Chemical Biological Medical Systems/Transformational Medical Technologies–Therapeutics

INVESTMENT COMPONENT

- **Modernization**
- Recapitalization
- Maintenance

MISSION

Provides the warfighter with safe, robust, and affordable medical countermeasures against a broad spectrum of chemical, biological, radiological and nuclear (CBRN) threats; uses government and commercial best practices to acquire Food and Drug Administration (FDA)-approved CBRN medical countermeasures and diagnostics.

DESCRIPTION

Chemical Biological Medical Systems/Transformational Medical Technologies–Therapeutics consists of the following components:

Advanced Anticonvulsant System (AAS) will consist of the drug midazolam in an autoinjector. The midazolam-filled autoinjector will replace the fielded Convulsant Antidote for Nerve Agents (CANA) that contains diazepam. Midazolam, injected intramuscularly, will treat seizures and prevent subsequent neurological damage caused by exposure to nerve agents. AAS will not eliminate the need for other protective and therapeutic systems.

Improved Nerve Agent Treatment System (INATS] is an enhanced treatment regimen against the effects of nerve agent poisoning. The new oxime component of INATS will replace 2-PAM in the Antidote Treatment Nerve Agent Autoinjector (ATNAA).

Medical Radiation Countermeasure (MRADC) Acute radiation syndrome (ARS) manifests as hematopoietic (bone marrow), gastrointestinal, and cerebrovascular subsyndromes depending on the dose of radiation received. The lead MRADC is adult-derived mesenchymal stem cells (Prochymal™) that will treat the gastrointestinal subsyndrome of ARS. The portfolio of MRADC will, when used as a system, provide a robust capability to the warfighter.

Intracellular Bacterial Pathogens (IBP) will mitigate the threat of illness or death, as well as lessen issues with performance degradation resulting from exposure.

Hemmorhagic Fever Viruses (HFV) medical countermeasures will mitigate the threat of illness or death, as well as lessen issues with performance degradation resulting from exposure. Due to the general severity of these diseases, HFV therapeutics will be administered to infected Warfighters while under direct medical observation.

SYSTEM INTERDEPENDENCIES

None

PROGRAM STATUS

- **1QFY10:** AAS Phase 2 clinical study complete
- **1QFY10:** MRADC pivotal non-human primate (NHP) studies begin
- **2QFY10:** AAS definitive NHP efficacy study complete
- **2QFY10:** INATS Phase 1 clinical study begins
- **3QFY10:** MRADC pivotal NHP studies complete
- **4QFY10:** INATS Phase 1 clinical study begins
- **4QFY10:** MDRAC Biologics License Application (BLA) submission to FDA

PROJECTED ACTIVITIES

- **1QFY11:** AAS new drug application submission to FDA
- **1QFY11:** INATS Phase 2 clinical study begins
- **1QFY11:** HFV Phase 1 trials begin
- **3QFY11:** HFV Milestone B decision
- **4QFY11:** IBP Phase 1 trials begin
- **4QFY11:** HFV Phase II Piviol Animal Studies

ACQUISITION PHASE

- **Technology Development**
- **Engineering & Manufacturing Development**
- Production & Deployment
- Operations & Support

Chemical Biological Medical Systems/Transformational Medical Technologies–Therapeutics

FOREIGN MILITARY SALES
None

CONTRACTORS
AAS:
Meridian Medical Technologies
(Columbia, MD)
INATS:
Southwest Research Institute
(San Antonio, TX)
MRADC:
Osiris Therapeutics (Columbia, MD)