MEDICAL SYSTEMS

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Advanced Planning Briefing to Industry

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Outline

- Overview
- S&T and Warfighter Needs
- Technical Challenges
- Acquisition Strategy / Funding / Schedule
- Upcoming Business Opportunities
- Contacts

Science &Technology (S&T) Overview

- **Develop Pre-treatments and Therapeutics for Protection Against Chemical and Biological Agents and Radiological Exposure; Develop, Assess and Validate Diagnostic Assays for Chemical and Biological Agents**

- **Utilize New Biotechnologies to Develop Broad-spectrum Countermeasures Against Conventional, Emerging, and Engineered Biological Threats**

- **Transition FDA-Approvable Vaccines, Drugs and Diagnostic Assays / Devices to Advanced Development**

Program Overview

Chemical Biological Medical Systems (CBMS)

Develop, Procure, Field, and Sustain Premier FDA Approved Medical Protection, Treatment and Diagnostic Capabilities Against Chemical, Biological, Radiological, and Nuclear (CBRN) Warfare Agents

S&T Needs

- **Rapid, Broad-Spectrum Chemical Warfare Agent (CWA) and Biological Warfare Agent (BWA) Protection**
- **Multi-agent BWA Prophylaxis**
- **Early Indicators of Exposure / Infection**
- **Effective Countermeasures Against Novel Chemical and Genetically Modified Biological Threats**
- **FDA Approval of Medical Countermeasures and Diagnostics**
- **Radiological Countermeasures**

Warfighter Needs

- **CBMS Products are Integrated into the DoD "System of Systems" Approach by Providing Prophylactic, Therapeutic, and Diagnostic Capabilities to Protect and Treat Service Members From the Effects of CBRN Agents**
  - **Medical Identification & Treatment Systems (CBMS - MITS)**
    - **Develop and Acquire Safe, Effective, and FDA Approved Products for Prophylaxis, Treatment, and Diagnosis of Chemical, Biological, Radiological and Nuclear Warfare Agent Exposure**
  - **Joint Vaccine Acquisition Program (CBMS - JVAP)**
    - **Develop, Produce, & Stockpile FDA Licensed Vaccine Systems to Protect the Warfighter from Biological Agents**

Warfighter Needs *(Cont'd)*

- **Post-Exposure Requirement: Provide the Capability to Treat Service Members for the Effects of CBRN Agents After the Appearance of Symptoms**
  - **Advanced Anticonvulsant 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**
  - **Bioscavenger will Prevent Incapacitation and Death from Exposure to Nerve Agents**
  - **Improved Nerve Agent Treatment System (INATS) Active Ingredient will Replace and Provide Better Protection Than Current Oxime, 2-PAM in Current Delivery System**
    - **System Approach Will Also Develop Broader Indications for Pretreatment Pyridostigmine Bromide**
  - **Medical Radiation Countermeasures will Enhance Survivability After Exposure to Ionizing Radiation**
  - **Critical Reagents Program (CRP) Provides Biological Threat Agent and Genomic Reference Material**

Warfighter Needs *(Cont'd)*

- **Diagnostics Requirement: Provide a Reusable, Portable, Modifiable Biological Agent Identification and Diagnostic System Capable of Simultaneous Reliable Identification of Multiple Biological Warfare Agents and Other Biological Agents of Operational Significance**
  - **Joint Biological Agent Identification and Diagnostic System (JBAIDS) Will Provide Portable Diagnostic Capability to Warfighter. Evolutionary Approach:**
    - **JBAIDS Increment I: System Capable of Identifying 10 Biological Warfare Agents (BWAs)**
    - **JBAIDS Increment 3, Next Generation Diagnostic System: Capability will be fully automated and integrated with on-board sample preparation, analysis and identification, and reporting. Increment 3 will be a smaller and less complex system that will minimize the need for consumables and extensive laboratory items of support equipment. It will be interoperable with the global information grid and will be FDA-cleared for use as a diagnostic device.**

