JPEO-CBD

CBMS
CHEMICAL BIOLOGICAL MEDICAL SYSTEMS

JPM Chemical Biological Medical Systems
Advanced Planning Brief to Industry

April 7, 2004

COL Stephen B. Berté
JPM CBMS
Joint Program Executive Office
for Chemical and Biological Defense
stephen.berte@us.army.mil

Outline

- Program Overview
- Warfigther needs
- Acquisition Strategy
- Technical Challenges
- Upcoming Business Opportunities
- Contacts

Overview

- **Develop, Procure, Field, and Sustain Premier *Medical Protection and Treatment Capabilities* Against Chemical and Biological Warfare Agents.**

- **Ultimate Outcomes Are FDA Licensed Drugs, Medical Devices and Vaccines**

Warfighter Needs

- **Provide Medical Protection Against Nerve Agent-induced Seizures and Subsequent Neurologic Damage**
  - **Advanced Anti-convulsant System (AAS) Will Replace Convulsant Antidote Nerve Agent (CANA) System**
  - **Intramuscular Auto-Injection of Drug (Midazolam) for Enhanced Control of Seizures**
  - **Effective Against Broader Spectrum of Nerve Agents and Non-traditional Agents (NTAs)**

Warfighter Needs (cont)

- **Provide Medical Protection Against a Broader Spectrum of Traditional As Well As Non-traditional Nerve Agents**
  - **Improved Nerve Agent Treatment System (INATS) Active Ingredient Will Replace and Provide Better Protection Than Current Oxime, 2-PAM**
  - **System Approach Will Also Develop Broader Indications for Pretreatment Pyridostigmine Bromide**
  - **INATS Will Use Current Delivery System**

Warfighter Needs (cont)

- **Provide Rapid, Portable Medical Diagnostic Capability for Biological Warfare Agents (BWAs) And Pathogens of Operational Concern**
  - **Joint Biological Agent Identification and Treatment System (JBAIDS) Will Provide Portable Diagnostic Capability to War Fighter.**
  - **COTS System Capable of Identifying 10 BWAs**
  - **Evolutionary Approach: Detection to Diagnostics; Expand BWA Capability; Reduce to Hand Held Device; Reporting System Interoperability**

Warfighter Needs (cont)

- **Provide Medical Prophylaxes for Protection Against Biological Warfare Agents**
  - **Prime Systems Contract Integrator: Dynport Vaccine Company (DVC) Uses Commercial Biotech to Meet DoD Vaccine Requirements**
  - **DVC Obtains and Maintains FDA Licenses**
  - **Special Studies Allows DVC To Evaluate and Integrate Emerging Technologies Into Vaccine Systems**

Acquisition Strategy

- **Outcomes Are FDA Licensed Products**
- **Looking for Industry off the Shelf Solutions**
- **Leveraging International and Other Government Agency Efforts**
- **Seeking More Funding to Support More Products**

Technical Challenges

- **Proving Product Efficacy**
  - **FDA Animal Rule Rule Allows Use of Animal Instead of Human Trials to Prove Product Efficacy**
  - **Animal Rule Approach Not Necessarily Cheaper or Faster**

- **Facilities**
  - **Capable of Animal Testing for Biological and Chemical Warfare Agent Countermeasures**

- **Manufacturing**
  - **FDA Process Is Averse to Technology Insertion**
  - **Complexity of Biological Manufacturing Process**

Technical Challenges (cont)

AAS

- **Proving Efficacy Using FDA Directed Combination of Animal Rule and Human Testing (Epileptic Seizures Comparable to Nerve Agent Seizures)**

INATS

- **Active Ingredient Has Not Previously Been in Humans**

JBAIDS

- **FDA Approval of Device and Multiple Assays**
- **Miniaturization & Interoperability**

Upcoming Business Opportunities

AAS:

- **RFP for System Integrator** — **FY04**

INATS

- **RFP for System Integrator** — **FY06**

JBAIDS

- **RFP for Miniaturization (unfunded)** — **FY08**

JVAP

- **Subcontracts through DVC**

Points of Contact

- **PM Medical Identification & Treatment Systems**
  - **LTC Edward Clayson 301-619-8425**
    edward.clayson@us.army.mil

- **PM Joint Vaccine Acquisition Program**
  - **LTC Travis Bernritter, 301-619-7083**
    travis.bernritter@us.army.mil

- **DVC**
  - **Business Development Director:**
    - **Barbara Solow, 301-607-5241**
  - **Contracts:**
    - **Donna Dawson, 301-607-5009**
  - **President:**
    - **President: Terry Irgens, 301-607-5001**