purpose
4.19	Relevant quality agreements (if applicable), SOPs, and Design Control / QMS documentation.		5.3	Task 5	Funded at gov. expense	Unlimited
4.20	Component lifecycle report; Altium schematics and PCB files, PCB assembly drawings, and Gerber files; Altium BOMs; Test fixture.		5.8	Task 6.1	Funded at gov. expense	Unlimited
4.21.1	Manufacturing of first (b) (4) MINI devices ((b) (4) per week).		5.11	Task 6.2	Funded at gov. expense	Gov. Purpose
4.21.2	Manufacturing of additional (b) (4) devices ((b) (4) per week).		5.13	Task 6.2	Funded at gov. expense	Gov. Purpose
4.21.3	Manufacturing of remaining (b) (4) devices ((b) (4) per week).		5.15	Task 6.2	Funded at gov. expense	Gov. Purpose
4.21.4	Shipment of all remaining units.		5.21	Task 6.2	Funded at gov. expense	Gov. Purpose

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Rights
4.22	List of sites with quantity and timing of device shipments.	(b) (4)	5.22	Task 7.1	Partially funded at gov. expense	Unlimited
4.23	Physician education materials covering product and clinical evidence.		5.22	Task 7.2	Partially funded at gov. expense	Unlimited
4.24	MINI systems delivered to sites.		5.22	Task 7.3	Funded at gov. expense	Unlimited
4.25	Training program description and materials.		5.22	Task 7.4	Partially funded at gov. expense	Unlimited
4.26	Description of support processes.		5.22	Task 7.5	Partially funded at gov. expense	Unlimited
4.27	IRB ((b) (4) submission package.		5.9	Task 8.1	Partially funded at gov. expense	Gov. Purpose
4.28	HRPO submission and IRB ((b) (4) /HRPO approval letters.		5.12	Task 8.1	Partially funded at gov. expense	Gov. Purpose
4.29	Interim report summarizing (b) (4) clinical findings from Part 2 of study.		5.17	Task 8.2	Partially funded at gov. expense	Gov. Purpose
4.30	Final report summarizing (b) (4) clinical findings from the study.		5.19	Task 8.2	Partially funded at gov. expense	Gov. Purpose
4.31	Kick-off report and meeting.		5.1	Task 9.1	Funded at gov. expense	Unlimited
4.32	Monthly financial status and expenditure reports.		5.5	Task 9.2	Funded at gov. expense	Unlimited
4.33	Monthly Reports.		5.5	Task 9.3	Funded at gov. expense	Unlimited
4.34	Quarterly technical and business reports.		5.24	Task 9.4	Funded at gov. expense	Unlimited
4.35	Final technical and business report.		5.25	Task 9.5	Funded at gov. expense	Unlimited
4.36.1	Interim patent report.		5.23	Task 9.6	Funded at gov. expense	Unlimited

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Rights
4.36.2	Final patent report.	(b) (4)	5.23	Task 9.6	Funded at gov. expense	Unlimited
4.37	WBS Submission.		5.5	Task 9.7	Funded at gov. expense	Unlimited
4.38	IMS Submission.		5.5	Task 9.8	Funded at gov. expense	Unlimited
4.39	Draft and Final Meeting Minutes.	Various throughout project	5.5	Task 9.9	Funded at gov. expense	Unlimited

5.0 MILESTONE PAYMENT SCHEDULE

MS #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.1	Project commencement; Deliverable 4.31	(b) (4)	(b) (4)
5.2	Submission of pre-EUA package; Deliverable 4.18.1		(b) (4)
5.3	Completion of Quality Management System enhancements; Deliverable 4.19		(b) (4)
5.4	Completion of MINI wearable system (b) (4) units); Deliverables 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, and 4.8		(b) (4)
5.5	Completion of monthly period; Deliverables 4.32, 4.33, 4.37, 4.38, and 4.39		(b) (4)
5.6	Completion of design verification and validation; Deliverables 4.9, 4.10, 4.11, and 4.12		(b) (4)
5.7	IRB submission ((b) (4) Deliverable 4.13		(b) (4)
5.8	Completion of volume device manufacturing – planning; Deliverable 4.20		(b) (4)
5.9	IRB submission ((b) (4) Deliverable 4.27		(b) (4)
5.10	HRPO submission and IRB ((b) (4) /HRPO approvals; Deliverable 4.14		(b) (4)
5.11	Production of first (b) (4) MINI devices; Deliverable 4.21.1		(b) (4)
5.12	HRPO submission and IRB ((b) (4) /HRPO approvals; Deliverable 4.28		(b) (4)
5.13	Manufacturing of additional (b) (4) devices ((b) (4) per week) and annual technical and business status report; Deliverables 4.21.2 and 4.35		(b) (4)
5.14	Completion of (b) (4) human clinical study Part 1; Deliverable 4.15		(b) (4)
5.15	Manufacturing of remaining (b) (4) devices ((b) (4) per week); Deliverable 4.21.3		(b) (4)
5.16	Interim results of (b) (4) human clinical study Part 2; Deliverable 4.16		(b) (4)

