

A Leader in the Battle Against Sepsis



INVESTOR PRESENTATION
WINTER 2012

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TSX: SDI

Conducting pivotal Phase III trial for a novel treatment of patients with septic shock

Sepsis: Large unmet medical need

>\$1 B market potential in North America

Cash: \$18.5M

Shares O/S : 114M (>7,000 shareholders = liquidity)

Market Cap : \$30M (large valuation upside)

Near-term licensing/partnering opportunities



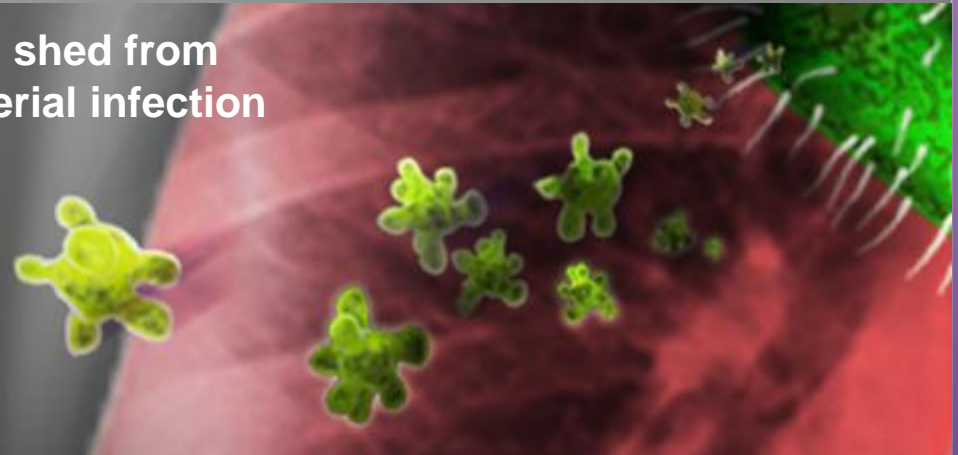
What is Sepsis?

- Sepsis is a life threatening condition with multiple causes
- Sepsis is common (1 in 10 ICU admissions in North America)
- **Sepsis is fatal**
 - **Over 250,000 deaths in North America each year**
 - **10th most common cause of death in North America**
 - **Kills more people than heart attacks**
- Sepsis is costly – over \$17 billion annually in U.S.
- Sepsis is a world-wide problem
- No existing effective treatments = A Large Opportunity

