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biosolutions™

Emergent's Anthrax Programs

Medical Countermeasures
Workshop

November 4, 2009

EBS
LISTED
NYSE.



emergent

Company Highlights

- 1 Growing **biodefense franchise with product sales** from licensed anthrax vaccine
- 2 **Maturing pipeline** of advanced-stage products built on proprietary platform technologies
- 3 Expanding biologics **manufacturing capabilities**
- 4 Extensive track record of **strategic M&A** transactions
- 5 Seven year history of **financial strength**

Corporate Overview

Business Focus

Disease Focus

Infectious
Diseases

Product Focus

Vaccines &
Immune-related
Therapeutics

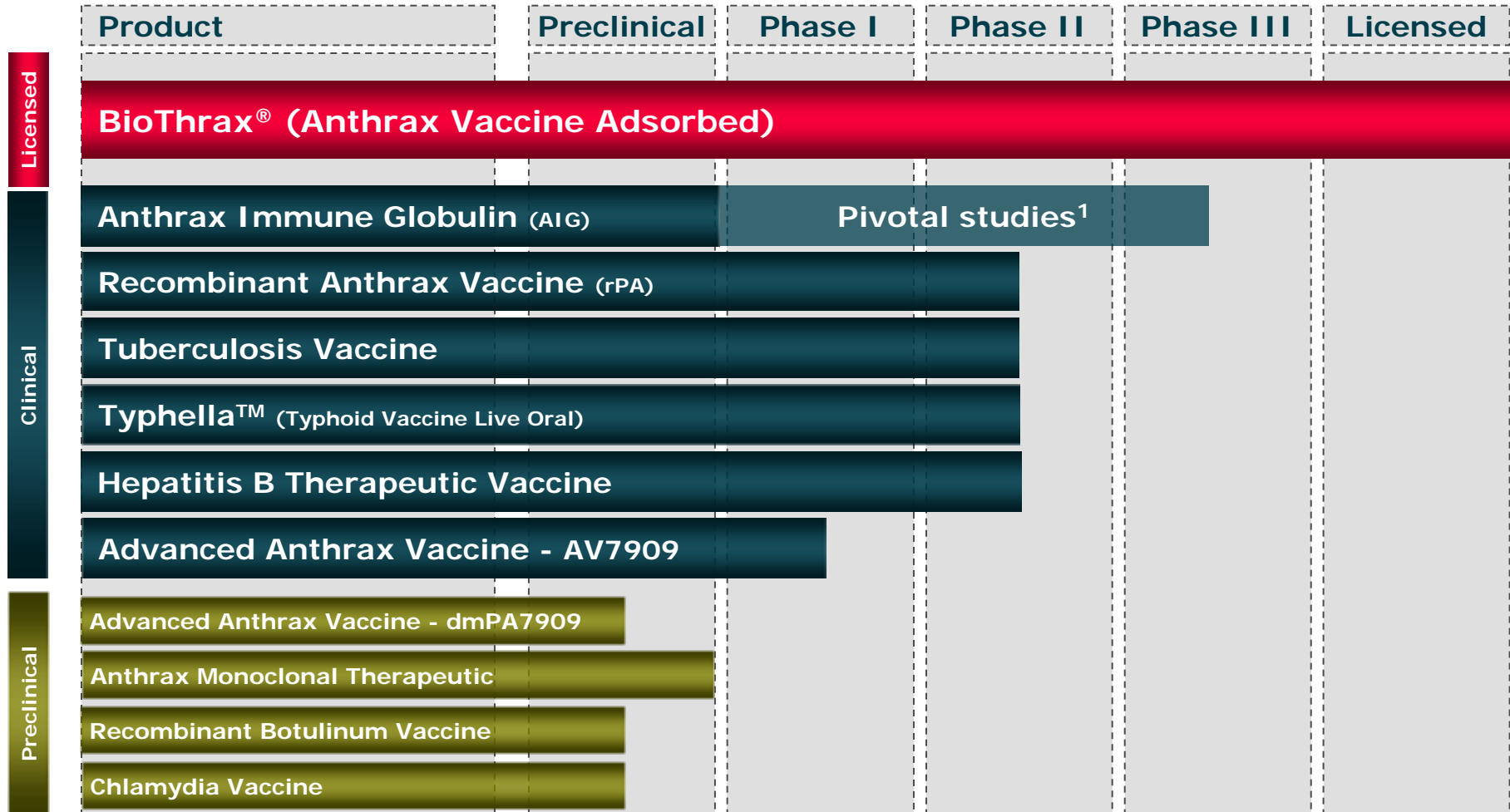
Customer Focus

Government

Commercial

Corporate Overview

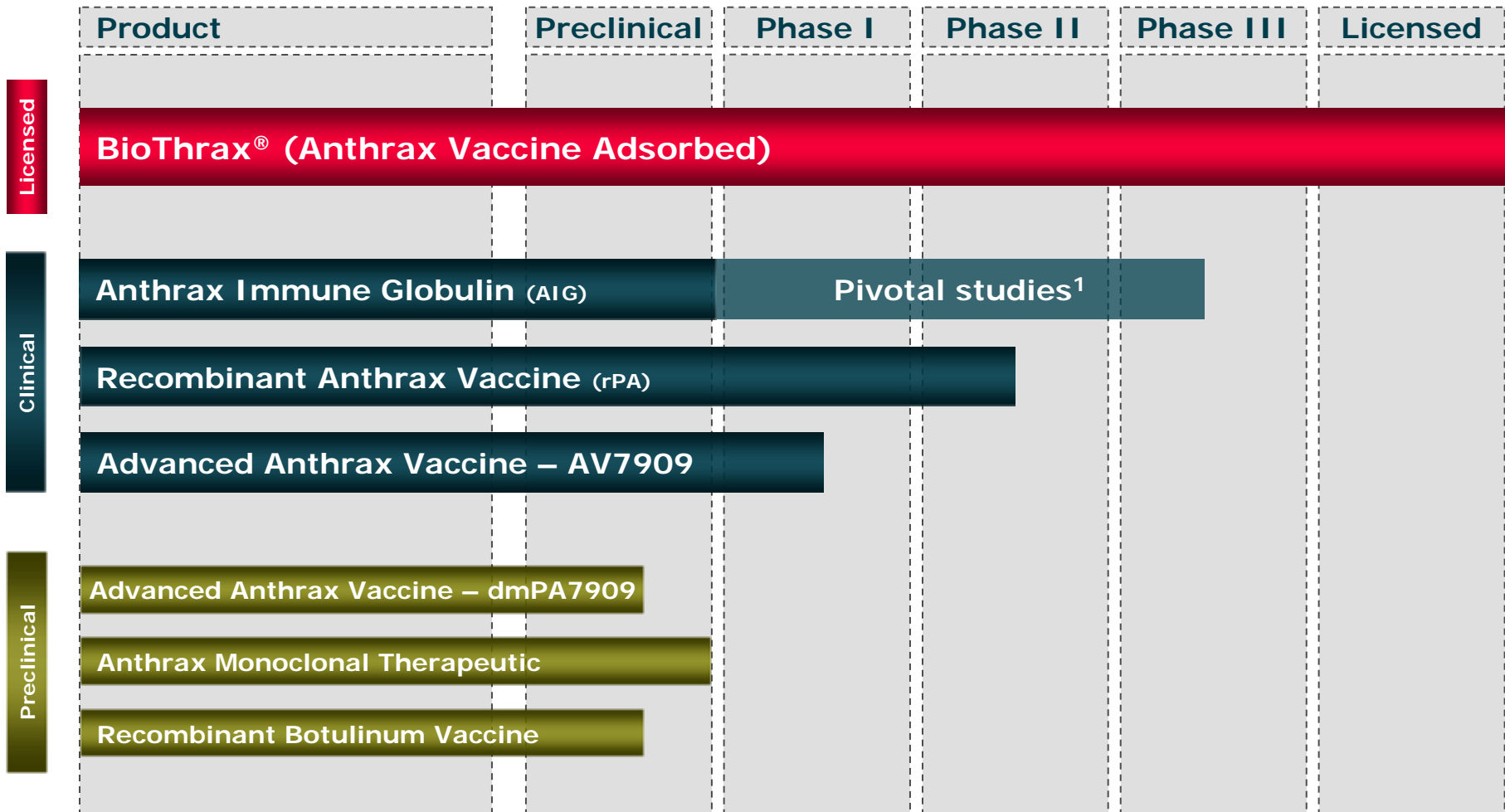
Maturing Product Pipeline



¹ Pivotal studies in animals and humans expected to proceed in parallel under the FDA animal rule

Biodefense Franchise

Maturing Biodefense Franchise Targeting Anthrax and Botulism



¹ Pivotal studies in animals and humans expected to proceed in parallel under the FDA animal rule