Warfighter Needs *(Cont'd)*

- **Pre-Treatment Requirement: Provide the Capability to Protect Service Members From the Effects of Biological Agents Before the Appearance of Symptoms**
  - **CBMS - JVAP Uses the Prime Systems Contractor Approach with DynPort Vaccine Company (DVC) to Meet DoD Biological Defense Vaccine Requirements for Vaccines Currently in Development**
    - **DVC Obtains and Maintains FDA Licenses**
  - **Recombinant Botulinum A/B Vaccine Program (rBV A/B) will Provide Protection From Aerosol Exposure to Botulinum Toxin A/B**
  - **Plague Vaccine Program will Provide Protection from Aerosol Exposure to Yersinia Pestis**

S&T Technical Challenges

- **Pre-treatments**
  - Understand Immune Responses to Vaccination
  - Exploit DNA-based or Genetic Immunization Platforms for Rapid Vaccine Development
  - Develop Broad-spectrum, Multi-agent Vaccines to Counter Emerging Threats
  - Develop a Catalytic Nerve Agent Bioscavenger
- **Therapeutics**
  - Develop Broad-spectrum Therapeutics for BWA
  - Develop Surrogate Efficacy Measures and Animal Models for FDA Approval of Countermeasures
  - Develop Effective Countermeasures Against Toxins and Chemical Agents
  - Minimize Systemic, Neurologic, Ocular, and Cutaneous Injury by CWA

S&T Technical Challenges *(Cont'd)*

- **Diagnostics**
  - **Provide S&T Support to Advanced Developer in the Development/ Assessment of an Integrated Nucleic Acid and Immunodiagnostics Platform (JBAIDS Increment 3, Next Generation Diagnostic)**
  - **Exploit Systems Biology Tools to Develop Novel Biomarkers as Targets for Assay Development**
  - **Identify Presymptomatic Diagnostic Signatures**
  - **Simplify Sample Processing**
  - **Assay Improvement/ Expansion**
- **Medical Radiological Defense**
  - **Develop Effective Pre- and Post-exposure Radioprotectants**
  - **Reconstitute or Facilitate Repair of Radiogenic Damage to Hematologic, Immunologic, Gastrointestinal, and Neurological Systems**

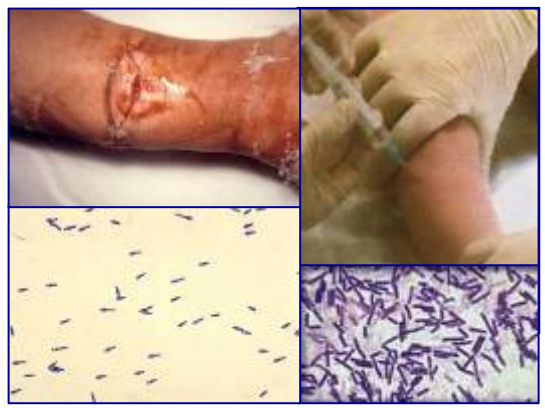
S&T Technical Challenges *(Cont'd)*

- **Transformational Medical Technologies Initiative (TMTI)**
- **Program Goals**
  - **Two (2) Platform Technologies to Identify Unknowns and Rapidly Develop Threat Countermeasures**
  - **Genetic Sequences for Pertinent Threats**
  - **Two (2) Broad Spectrum Countermeasures**
    - **One (1) Viruses (Especially Hemorrhagic Fever Viruses)**
    - **One (1) Intracellular Pathogens**
- **Two Investigational New Drugs (INDs) Within Five (5) Years Leading to Fielding FDA Licensed Products**

Program Technical Challenges *(Cont'd)*

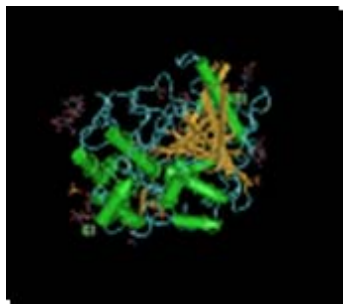
- **CBMS**
  - **Evolving FDA Guidance**
  - **Animal Rule**
  - **Manufacturing Scale Up**
  - **Industrial Base Sustainment**
  - **Biosurety Requirements for BSL 3/4 Commercial Facilities**

