PROBLEM STATEMENT

Requirement Title: Domestic Bioindustrial Manufacturing Investment

Critical Sector: Biomanufacturing

Background: The Department of Defense (DoD) requires domestic, resilient, and secure supply chains for critical materials, reduced cost and burden of logistics to maintain readiness posture, and sustainable defense solutions. Leveraging disruptive technologies, and specifically biotechnology and bioindustrial manufacturing capabilities, is key to operationalizing a strategy to upgrade the domestic industrial base (DIB). The Office of the Principal Director for Biotechnology within the Office of the Under Secretary of Defense for Research and Engineering (OUSD (R&E)) has provided guidance to Defense Production Act Investments (DPAI) to make investments in biotechnology and biomanufacturing in five areas: fabrication, firepower, fitness, food, and fuel (the "5Fs"). The results of the effort will prepare the participants for future investments, including potential future DPA investments, and to inform the DoD of the products that provide the best opportunities for insertion into DoD materiel.

Desired Objective: The DoD's Bioindustrial Manufacturing Investment objective is to invest in prototype projects in the 5f's and, in doing so, to build the long term capability and viability of sources of high-quality critical material. The DoD seeks to engage in prototype projects that will develop and demonstrate technical and business processes to produce pure, stable, high-quality biomanufactured product(s).

The DoD intends to award multiple prototype projects in each of the 5Fs. Proposers must have at least one product in manufacturing development, and proposed products must be at least technology readiness level (TRL) 4, but preferably, TRL6, in one of the 5F categories. Proposers are not required to have current production capability beyond pilot scale and are not required to have knowledge or understanding of military markets, though capabilities in both areas may increase the likelihood of being selected.

"5Fs": Proposers should focus on the bioproduction of material(s) that fit within the 5F categories as described below and address known or explainable domestic supply chain issues. Materials of interest shall address current and evolving DoD needs, such as resolving long-term shortages, filling a gap in the domestic industrial base, or bioproduction of material that cannot be, or is no longer able to be, produced through conventional (e.g., chemical) processes (e.g., due to new regulations). Bioproduction of materials with improved performance characteristics is also of interest. Simple substitution of a biomanufactured product for material that is not in limited supply (e.g., "cultured" meat whole proteins) is not of interest. Pharmacological/medical products, diesel replacement fuel, and enabling technologies such as software or advanced enzyme design are also not of interest.

- **Food:** Bio-generated foodstuff ingredients that adhere to military specifications and improve supply chain considerations for and/or increase warfighter satisfaction with ready-to-eat meals (e.g., replacement of imported components, provision of enhanced flavor/texture and extended-life preservatives).

- **Fuel:** Drop-in-ready fuel components and additives for, and production of, high-energy-density or endothermic fuels that provide opportunities for sustainable supply chain production by eliminating or decreasing petroleum project dependence.
- **Fitness:** Bio-based products or material precursors that increase operational robustness by maintaining operational fitness of fielded systems and increasing resilience of supply chains to and at the point of need. Materials and products may include, but are not limited to, surfactants, lubricants, corrosion inhibitors/paints/coatings, and solvents.
- **Fabrication:** Platform materials and molecules for construction of defense products, e.g., bioplastics/polymers, adhesives, fibers, textiles, rubber, and property- or performance-enhancing additives.
- **Firepower:** Platform molecules or materials for production of energetics, munitions, and propellants as drop-in replacements that bolster or create domestic supply chains.

Proposers should include documentation of current product and manufacturing capabilities; plans to obtain/employ resources to develop strategic business and marketing plans; plans to obtain/employ resources to develop manufacturing process and equipment designs (pilot/low-rate initial production to full rate production scale); identification of other business, marketing, or technical risks challenges to be mitigated.