Biodefense Franchise

Anthrax Program — Opportunities

Vaccine

Therapeutic

Pre-Exposure
(Prophylaxis)

Post-Exposure
(Pre-Symptomatic)

Post-Exposure
(Symptomatic)

BioThrax[®]

BioThrax[®]
(under EUA)

Immune Globulin

rPA

rPA

AIG

AV7909

AV7909

Monoclonal Antibody

dmPA7909

dmPA7909

**Anthrax Monoclonal
Therapeutic**



Licensed



Clinical



Preclinical

Anthrax Vaccine Programs

BioThrax[®] History of US Gov't Contracts

Signed	Doses	Contract Value	Contract Term	Delivery Status
Sep 2004	5M	\$124M	Sep 2004 – Sep 2007	Completed
May 2005	5M	\$120M	May 2005 – May 2006	Completed
May 2006	5M	\$123M	May 2006 – May 2007	Completed
Sep 2007	18.75M	\$448M	Sep 2007 – Sep 2010	Completed
Oct 2008	14.5M	\$405M	Sep 2009 – Sep 2011	Completion anticipated Sep 2011
TOTAL	48.25M	\$1,220M		

Anthrax Vaccine Programs

BioThrax[®] Opportunities for Growth

Completed: 08/09

1

Continue deliveries under current **\$448M/18.75M** dose contract with HHS through 3Q 2009

Completed: 06/09

2

Secure FDA approval for sBLA for **4-year dating**

Begun: 10/09

3

Initiate deliveries under follow-on **\$405M/14.5M** dose contract with HHS through 3Q 2011

4

Complete further **reduction in immunization to 3-dose schedule**

5

Expand licensing and sales activities in **foreign markets**

Anthrax Vaccine Programs

Recombinant Anthrax Vaccine (rPA)

Development Highlights

- Recombinant vaccine based on Protective Antigen (rPA)
- *Bacillus* expression system (non-spore forming)
- Highly purified; alum adjuvant; IM; 2-8°C storage
- Candidate evaluated in Phase I and Phase II trials
- Protection conferred in non-clinical studies

Market Opportunity

- HHS announced development/procurement RFP for **25M** doses
- Proposal submitted to BARDA
- EBS notified “in competitive range” by BARDA
- **Contract size anticipated to exceed \$500M**

Anthrax Vaccine Programs

Advanced Anthrax Vaccine – AV7909

Development Highlights

- Vaccine based on BioThrax[®] and novel adjuvant CPG 7909
- Rapid immunity after 2 doses observed
- Efficacy study in Phase Ia trial completed
- Phase Ib study funded by BARDA to be initiated in 2010