- **CBMS - JVAP**
  - **Plague Vaccine Program**
    - **Animal Model**
    - **Correlate of Protection**
  - **Recombinant Botulinum A/B Program**
    - **Assays to Measure Protein Concentration**



Program Technical Challenges

- **CBMS - MITS**
  - **Improved Nerve Agent Treatment System (INATS)**
    - **Active Ingredient is New Active Pharmaceutical Ingredient (API) in U.S.**
      - **Stability of the Formulation or Toxicology Problems with Candidate Oxime**
      - **Compatibility and Stability of Candidate Oxime in an Autoinjector System**
  - **JBAIDS – Next Generation Diagnostic System**
    - **FDA Approval of Device and Multiple Assays**
    - **Miniaturization & Interoperability**
    - **Automation and Integration of Sample Preparation**
    - **2 Years or More Stability of Consumables**



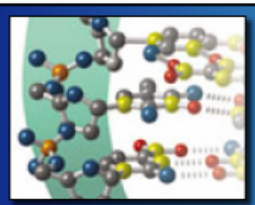
S&T Capability Strategy

- **Place Greater Emphasis on Developing Broad-Spectrum Medical Countermeasures**
- **Exploit Cutting Edge Technologies to Improve Medical Countermeasures**
- **Accelerate Development Cycle (Rapid Vaccine and Drug Development)**
- **Leverage Existing Capabilities Found in Other Federal Agencies, Industry, and International Partners**
- **Sustain Long-term Investment in Developing Candidates for Capability Gaps**
- **Ensure Knowledge Base to Support Future Technology Development**

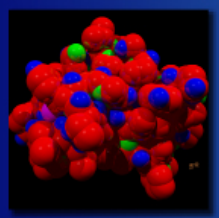
Transformational Medical Technologies Initiative Strategy

Scientific Thrust Areas | **Integrated Cross-Cutting Technologies** | **Deliverables**

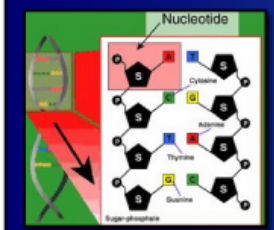
Genomic Identification



Small Molecule Discovery

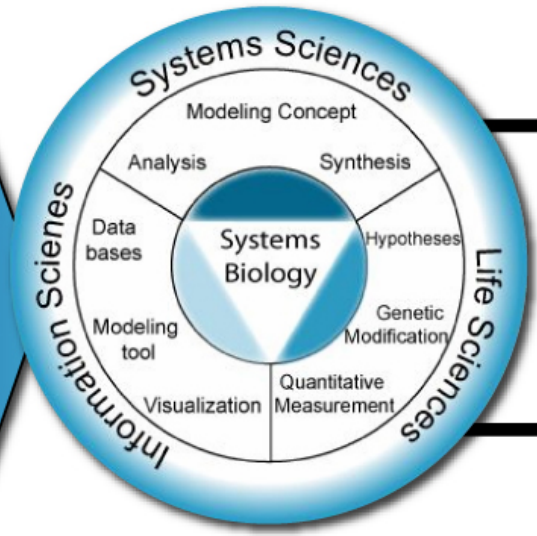


Protein Based Therapeutics

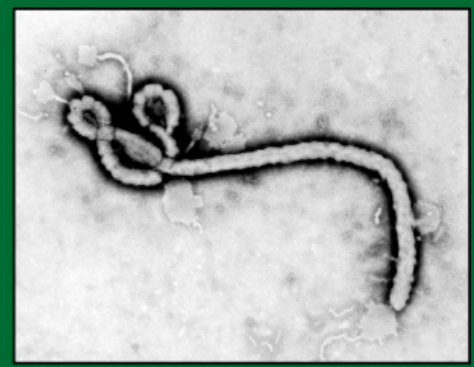


Nucleotide Therapeutics

Human Immune Enhancement

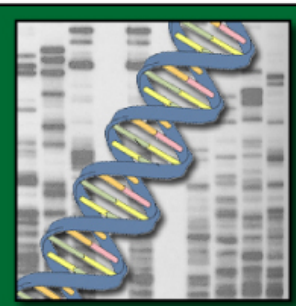


- Microarray Technology
- Bioinformatics
- Proteomics
- Genomics
- siRNA



BROAD SPECTRUM TREATMENTS
- Hemorrhagic Fever Viruses
- Intracellular Bacterial Pathogens

