

# CANGENE CORPORATION

## Global Health Security Initiative

November 4-5 2009



[WWW.CANGENE.COM](http://WWW.CANGENE.COM)

**CANGENE**

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# A Focus on Therapeutics for Infectious Diseases

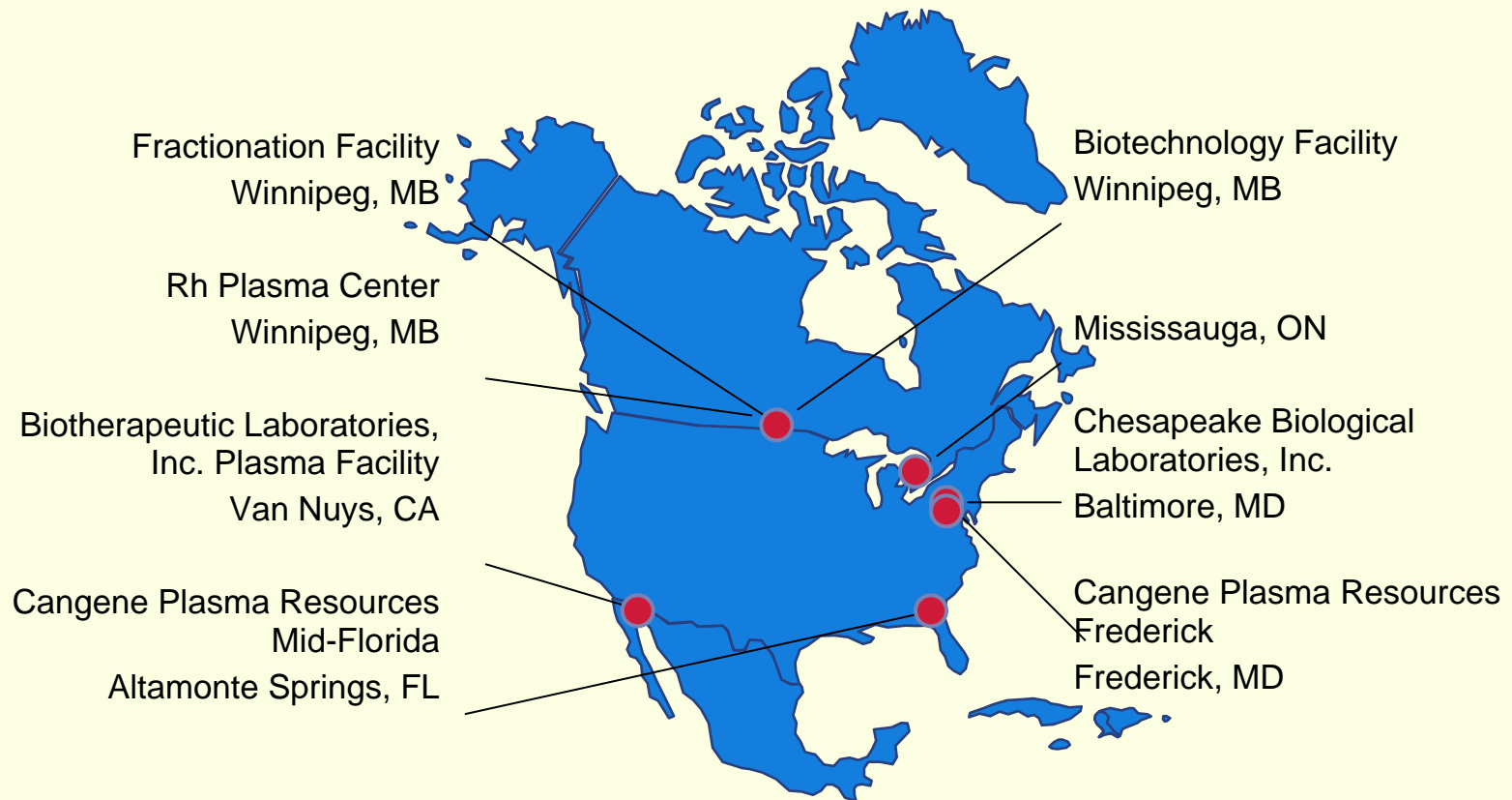


CANGENE CORPORATION

# A leader in specialty plasma products



# STRONG NORTH AMERICAN PRESENCE



# CANGENE CORPORATION

## 4 FDA-approved drugs



# CANGENE CORPORATION

**Nearly US\$1 billion in U.S.  
government Biodefense  
contracts signed since  
2002**



# BIODEFENSE HISTORY

- Initiated Biodefense Work in 1999
- USG Contracts with BARDA, CDC, DoD:
  - Vaccinia Immune Globulin
    - (Licensed by FDA and Health Canada)
  - Anthrax Immune Globulin
  - Botulism Antitoxin
- All 3 products used to treat human cases
- All 3 products in the US Stockpile (SNS)
- All 3 products are available from ongoing Manufacturing Program