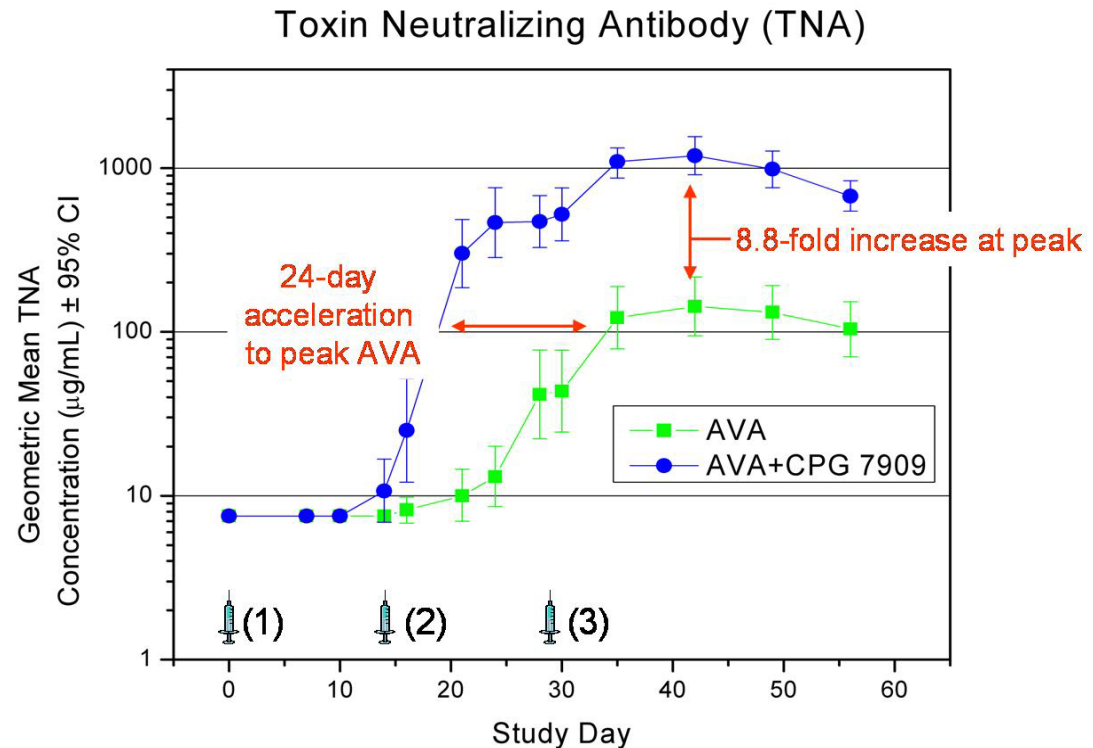
Market Opportunity

- NIAID grant and development contract award of **\$33M**
- Life cycle extension based on advancement of licensed BioThrax[®] vaccine
- Continued sales to U.S. Gov't for SNS and foreign governments

Anthrax Vaccine Programs

AV7909 Phase 1a Study – TNA Results

- Study results
 - The TNA assay results paralleled those observed with the ELISA.
 - The peak TNA concentration for the AV7909 group was 8.8-fold higher ($P < 0.001$).
 - The time to reach the max concentration of TNA 45 days for the AVA alone and 21 days for AV7909 ($P < 0.001$).
 - TNA levels achieved after three doses (0, 2, 4 weeks) of AVA alone could be achieved after only two doses of AV7909 (0, 2 wks).



Anthrax Vaccine Programs

Advanced Anthrax Vaccine – dmPA7909

Development Highlights

- Vaccine based on protease-resistant double mutant rPA and novel adjuvant CPG 7909
- Rapid immunity after 2 doses in animals
- Thermostable dry-powder formulation
- Proof-of-concept established in a challenge model
- GMP manufacturing to be completed in 2010

Market Opportunity

- NIAID grant award of **\$4.9M**
- Continued sales to U.S. Gov't for SNS and foreign governments