GENETIC ID AND ANALYSIS

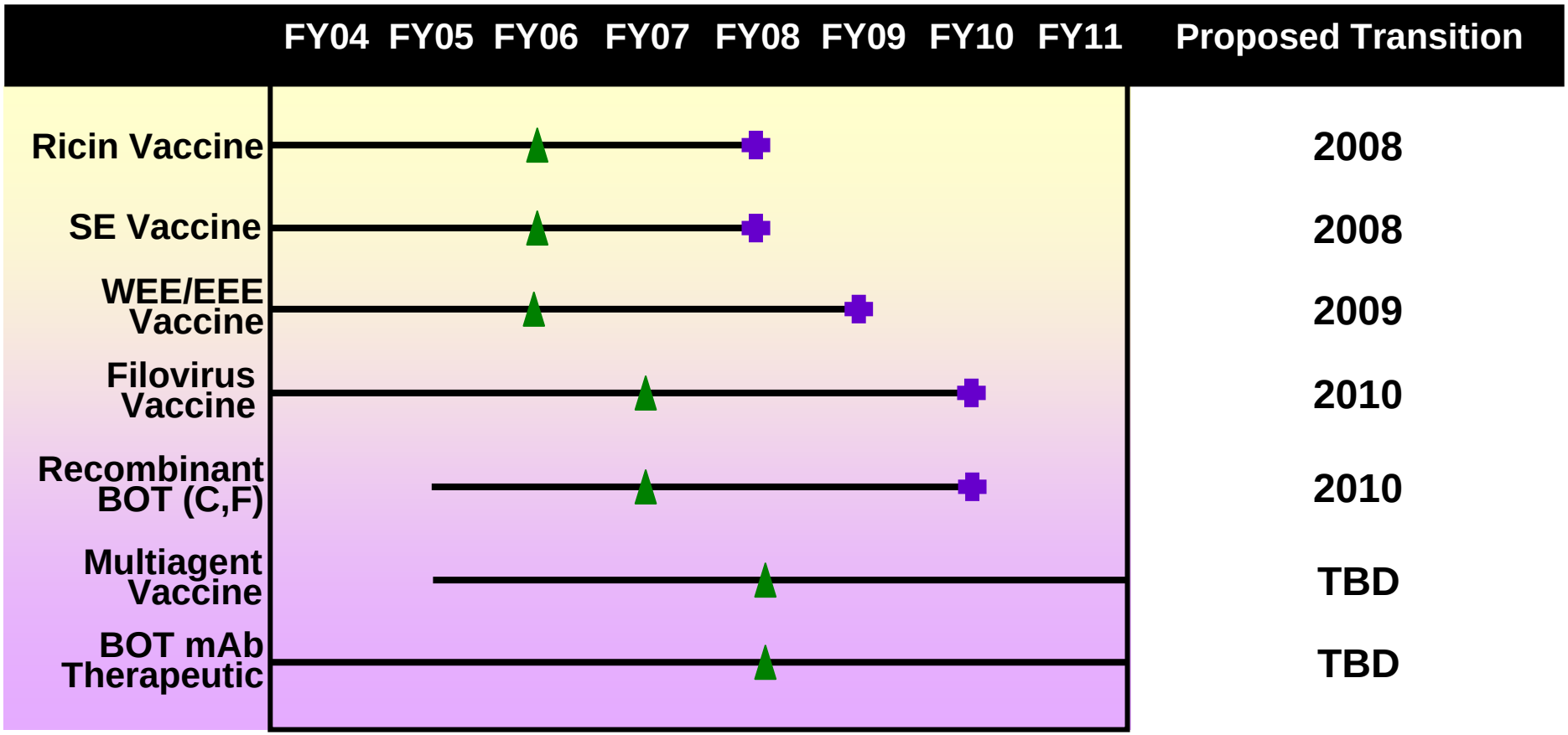


An Innovative Approach Using Revolutionary Technologies to Expedite the Development of Products to Counter Emerging Biological Threats