50% of Patients with Severe Sepsis have High Levels of Endotoxin

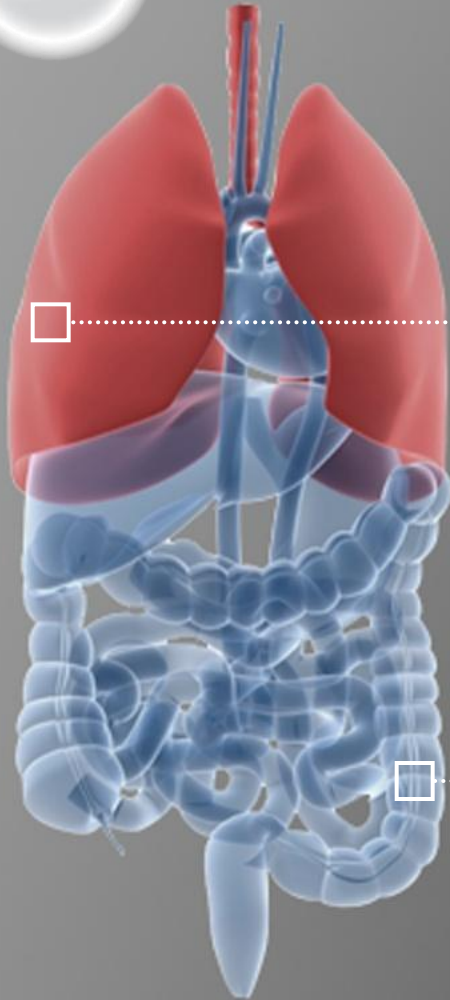
Endotoxemia

Endotoxin shed from local bacterial infection



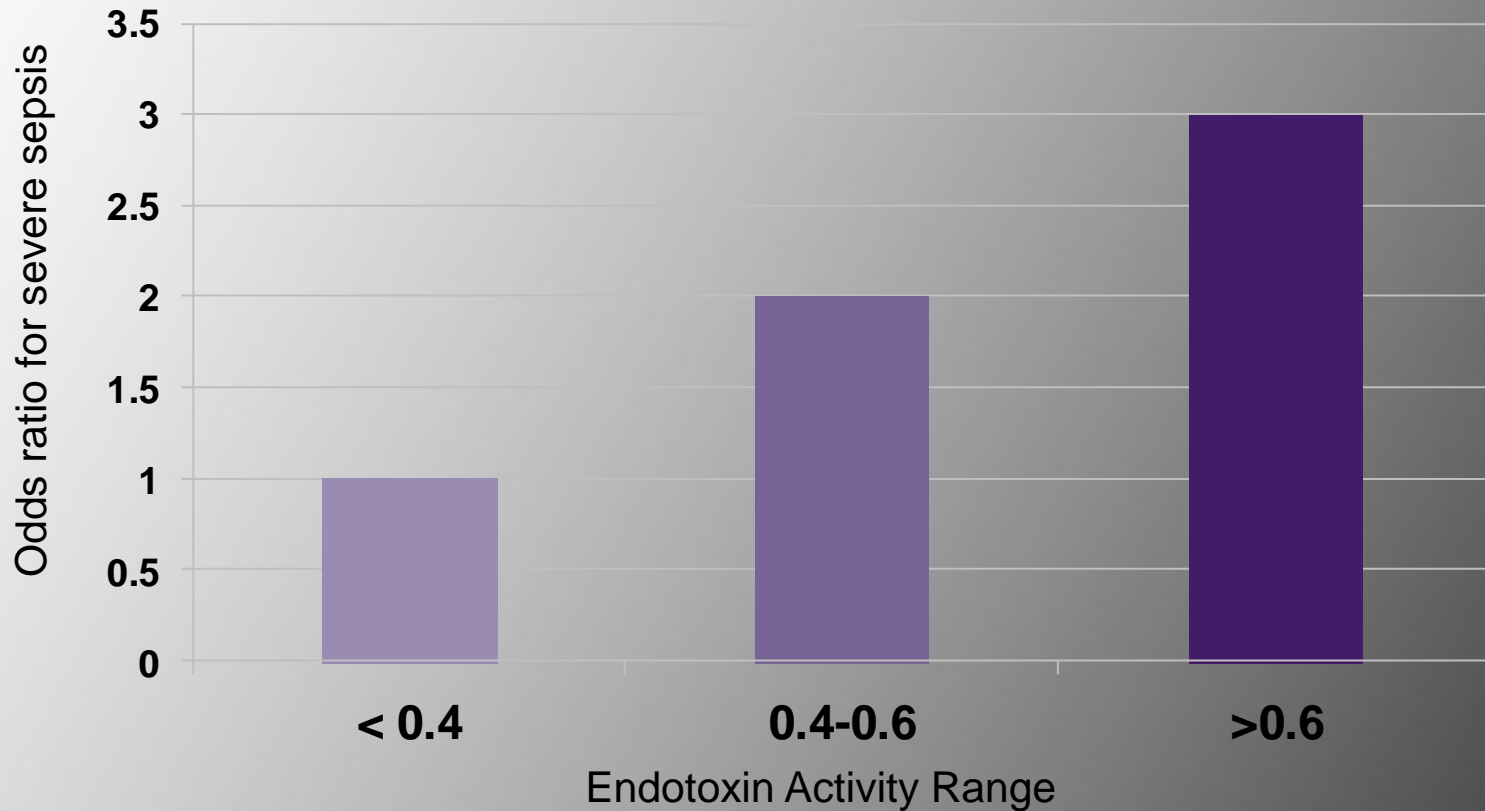
Endotoxin translocation from GI Tract

- Every human has 25-30 grams of endotoxin in their GI tract
- Less than 0.001 grams of endotoxin is enough to kill a person