# ANTHRAX IMMUNE GLOBULIN

- Human Polyclonal Antibody for Treatment of Toxemia Associated with Inhalational Anthrax Disease
- Liquid Product, Stored Frozen with Anticipated 10 year Shelf-Life
- Contract with DHHS/BARDA for 10,000 Doses
- Met FDA Criteria for “Emergency Use Authorization”
- Deliveries continue to the US SNS



# AIG (cont.)

- Phase 1 Safety Study in 92 Healthy Volunteers
- Conducted 7 developmental studies in seeking FDA approval under:
  - 21CFR 601 Part H: "Approval of Biological Products when Human Efficacy Studies are not Ethical or Feasible"
- BLA Submission to FDA in Process
- Non-clinical studies to-date have demonstrated a significant survival benefit in the treatment of inhalational anthrax
  - Final studies are on-going
- Product used in 2 Patients with Inhalational Anthrax



# BOTULISM ANTITOXIN

- Heptavalent Equine Polyclonal Antibody
  - Targets all 7 Botulinum Serotypes
- Liquid Product, Stored Frozen with Anticipated 10 year Shelf-Life
- Contract with DHHS/BARDA for 200,000 Doses
- Met FDA Criteria for “Emergency Use Authorization”
- Deliveries are Ongoing to the SNS



# BAT (cont.)

- Seeking FDA approval under 21CFR 601 Part H
- Phase 1 Safety studies in 54 patients
- 11 Non-clinical Studies Completed:
  - Demonstrated Post Exposure Survival Benefit
  - Studies for Therapeutic Benefit are on-going
- Product used in 4 Patients for Emergency Cases



# RICIN

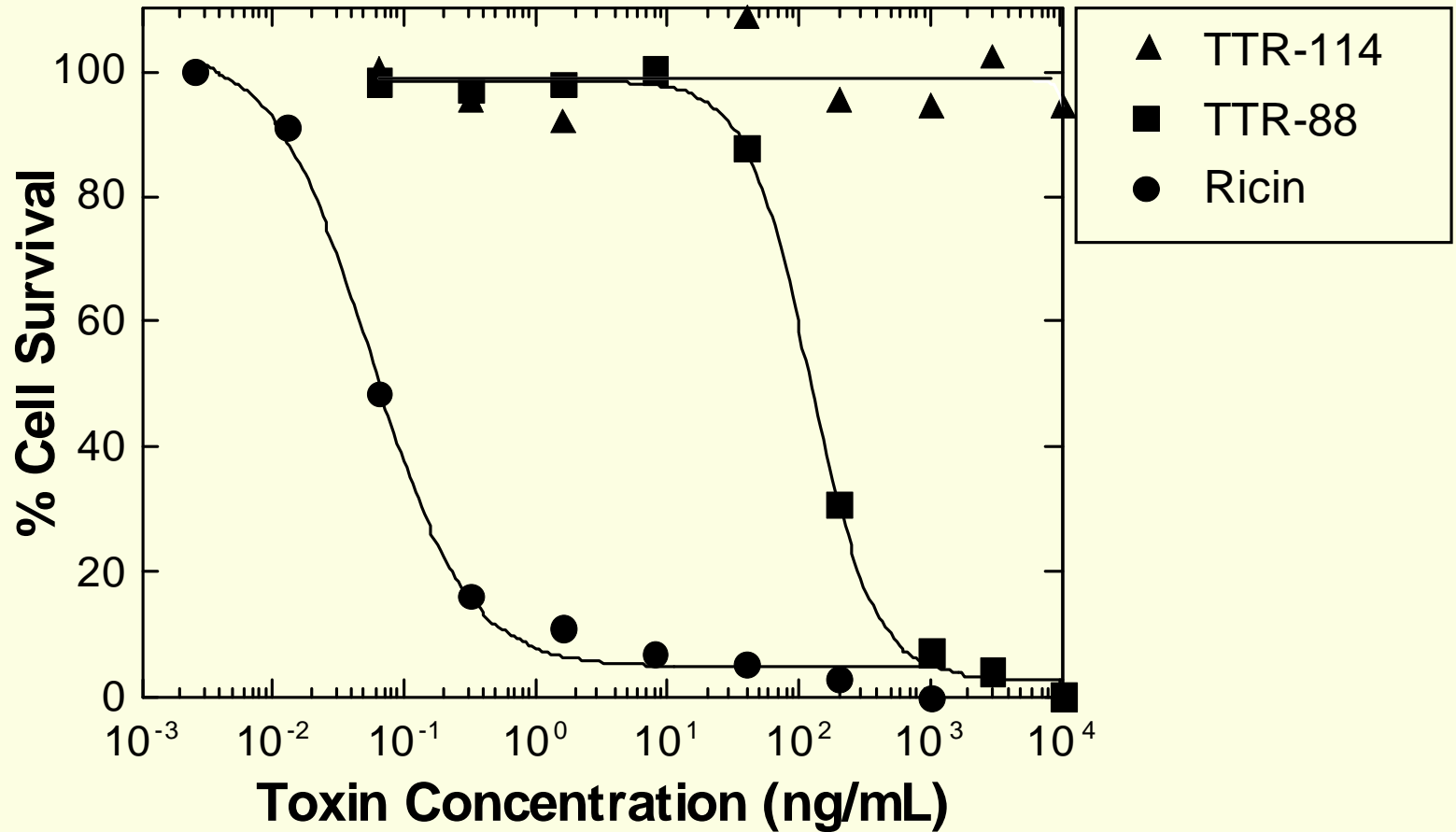
- Despeciated Equine Polyclonal Antibody
- Antibody Raised against r-Toxoid (A&B Chains)
- Toxid acquired in Cangene's Purchase of Twinstrand Therapeutics
- Manufactured at Pilot Scale using Cangene's Equine Production Process
- Toxin Results in Greatly reduced Toxicity
- Demonstrated in-Vivo and in-Vitro Neutralization