Anthrax Vaccine Programs

dmPA7909 – POC GP Challenge Study

Gp	Vaccine Composition			Results		
	dmPA (µg)	CPG 7909 (µg)	Aluminum (µg)	TNA (µg/mL)	Alive/Total	% Survival
1	50	0	0	174±104	7/14	50
2	10	0	0	61±64	2/14	14.3
3	50	200	0	6550±2087	14/14	100
4	10	40	0	3592±1382	14/14	100
5	50	0	250	3656±1894	13/14	92.9
6	10	0	50	2127±959	13/14	92.9
7	50	200	250	6226±1992	14/14	100
8	10	40	50	5606±2024	14/14	100
9	200 µl BioThrax® (2/5 human dose)			1840±864	13/14	92.9
10	0	0	0	19±15	0/14	0

Anthrax Therapeutic Programs

Anthrax Immune Globulin (AIG)

Development Highlights

- Therapeutic based on human polyclonal antibodies
- Treatment for individuals symptomatic of anthrax disease
- Based on licensed, large-scale manufacturing process
- Completion of critical human and non-clinical trials anticipated in 2010 – 2011
- Submission of BLA anticipated in 2011

Market Opportunity

- BARDA/NIAID development contract awards of **\$13.2M**
- No AIG product currently licensed by FDA
- U.S. Gov't polyclonal dose requirement: up to **100K**
- Estimated U.S. market size: **\$1B** (based on \$10K/dose)
- **RFP for procurement possible in 2010 – 2011**

Anthrax Therapeutic Programs

AIG – Completed Non-clinical Studies

- **ANHP0 (non-GLP Study)**: Pilot tolerability and PK study in NHPs conducted at Bridge Laboratories (Gaithersburg, MD). Report was submitted to the FDA in November, 2008.
- **AR1 (GLP Study)**: PK and tolerability study in rabbits conducted at Battelle (West Jefferson, OH) (NIAID U01 Grant funded). Report was submitted to the FDA in May, 2009.
- **ANHP1 (GLP Study)**: PK and tolerability study in NHPs conducted at Battelle (West Jefferson, OH). Final Audited Draft Report is under review at Emergent.
- **AR2 (non-GLP Study)**: Pilot therapeutic and efficacy study in rabbits conducted at Battelle (NIAID U01 Grant funded). Final Audited Draft Report is under review at Emergent.
- **ANHP2 (non-GLP Study)**: Therapeutic and efficacy study in NHPs conducted at Battelle. Draft Report is due in December, 2009.

Anthrax Therapeutic Programs

Anthrax Monoclonal Therapeutic

Development Highlights

- Therapeutic based on human monoclonal antibodies
- Recombinant candidate produced in cell culture
- Unique Mechanism of Action
- Efficacy demonstrated in preclinical studies
- Initiation of Phase I study anticipated in 2009

Market Opportunity

- BARDA development contract award of **\$24.3M**
- U.S. Gov't monoclonal dose requirement: up to **100K**
- Estimated U.S. market size: **\$700M** (based on \$7K/dose)
- **RFP for procurement anticipated in 2010**

Anthrax Therapeutic Programs

Anthrax Monoclonal Therapeutic – Development Activities to Date

- Manufactured two cGMP lots of drug product
- Conducted IND-enabling toxicity studies
 - No observed safety concerns
- A number of efficacy studies have been conducted in various animal models
 - Fischer Rats
 - Mice
 - Guinea Pigs
 - Rabbits
 - Non-human primates
- Phase I clinical trial to start in near term

Emergent's Anthrax Programs

Expected Near Term Milestones

BioThrax®

- Pursue additional sales to foreign governments
- Complete product enhancement initiatives (PEP, 3-dose regimen)

Recombinant Anthrax Vaccine (rPA)

- Secure procurement contract for up to 25M doses
- Initiate Phase IIb clinical study

Advanced Anthrax Vaccine – AV7909

- Utilize \$33M NIAID funding (U01 grant and development contract)
- Initiate Phase Ib clinical trial

Anthrax Immune Globulin

- Complete studies and file BLA
- Secure procurement contract from U.S. Gov't for SNS

Advanced Anthrax Vaccine – dmPA7909

- Utilize \$4.9M NIAID funding (U01 grant)
- Complete Phase I GMP manufacturing

Anthrax Monoclonal Therapeutic

- Initiate Phase I clinical study