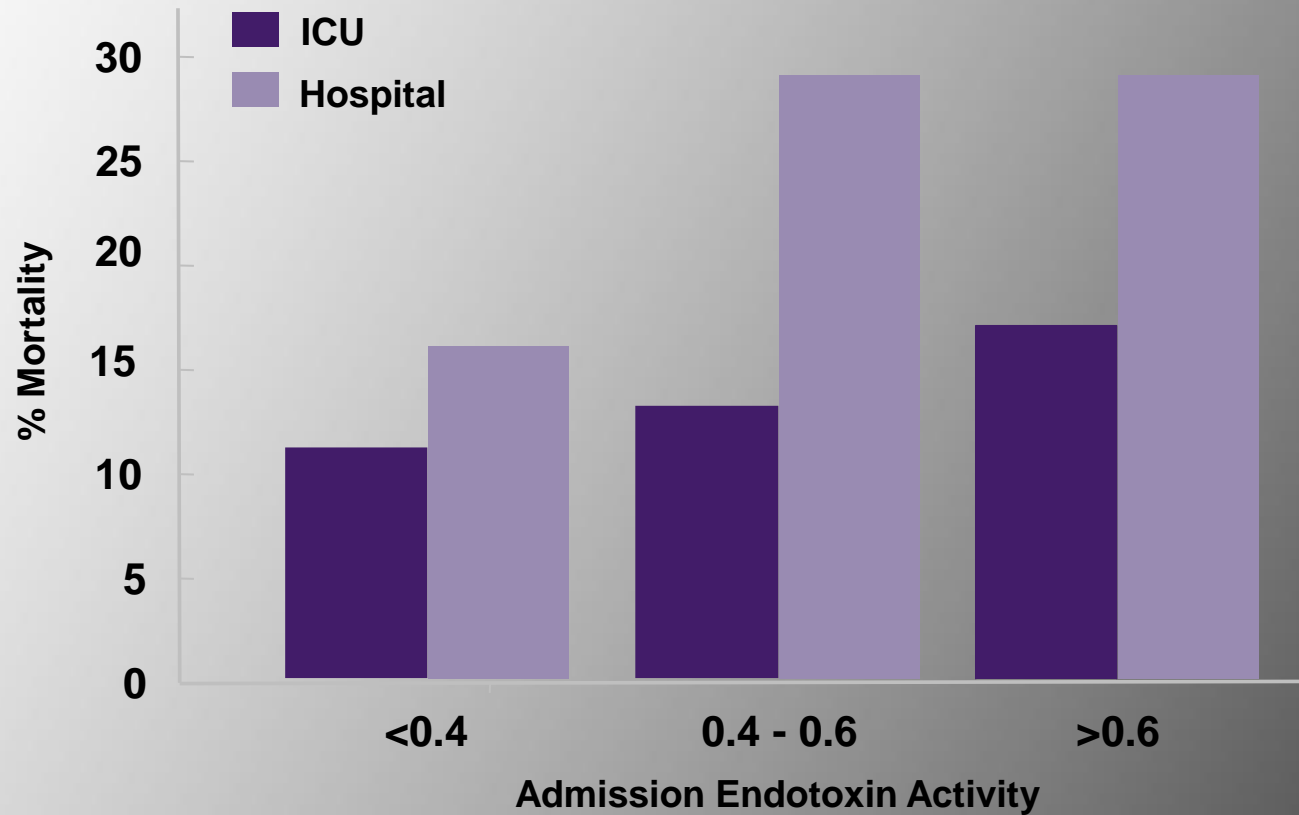


EAA™: Severe Sepsis

Odds ratio = 3.0 (C.I. 1.7-5.4)
p = 0.0002 (linear trend)



High Endotoxin Levels: Increased Mortality



A Diagnostic to Guide a Targeted Therapeutic



DIAGNOSTIC:
Endotoxin Activity Assay (EAA™)

MEASURE
levels of endotoxin
in blood



THERAPEUTIC:
Toramyxin

REMOVE
endotoxin



**A theranostic
treatment for
severe sepsis
& septic shock**

INCREASE
the chances of
survival

The Diagnostic: Endotoxin Activity Assay

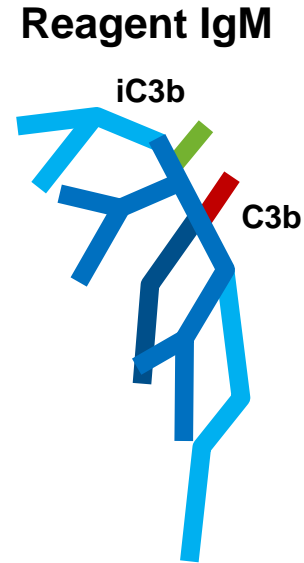
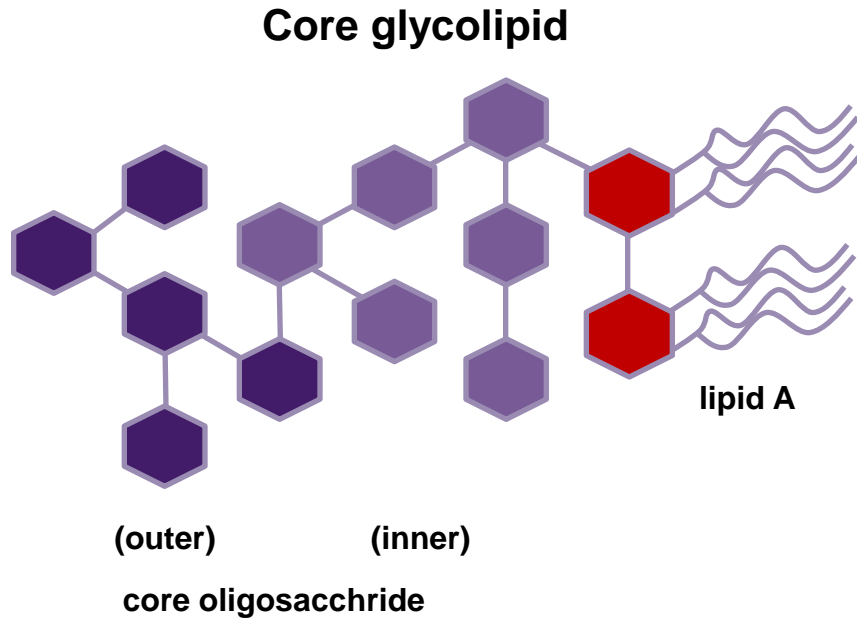
Endotoxin Activity Assay (EAA™)