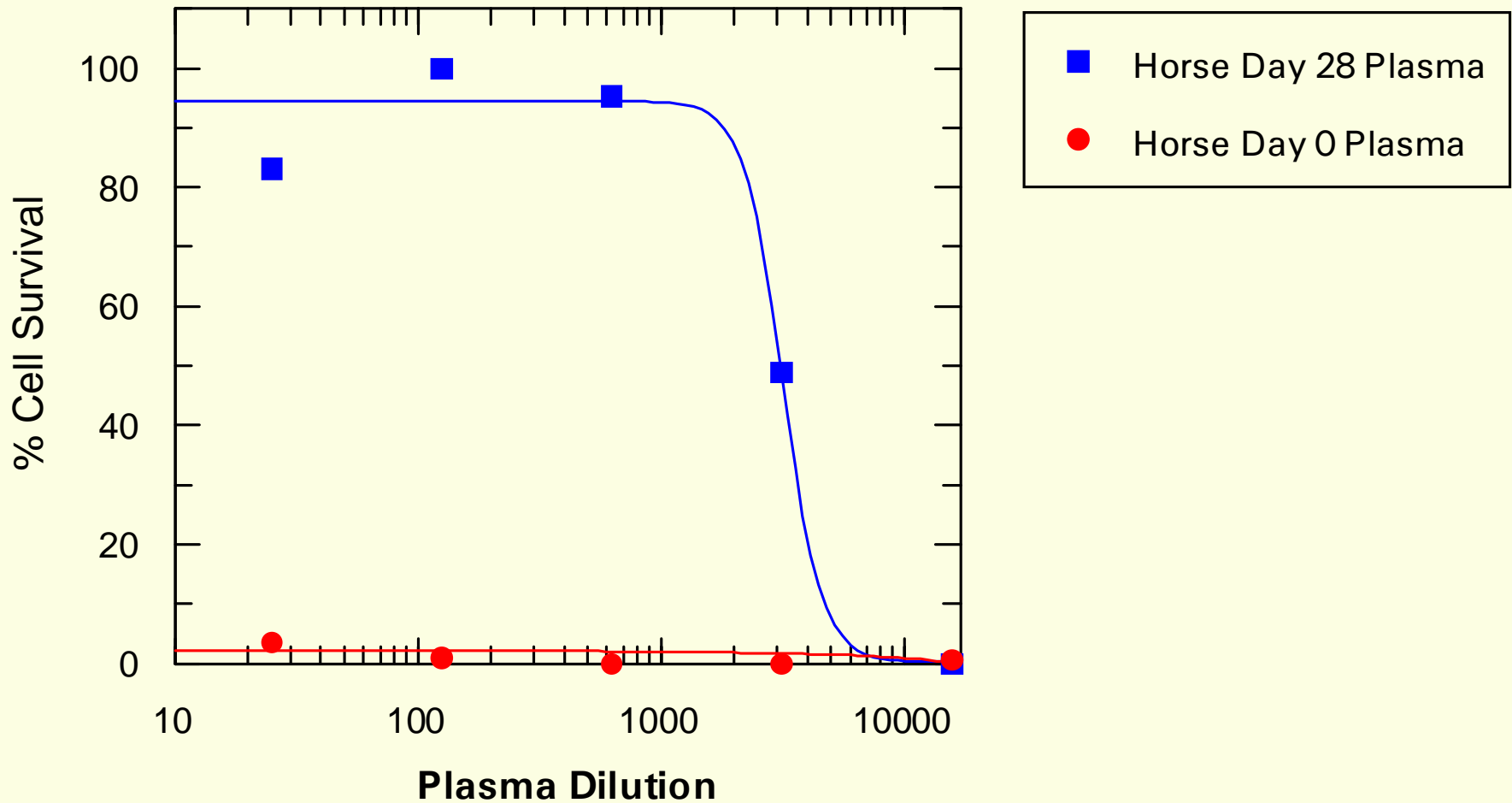
# **Ricin Countermeasure Results Equine Data**