MS #	Milestone Description (Deliverable Reference)	(b) (4)	Total Program Funds
5.17	Interim results of (b) (4) human clinical study; Deliverable 4.29		(b) (4)
5.18	Completion of (b) (4) human clinical study Part 2; Deliverable 4.17		(b) (4)
5.19	Completion of (b) (4) human clinical study; Deliverable 4.30		(b) (4)
5.20	Submission of final EUA package and receive EUA from FDA; Deliverable 4.18.2		(b) (4)
5.21	Shipment of all remaining devices; Deliverable 4.21.4		(b) (4)
5.22	Completion of MINI system deployment; Deliverables 4.22, 4.23, 4.24, 4.25, and 4.26		(b) (4)
5.23	Preparation and filing of patents related to this project; Deliverable 4.36.1 and 4.36.2		(b) (4)
5.24	Completion of quarterly period; Deliverable 4.34		(b) (4)
5.25	Project completion, including Final technical and business status report; Deliverables 4.35		(b) (4)
		Total (FFP):	**$1,023,776**
		Period of Performance:	**6 Months**

6.0 SHIPPING PROVISIONS

All Quarterly, Annual and Final Reports will be sent to: deliverables.mcdc@ati.org

All deliverables intended for the AOR will be sent to: (b) (6)

A copy of all data deliverables will be sent to:

usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil

The shipment of any physical deliverables will be coordinated with the Government sponsor.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

Unless specified otherwise in this agreement, no party relinquishes rights to any background patents to any other party under this agreement. Additionally, no party to the awarded agreement shall enter into an agreement with any contract manufacturer or other third party, whereby the third party will obtain rights in Subject Inventions or Subject Data, as those terms are defined in Other Transaction Agreement number W15QKN-16-9-1002, absent the mutual consent of the parties to the awarded agreement.

7.1 Patent Rights-

Article X, §B ("Allocation of Principal Rights") and §E ("Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File") of Other Transaction Agreement number W15QKN-16-9-1002, is hereby amended for the purpose of this Project Agreement as follows:

a) **Subject Inventions. Grants of Non-Exclusive License to Subject Inventions.** Any Subject Invention[2] that is Made by a party under this agreement will be owned by the party having Made the invention. For each Subject Invention Made solely by the Contractor, the Government will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention and the right to sublicense same to third parties to practice the invention for any purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. For any Subject Invention Made solely by the Government, the Contractor will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention or allow a third party to practice the invention for any purpose.

b) **Grant of Rights of First Refusal to Exclusive License of Subject Invention.** For each Subject Invention Made solely by the Contractor, the Contractor shall provide the Government a right of first refusal for an exclusive license to the Subject Invention, within a commercially reasonable time prior to the offer of license to any third party, and subject to no less than a fifty percent (50%) share of royalty based on gross royalty revenue received by the Government. For each Subject Invention Made solely by the Government, the Government shall provide a right of first refusal for an exclusive license to the Subject Invention, within a commercially reasonable time prior to the offer of license to any third party, and subject to a reasonable share of royalty income and subject to a retention of Government use for research purposes only, for purposes of FDA licensure of the technology described herein, limited to the field of use described in the product indication, subject to termination terms substantially similar to the events described in "Regulatory Rights" below:

c) **Joint Inventions.** Any Subject Invention Made jointly by the Contractor and any Government employee shall be jointly owned by the Parties. The Contractor shall have the first option to prepare and file the patent application(s) covering the Subject Invention, at its own expense. In the event that the Contractor declines to file or complete prosecution of such patent application at its own expense in a timely manner, the Contractor waives its co-ownership interest therein, and agrees to assign its full right, title and interest to such joint Subject Invention to the Government, so as to allow the Government to prepare, file or continue prosecution of such patent application(s), in exchange for a non-exclusive, irrevocable, transferable, paid-up license to practice such Subject Invention throughout the world. In the event that the Contractor elects to file and complete prosecution of such patent applications, the Government shall receive a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention, have the invention practiced throughout the world by or on behalf of the Government, and sublicense the invention to third parties for any

[2] "Subject Invention" is hereby redefined as "any invention of the Government, PAH, or developed jointly by the parties, that was conceived or first actually reduced to practice in the performance of work under this Agreement."

purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. The Contractor will receive a right of first refusal for an exclusive license to the subject joint invention upon terms identified in Section (b) above.

d) **Filing of Patent Applications.** The party having the right to retain title to, and file patent applications on, a specific Subject Invention, may elect not to file patent applications, provided it so advises the other party within ninety (90) days from the date it reports the Subject Invention to the other party, or at least ninety (90) days before a statutory bar date or public disclosure, whichever occurs earlier. Thereafter, the other party may elect to file patent applications on the Subject Invention and the party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other party.

e) **Patent Expenses.** The expenses attendant to the filing of patent applications shall be borne by the party filing and/or prosecuting the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention, along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The Parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this agreement.

f) **Relationship to Base OTA Patent Terms.** If there is a conflict between this Section and Article X of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article X of W15QKN-16-9-1002, those sections remain operative.