**EAA™ is the
only FDA cleared
diagnostic for the
measurement of
endotoxin**

**Highly sensitive and specific:
EAA™ provides results in
30 minutes**

How does the EAA™ Measure Endotoxin



Key reagent: IgM to Lipid A
Affinity (Kd) = 13 nm

Whole blood milieu provides complement proteins and promotes IgM binding with Lipid A

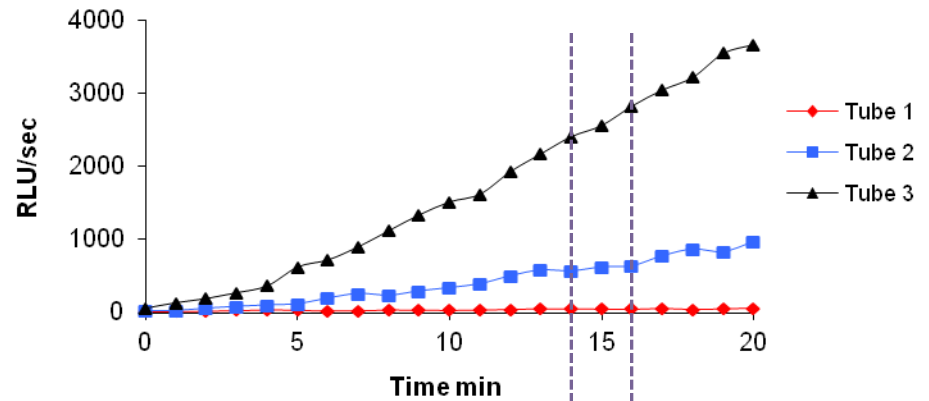
Read Time Optimized in 15 minutes



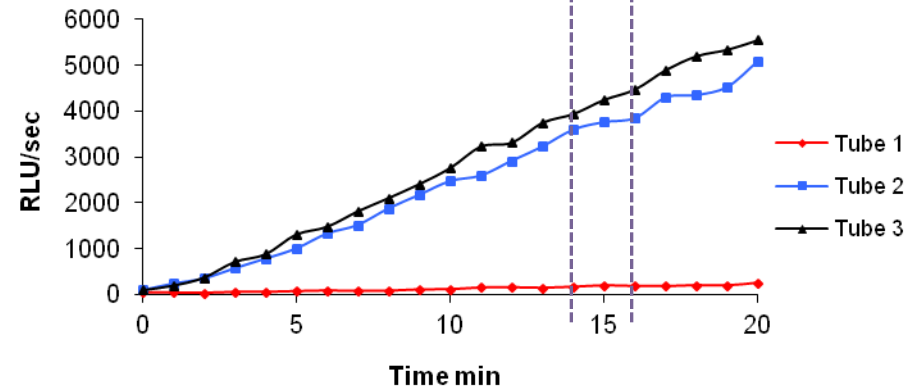
- Tube 1: Baseline neutrophil activation (patient is own control)
- Tube 2: Contains IgM antibody
- Tube 3: Tube 3 = IgM plus exogenous excess LPS

$$EAA^{TM} = \frac{(\text{sampleT2} - \text{controlT1})}{(\text{maxT3} - \text{controlT1})}$$