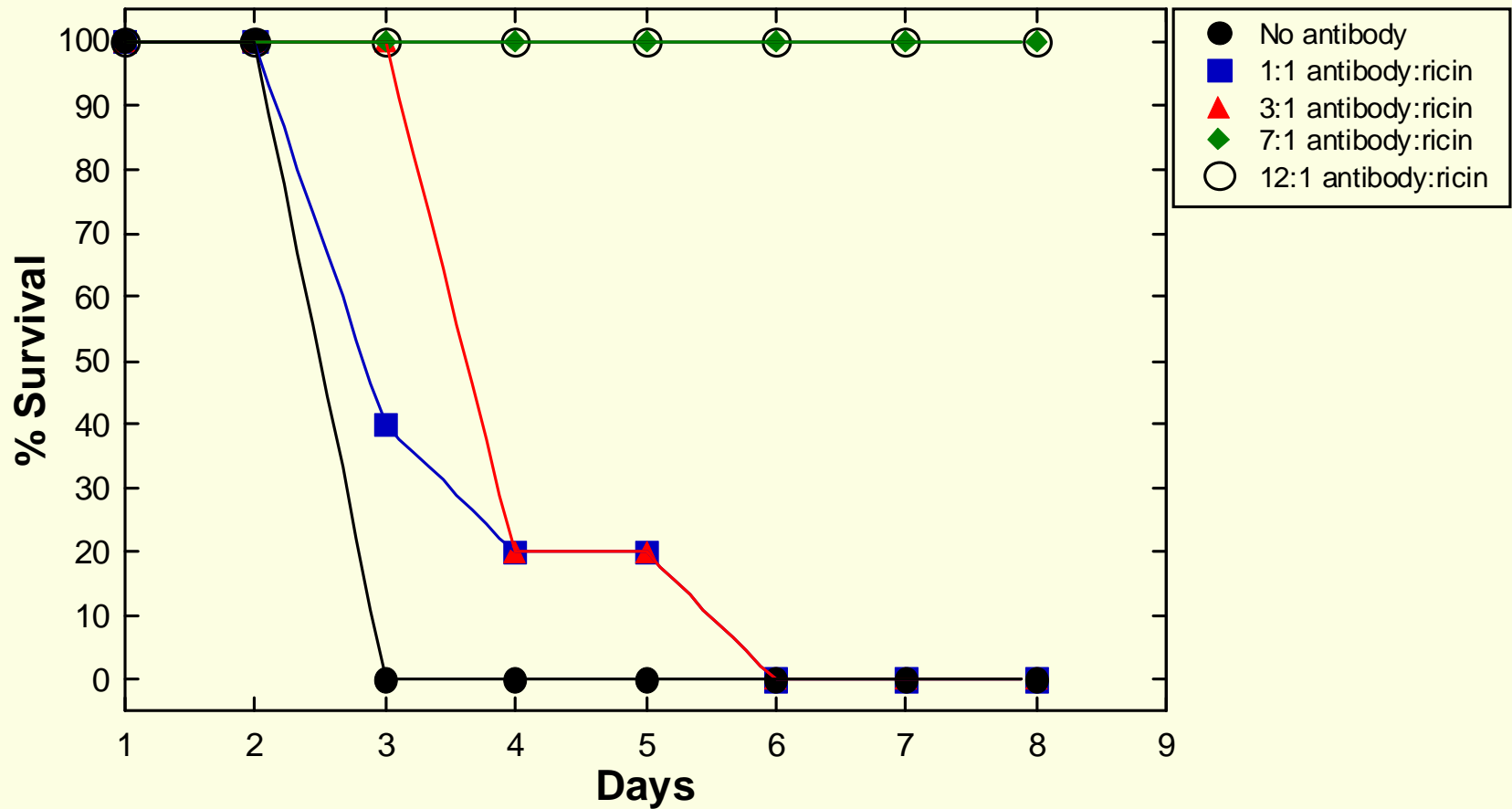
# Cytotoxicities of Ricin and Toxoids



# In Vitro Ricin Neutralization



# In Vivo Ricin Neutralization



# RICIN

- Current Status
- Production Scale-up for production of Clinical Product underway
- Dose Ranging and Toxin Neutralization Studies in Relevant Animal Model Planned



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For Product Information

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