

**OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)**

BETWEEN

**JANSSEN RESEARCH & DEVELOPMENT, LLC**

920 ROUTE 202

RARITAN, NJ 08869, USA

AND

**THE UNITED STATES OF AMERICA**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY**

O'NEILL HOUSE OFFICE BUILDING

WASHINGTON, DC 20515

CONCERNING

(b)(4)



Agreement No.: HHSO100201800012C

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

Total Estimated Government Funding of the Agreement (b)(4)

Total Estimated Recipient Funding of the Agreement: (b)(4)

Funds Obligated: (b)(4)

Effective Date of Agreement: September 21, 2018

Period of Performance: September 21, 2018 – December 31, 2024

Authority: Section 319L(c)(5) of the Public Health Service Act, 42 USC 247d-7e(c)(5).

Line of Accounting and Appropriation:

(b)(4)

This Agreement is entered into between the United States of America, hereinafter called the Government, represented by the Department of Health and Human Services (HHS) and the JANSSEN RESEARCH & DEVELOPMENT, LLC, hereinafter called the Recipient, pursuant to and under U.S. Federal law.

**FOR JANSSEN RESEARCH & DEVELOPMENT, LLC**

**FOR THE UNITED STATES OF AMERICA  
BIOMEDICAL ADVANCED RESEARCH  
DEVELOPMENT AUTHORITY,  
CONTRACTS MANAGEMENT AND  
ACQUISITION, ASSISTANT SECRETARY FOR  
PREPAREDNESS AND RESPONSE**

(b)(6)

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**ARTICLE I: SCOPE OF THE AGREEMENT**

**A. Background**

Chemical, Biological Radiological and Nuclear (CBRN) threats remain important public health concerns. BARDA's mission is to develop and procure needed medical countermeasures against a broad array of public health threats, whether natural or intentional in origin. The CBRN program within BARDA spans a number of threats and focus areas such as Anthrax, Smallpox, Botulinum Toxin, Ebola, Broad Spectrum Antimicrobials, Chemical Medical Countermeasures, Thermal Burn Medical Countermeasures and Radiological and Nuclear Countermeasures. Within the CBRN division, the Radiation and Nuclear group focus' on developing medical countermeasures to address nuclear detonation that result in radiation-induced illness, thermal and radiation burns, and trauma.

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The current portfolio envisioned Under this Agreement includes those assets described in (b)(4) The potential programs/platforms that may be developed under this Agreement have never been of action that may be developed as single or combination therapies that have the potential to address areas of high unmet medical need for biodefense. The portfolio covered under this Agreement may be augmented with additional molecules or devices and in-licensing drug, device or vaccine candidates.

Collaboration between BARDA and the Consortium Members Under this Agreement will provide the parties the flexibility to execute a portfolio approach to funding in the complex and uncertain environment of drug and medical device development. To maximize the potential to achieve the objectives of this Agreement, other medical countermeasure candidates that Consortium Members develop or in-license during the term of the Agreement may be considered by the Joint Oversight Committee (JOC) for inclusion in the portfolio.

For the (b)(4) assets listed in (b)(4) no definitive commitment has yet been made by either party to fund their development. The Consortium Members and BARDA will explore the inclusion of potential assets beyond (b)(4) Once more clearly defined project plans, scope and budget have been developed they will be presented to the JOC for decision on their inclusion under this Agreement.

**B. Definitions**

**Affiliate:** Any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise.

**Agreement:** The body of this Agreement and all attachments and modifications thereto, including Attachments 1 – 6 are expressly incorporated in and made a part of the Agreement.

**Asset:** Project or projects related to a drug, device or other technology which if successfully developed has the potential to be utilized as a medical countermeasure against CBRN threats.

**Biobanking:** A biobank is a type of repository that stores biological samples for use in research.

**Business Day:** A day that is not: a Saturday or Sunday; a Federal holiday in the United States; a bank holiday or national public holiday in the Netherlands or in any country where a Consortium Member is located.

**Confidential Information:** Non-public information, including but not limited to business, strategic, or management information, or data of a personal nature about an individual, or proprietary technical information, manufacturing information, trade secrets financial, administrative, cost, or pricing information, submitted to the Government by or on behalf of Recipient or by the Government to the Recipient in connection with, or during performance of the Agreement, whether or not either Party required or requested that such information be submitted. "Confidential Information" does not include "Data" as defined below.

**Consortium:** That group of Consortium Members that are: (i) Affiliates of one another; and (ii) have agreed with one another to collaborate to perform the objectives and obligations set forth in this Agreement.

**Consortium Member:**

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any new member that

**Data:** Recorded information first created in performance of the Program, regardless of form or method of recording, which includes but is not limited to, technical data and software, but does not include Subject Inventions, trade secrets, data of a personal nature about an individual, or financial, administrative, cost, pricing, or management information.

**Effective Date:** The date of execution of this Agreement by the Parties. If this Agreement is executed in counterparts, the Effective Date shall be the date of the last signature.

**Field:** Means the development and use as medical countermeasure to address CBRN threats as well as emerging infectious diseases and bacterial infections.

**Foreign Firm or Institution:** A firm or institution organized or existing under the laws of a country other than the United States, its territories, or possessions. The term includes, for purposes of this Agreement, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

**Government:** The United States of America, as represented by HHS/BARDA. For purposes of this Agreement, the Government and HHS and BARDA may be used interchangeably.

**Invention:** Any invention or discovery which is or may be patentable under Title 35 of the United States Code.

**Know-How:** Information, practical knowledge, techniques, and skill development.

**Limited Rights:** The rights to use, modify, reproduce, perform, display, or disclose Data, in whole or in part, within the Government solely for its research purposes in the Field.

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

**Other Transaction Agreement Specialist (OTAS):** Is a supporting official that executes agreement modifications on behalf of the Other Transaction Agreement Officer

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

**Party:** Either Recipient or Government, and "Parties" means both Recipient and Government.

**Practical Application:** With respect to a Subject Invention, to manufacture, in the case of a composition of product or a medical device; to use in manufacturing, in the case of an invention useful in manufacturing; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions so as to establish that the Subject Invention is capable of being utilized.

**PMO Steering Committee:** The Project Management Organization Steering Committee consists of individuals appointed by the Recipient for the dual responsibilities of day-to-day management and execution of the overall Program and providing technical and administrative infrastructure to ensure all executory functions in the accomplishment of the current Statement of Work.

**Project:** Work activities within the overall Program, focused on specific assets or support of those assets and/or the overall Program.