Program Acquisition Strategy

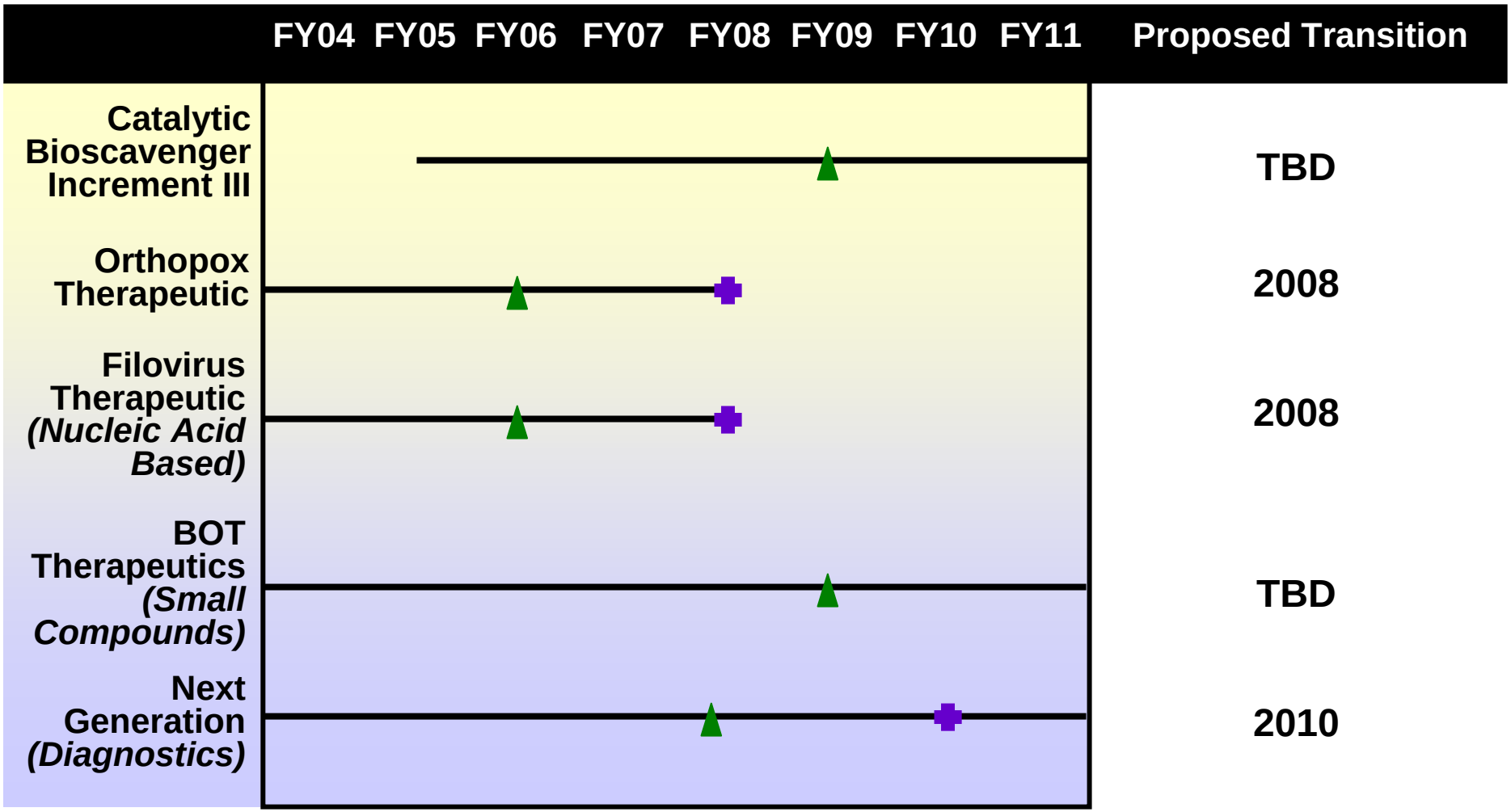
- **Partnering: Occurs Through Collaboration with Industry, Academia, Other Government Agencies, and International Partners to Meet the Needs of the Warfighter**
- **Regulatory Compliance: Essential Since FDA Approval is a Key Performance Parameter (KPP) for Acceptable Medical Countermeasure Material Solution**
- **Lifecycle Management: Important to Ensure that the Medical Countermeasure Material Solutions are Sustained and Thus Readily Available to the Warfighter**
  - **Manages Product Line *Within* Available Resources**
    - **Funds Product Development Efforts to *Minimize* Schedules**
    - **Expands or Contracts Product Line Based on Available Funding**
- **Planning for the Future: Imperative to Meet Existing and Future Threats**
  - **Addresses User *Requirements* Based on Capabilities Needed and Joint Staff Priorities**