The Government may select companies to enter prototype agreements at the Prototype Assessment and Planning phase that may result in the following deliverables for biomanufacturing technologies:

(1) Manufacturing Plans – Process and Equipment Design: Engage in design, planning, engineering, and analysis for the capacity to produce pure, stable, high-quality, biomanufactured product(s). This effort is limited to paper-based studies and plans, though sample materials from existing capabilities may be delivered. Tasks may include, but are not limited to:

a. Identify and describe the specific products, volumes, and specifications the company intends to provide the DoD. Characterize the current material and assess quality and characteristics against specifications. Document and justify the material TRL.
b. Document and characterize each step in the current production process. Include feedstock and other process inputs and associated requirements; by-products and/or side-products; and down-stream processing steps. Provide written estimates for yields and capacity and document the basis for those assumptions. Document and assess current facility operations, including production support processes. Assess the Manufacturing Readiness Level of the current process.
c. Develop scaled-up process and capacity metrics required to meet product (e.g., form, quality, quantity, etc.), business, and market targets. Identify facility requirements for scaled-up process. Research, assess, and identify suitable optimal or likely physical locations for the production facility, including characterizing and specifying current or new (brownfield or greenfield) locations, site considerations, and geographic factors.

d. Develop initial engineering plans for scaled up production process and facility, such as: initial drafting of a complete process flow diagram; general or specific facility layouts; draft engineering specification for utilities, plumbing/piping, wiring, and other operational needs; engineering design of custom equipment, and specification of standard process, monitoring, and test and evaluation equipment; definition of key process parameters (KPPs); and other design and setup considerations. Include all up-stream and down-stream processing as required.
e. Complete a capital expense ('CapEx') cost estimate for scaled up production facility and equipment. Complete an operational expense ('OpEx') cost estimate for start-up costs and ongoing operations costs.
f. Identify, assess, and/or integrate into the plans and reports for any local, state, or federal environmental, chemical management, and other manufacturing regulations or required assessments. Special attention should be given to safety and security measures.
g. Create a draft schedule for a project to build a facility and acquire, modify, install, and qualify production of bioproduct(s).
h. Deliver prototype samples from the current capability and/or improved capabilities resulting from Deliverable 6 (as applicable).

(2) Business Process and Plan: Develop a strategic business plan that guides development and growth of business operations to become, or maintain a position as, a competitive, economically viable, responsive merchant supplier to the government and, if applicable, commercial sectors for biomanufactured product(s). Plans should cover 5 years and may include considerations such as:

a. Availability of resources and business/operations tools to be employed in developing and executing the plan.
b. Key issues related to the establishment of a viable manufacturing supply, including but not limited to unit cost(s), minimum sustaining rates, competitive pricing, performance or pricing advantages.
c. Supply Chain Risk Management (SCRM). Cultivation and/or maintenance of viable key sub-tier suppliers, such as feedstock supply, ingredient and/or other constituent supply, at full scale production rates. Definition of sub-tier supplier risks or challenges whether engineering, geography, manufacturing (capacity), or schedule related. Incoming/outgoing transportation may be considered. May include collection of data and vetting of supply chain ownership and/or personnel, assessments and monitoring of continuity of operations and foreign influence/risk.
d. Workforce needs – scale of and sources for all disciplines required for business and manufacturing operations, including (as needed) education and workforce development plans.
e. Technology Protection planning – Safeguarding of technology and technical know-how (i.e., formal or informal intellectual property) is of utmost importance to national security and international competitive concerns. Business plans should include tactics, measures, and procedures for the protection of the proposer's products and capabilities (e.g.,

physical and cyber security) against internal and external, domestic and international malicious actors and actions.

(3) Market and Business Development Processes and Plans: Develop a strategic marketing plan that guides market and marketing development toward growth of product demand, and supports the business as a competitive, economically viable, responsive merchant supplier to the government and, if applicable, commercial sectors for biomanufactured product(s). Plans should cover 5 years and may include considerations such as:

a. Market assessment(s) to validate/verify the technical product requirements, demand levels, and market trends.
b. Projections and assumptions used to support development of a business plan for production of biomanufactured product(s).
c. Current and future customer needs for the bio-produced material(s), including pricing, pricing elasticity (foreign and domestic) and make vs. buy decisions based on impacts of domestic production related regulations.

