

# Chemical Biological Medical Systems–Therapeutics

## INVESTMENT COMPONENT

Modernization

Recapitalization

Maintenance



## MISSION

To provide the warfighter with safe, robust, affordable medical countermeasures against a broad spectrum of CBRN threats; use government and commercial best practices to acquire FDA-approved CBRN medical countermeasures and diagnostics.

## DESCRIPTION

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

### Advanced Anticonvulsant System (AAS):

The 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):

The 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.

## SYSTEM INTERDEPENDENCIES

None

## PROGRAM STATUS

- **1QFY09:** AAS large-scale manufacturing and validation completed

- **1QFY09:** INATS pre-clinical safety studies complete
- **2QFY09:** INATS Investigational New Drug (IND) application submission to FDA
- **4QFY09:** MRADC pilot non-human primate (NHP) studies complete
- **1QFY10:** AAS Phase 2 clinical study complete
- **1QFY10:** MRADC pivotal NHP studies begin

## PROJECTED ACTIVITIES

- **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
- **4QFY09:** MDRAC Biologics License Application (BLA) submission to FDA
- **1QFY11:** AAS New Drug Application submission to FDA
- **1QFY11:** INATS Phase 2 clinical study begins

## ACQUISITION PHASE

Technology Development

Engineering & Manufacturing Development

Production & Deployment

Operations & Support

## Chemical Biological Medical Systems–Therapeutics

# INATS



### FOREIGN MILITARY SALES

None

### CONTRACTORS

#### AAS:

Meridian Medical Technologies  
(Columbia, MD)

#### INATS:

Southwest Research Institute  
(San Antonio, TX)

#### MRADC:

Osiris Therapeutics (Columbia, MD)