S&T Program Schedule / Transition to CBMS - JVAP

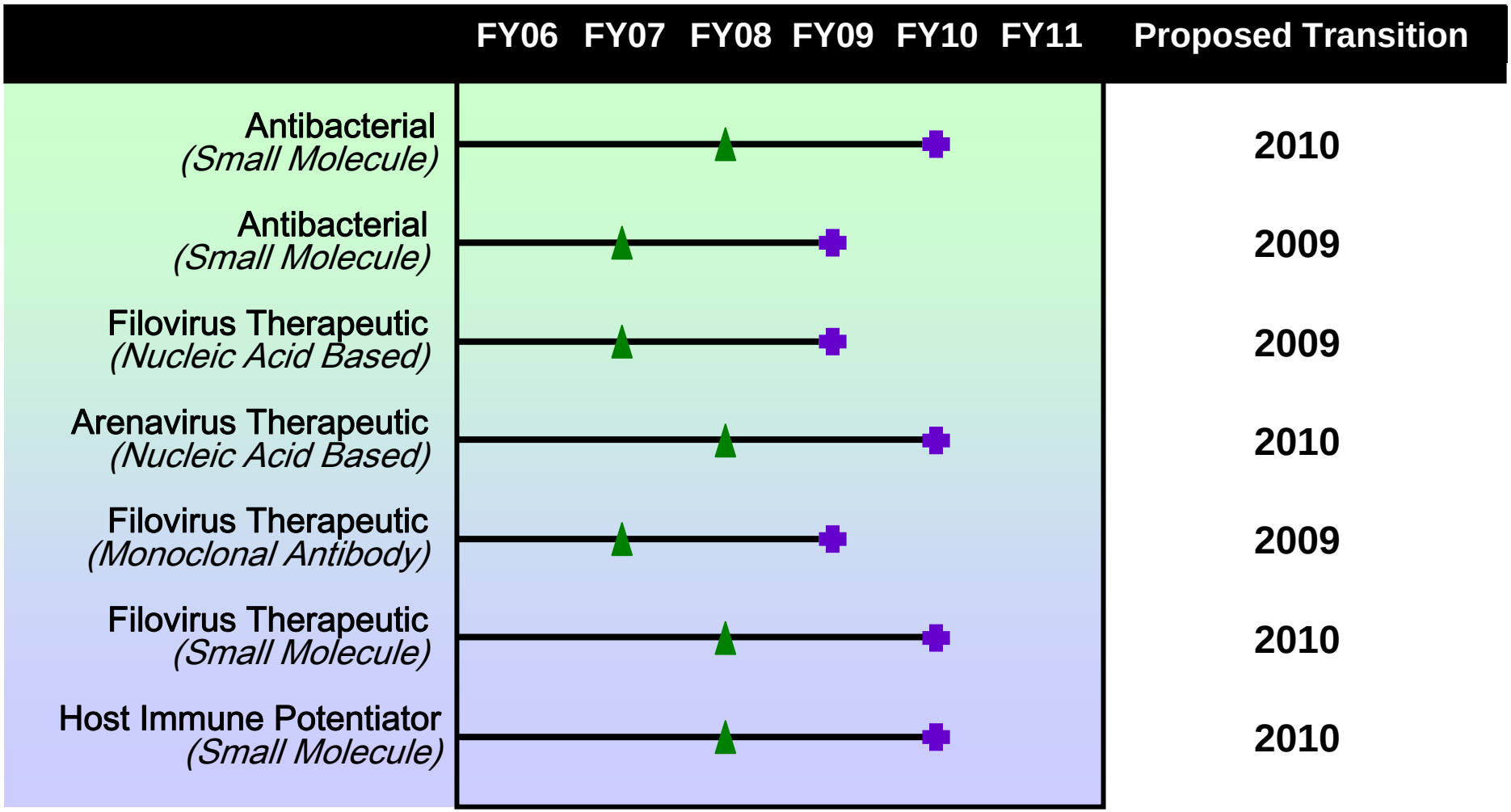


LEGEND: ▲ Technology Transition