Data Rights-

Article XI, §C of Other Transaction Agreement number W15QKN-16-9-1002, is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§A(12) and (C)(4), as follows:

a) **Subject Data Ownership.** Subject Data (defined as Technical Data under Article XI, §A(13), generated, directly or indirectly, related to the work performed under this agreement) shall be jointly owned by the Parties. Each party, upon request to the other party, shall have the right to review and to request delivery of all Subject Data, and delivery shall be made to the requesting party within two (2) weeks of the request, except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party. All Deliverables, as described in the Deliverable Table within the Statement of Work, or mentioned elsewhere in this document, are considered Subject Data

under this agreement.

b) **Confidential Information.** Neither Party, as the Receiving Party, shall, directly or indirectly, divulge or reveal to any person or entity any confidential information of the other Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this agreement.

c) **Exclusion.** Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this agreement; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

d) **Background Technical Data Rights Assertions.** Contractor asserts background technical data rights as follows:

Table 1: Data Rights Assertions

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Deliverables Affected
(b) (4)		Government Purpose	The Ultran Group, Inc.	Deliverables within Tasks 1, 2, 4, and 6.1
		Government Purpose	The Ultran Group, Inc.	Deliverables within Tasks 1, 2, 4, and 6.1

(b) (4) [redacted]	Government Purpose	The Ultran Group, Inc.	Deliverables within Tasks 2, 3, and 8
[redacted]	Government Purpose	The Ultran Group, Inc.	N/A
[redacted]	Limited	The Ultran Group, Inc.	NA
[redacted]	Limited	The Ultran Group, Inc.	N/A

e) **Relationship to Base OTA Data Rights Terms.** If there is a conflict between this Section and Article XI of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article XI of W15QKN-16-9-1002, those sections remain operative.

7.3 Regulatory Rights-

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that successful completion of this agreement will contribute to further efforts to achieve FDA clearance and commercialization of product(s) in this scope (the "Technology"). The Project Agreement Holder (PAH) may be the Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this agreement. If the PAH is the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t),

812.2(b), 812 Subpart C, or 814.20), they have certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND and DTRA-JSTO representative for all regulatory and quality activities. The PAH shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate. The PAH shall invite the SDMR to all FDA meetings and regulatory discussions applicable to this OTA Project.

This following clause protects the return on research and development investment made by the Government in the event of certain regulatory product development failures related to the Technology.

The PAH agrees to the following:

a. The PAH will provide to the Government all data including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval, to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the PAH will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions, which include data funded by this Agreement. The Government will review any such submissions promptly upon receipt. The PAH will reasonably consider any comments provided by the Government, and prior to submission, will provide notification to the Government of any additional edits or revisions. The PAH will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

b. Communications. The PAH will provide the Government with copies of all communications, both formal and informal, to or from FDA, regarding the Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with the FDA;

c. Non-compliance with section (a. & b.) may result in termination of the agreement.

d. Product Development Failure. Certain product development failures may trigger certain remedies in Section "e." below for the Government advanced developer funding the development of this Technology. This remedy is not available to the Government for any cause outside of the following:
    (i) if this agreement is terminated for nonperformance,
    (ii) if this agreement is successfully completed and the Government advanced developer funding this project agreement offers to provide funding to continue development to FDA approval for the indication identified in this project agreement, and the PAH refuses to or is unable to continue such development.

e. If any of the product development failures listed in Section "d." occur, the PAH, upon

the request of the Government:

(i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology, to the Government or its designee;

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

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

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

g. Public Law 115-92 Sponsor Authorization Letter

The PAH shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling the FDA to disclose information to JPEO-CBRND and its Government support contractors related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter was attached to the RPP as Exhibit 4.

JPEO-CBRND shall formally submit the executed letter to the FDA under the Regulatory Application only if the proposed product becomes a DoD medical product priority under Public Law 115-92.

If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO-CBRND will include the PAH in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO-CBRND will provide a summary of the interaction to the PAH within ten (10) business days.

h. Deliverable(s): Public Law 115-92 Sponsor Authorization Letter.

8.0 SECURITY

The security classification level for this effort is Unclassified.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

N/A

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

AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: JPEO-CBRND, JPM-Medical

ALTERNATE AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: JPEO-CBRND, JPM-Medical