The resulting prototype agreements for biomanufacturing technologies, may also result in the following deliverables:

(4) Process Assessment – Business: Assess current status and future needs for business operations capabilities, such as but not limited to:

a. Plan, prepare, and/or establish Defense Contract Audit Agency (DCAA) compliant accounting system.
b. Plan and/or prepare for CMMC compliant information technology (IT) systems.
c. Plan and/or prepare for manufacturing enterprise resource planning (ERP) systems.

(5) Process Assessment – Technical: Model and assess current and/or future process designs. Identify key process and product indicators (KPIs). Tasks may include, but are not limited to:

a. Model and/or demonstrate current process and analyze critical process steps; assess process capabilities, product characteristics, and feedstock variability on product quality and production efficiency.
b. Perform a techno-economic analysis (TEA) of the current process design for the purposes of accurate cost accounting and Cost of Goods calculation. Identify critical process elements that drive production metrics and product quality. Identify where engineered improvements are required and feasible at scale-up to establish economically viable production.
c. Integrate results from this analysis into Deliverables 1, 2, and 3.

(6) Chassis Improvement and/or Material Sampling: Assess key biological constituents and impact of chassis designs on process capabilities. A chassis is defined as the microorganism or biological material that is used to manufacture the product, e.g., a genetically modified bacterial strain, or enzyme(s). Design, test, and evaluate improved designs on process

productivity and quality. Provide sample materials to DoD for test and evaluation. Tasks may include, but are not limited to:

a. Demonstrate current process and analyze critical process steps; assess process capabilities, product characteristics, and impact on product quality and efficiency.
b. Complete initial biologic process design improvements critical to maturing toward scalable production. Test and analyze biological process improvements to evaluate/demonstrate efficacy of identified improvement concepts.
c. Produce and characterize sample material from existing and/or improved processes. Deliver samples to the government for testing (all safe material handling and compliant shipping requirements are incumbent on the producer).
d. No capital expense (e.g., test or process equipment) is authorized under this task.

Upon successful completion of the Prototype Assessment and Planning phase, The Government may select some companies to proceed to the Prototype Build phase. The Build phase may include, but is not limited to:

(1) Capacity Instantiation and Qualification: Detailed efforts may include but are not limited to:

a. Complete detailed biomanufactured infrastructure design, engineering, and cost/financial plans.
b. Prepare facility for biomanufacturing of proposed materials. Build out facility as needed for installation of production and support processes and equipment.
c. Acquire production and process support equipment. Inspect and receive critical equipment according to established acceptance plans. Install and qualify process and support equipment.
d. Instantiate or assure systems and processes for production management, including human resources, material and order management, shipping and receiving, etc.
e. Conducting Manufacturing Process Analysis, including value stream analysis/capacity assessment, Process Failure Mode Effects Analysis (PFMEA), Manufacturing Readiness Assessment(s), etc.
f. Develop and conduct a Manufacturing Line Test. Conduct First Article Test in accordance with the applicable specification. Provide samples as required to the Government for test and evaluation.
g. Ensure and maintain compliance with all relevant federal, state, and local safety, transportation and environmental laws, regulations, and permit conditions.
h. Maintaining Strategic Business Plans and Marketing Plans, updated at least annually, consistent with viable business operations.

To proceed to the Build phase, the Government will negotiate a revised SOW with the consortium member and request an updated cost proposal.

Anticipated Funding: The Government estimate is approximately $1.5M per award. Deliverables 1, 2, and 3 must be completed, and are expected to consume approximately 60% of the proposer's budget. One or more of Deliverables 4, 5, and 6 may be completed and are

expected to consume approximately 40% of the proposer's budget. This estimate is provided as guidance according to the DoD's general assessment of industry status; actual splits may vary according to individual proposer's existing capability and business/technical maturity (as proposed) and is subject to negotiation, if selected.

Anticipated Security Level of the Prototype Project: Unclassified (Controlled Technical Information and/or Controlled Unclassified Information may be required)

Estimated Period of Performance: up to 6 months for Prototype Assessment and Planning phase; and up to five years for the Build Phase

Anticipated Data Rights: Government Purpose Rights

Technical POC(s): To be provided (designated technical SMEs for each of the 5F categories)