Agreement (TTA) ✚ Transition Opportunity

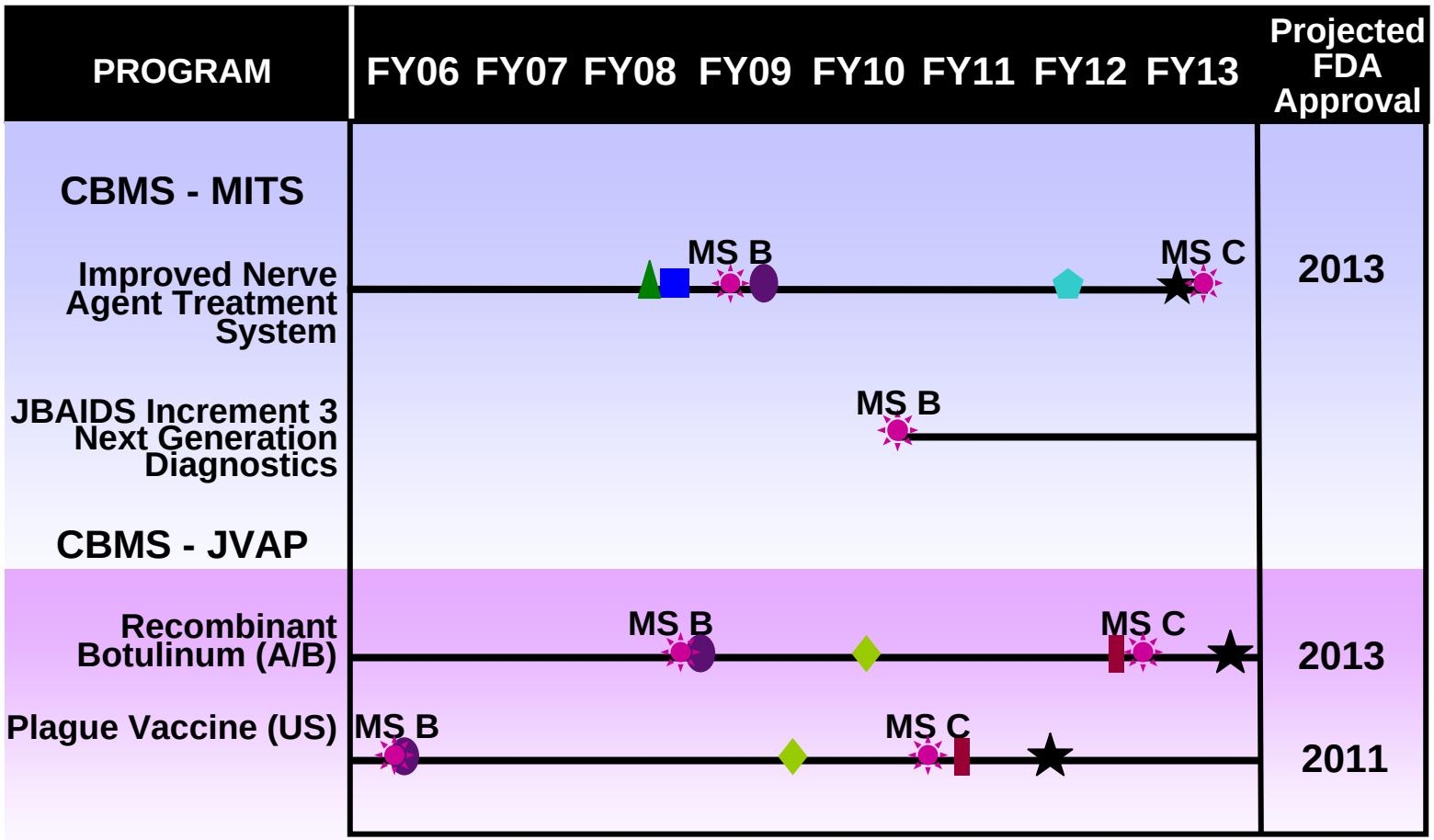
S&T Program Schedule / Transition to CBMS - MITS



TMTI Program Transition Schedule



CBMS: Current Business Opportunities



S&T Funding

$M	FY07	FY08	FY09	FY10	FY11	FY12	FY13	TOTAL
6.1 Research *(Core Program)*	31.7	24.7	24.6	23.6	22.6	23.2	22.8	173.1
6.1 TMTI	33	23	10.2	7.5	7.3	6.6	5.9	111.9
6.2 Research *(Core Program)*	68.6	77.6	76.7	72.5	72	80.5	82.2	530
6.2 TMTI	49.1	113	26.2	16.1	14	12.8	11.4	302.2
6.3 Research *(Core Program)*	52.8	66	68	73.5	68.8	70	70.8	469.8
6.3 TMTI	41.4	111.7	264.9	187.5	92.4	84.1	75.2	880.8
TOTAL	378.2	416	470.5	380.7	277	277.1	268.2	2467.8

Program Funding*

$M	FY08	FY09	FY10	FY11	FY12	FY13	TOTAL
CBMS							
BA4/5	22.0	33.9	47.8	33.2	9.3	2.2	148.4
PROC	2.0	2.0	2.0	2.0	2.0	2.0	12.0
Total	24.0	35.9	49.8	35.2	11.3	4.2	160.4

BA4 = Pre - Milestone B

BA5 = Post - Milestone B

Program funding estimates are notional based on historical data

S&T Upcoming Business Opportunities

Program	Estimated Target BAA Release	Target Funding Year
Transformational Medical Technologies Initiative – RFP	**4QFY07 and TBD**	**FY07 – FY11**
CB Defense Medical S&T Program – Tech Base	**1QFY08**	**FY09**
Small Business Innovation Research (SBIR) – Tech Base	**1QFY08**	**FY07**
Chem-Bio Defense Program (S&T) – BAA	**1QFY08**	**FY08**

Program Upcoming Business Opportunities

Program	Description	Year
CBMS - MITS		
JBAIDS	Develop Increment 3: Next Generation Diagnostic System	FY11-12
Improved Nerve Agent Treatment System (INATS)	Conduct post Milestone B to FDA approval activities	FY08-13
CBMS - JVAP		
rBot A/B Vaccine Program	Conduct Phase 3 clinical trial	FY08-12
rBot A/B Vaccine Program	Conduct large scale fill/finish	FY08-13
Plague Vaccine Program*	Conduct Phase 3 clinical trial	FY08-11
Plague Vaccine Program*	Conduct large scale fill/finish	FY08-11
CBMS - JVAP	Storage, testing, and maintenance of IND and legacy stockpile	FY08-13

*DVC Candidate

S&T Points of Contact

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Advanced Development Points of Contact

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- **Deputy Joint Project Manager, Chemical Biological Medical Systems (CBMS)**
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BACK UP

Total Program Funding*

$M	FY08	FY09	FY10	FY11	FY12	FY13	TOTAL
CBMS							
BA4	21.6	7.8	0.0	0.0	0.0	0.0	29.4
BA5	90.4	99.4	82.4	75.2	57.0	47.7	452.1
PROC	56.0	47.6	54.8	54.6	60.5	61.0	334.5
Total	168.0	154.8	137.2	129.8	117.5	108.7	816.0
TMTI							
BA4	0.0	0.0	122.6	139.8	133.9	134.0	530.3
BA5	0.0	0.0	0.0	114.1	109.3	109.4	332.8
RDTE	0.0	0.0	122.6	253.9	243.2	243.4	863.1

BA4 = Pre - Milestone B

BA5 = Post - Milestone B

***FY08-13 BES Funding as of January 23, 2007**