Low Endotoxin Sample



High Endotoxin Sample



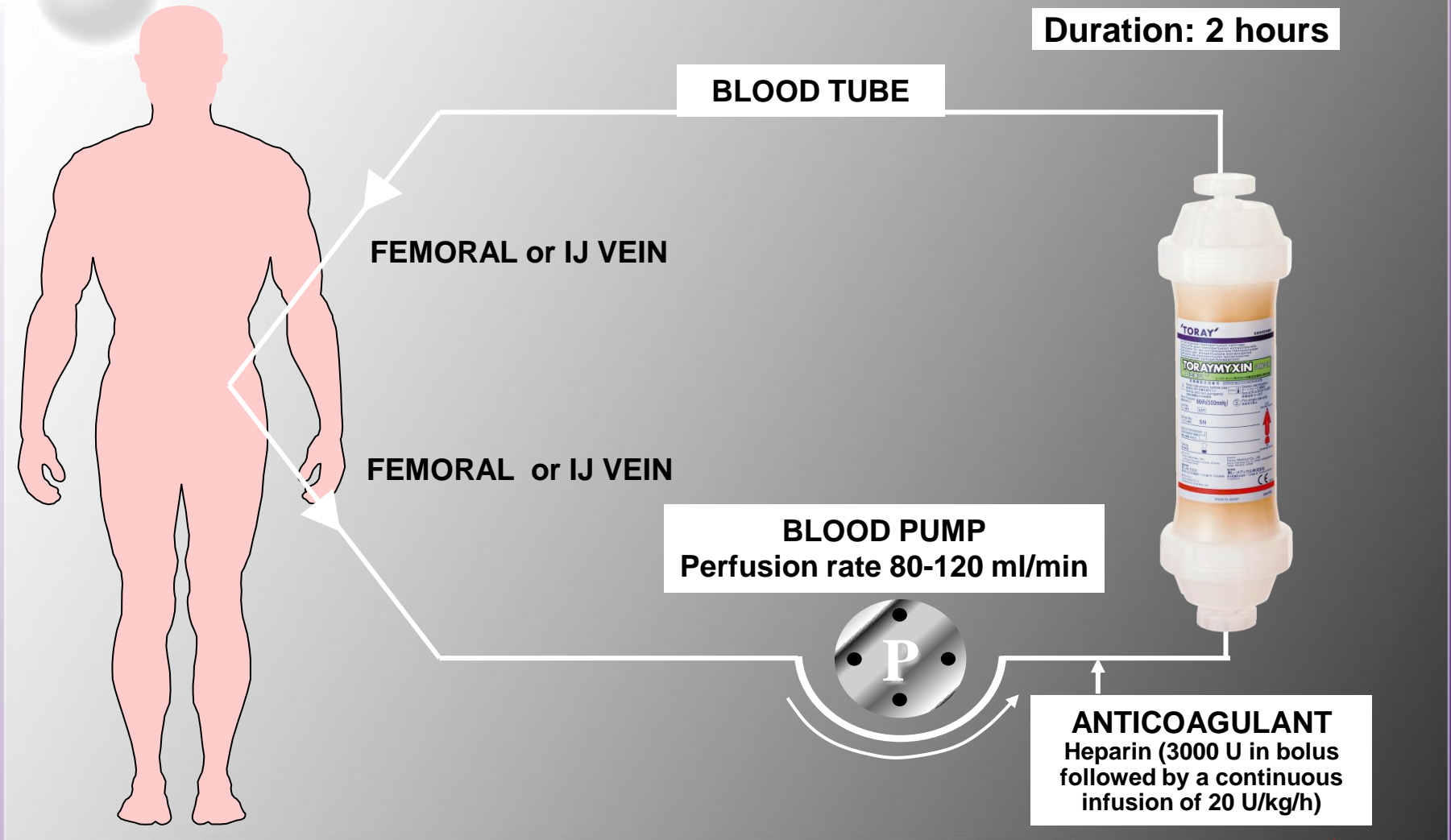
The Therapeutic: Toraymyxin

Toraymyxin is an adsorption column that removes endotoxin from the bloodstream

- More than 80,000 patients treated safely
- Approved in 18 countries
- Removes >90% of endotoxin
- Treatment = 2 columns over a 24 hour period
- Significant reduction in mortality



Direct Hemoperfusion with Adsorbent Column using Polymyxin B Immobilized Fiber



The Therapeutic: Toraymyxin

Extensive Clinical Experience

>50 published papers demonstrating significant mortality benefits

Journal of the American Medical Association article reported Toraymyxin:

- **Reduced 28 day mortality from 53% to 32%**
(p = 0.01) in patients with severe sepsis and septic shock in comparison to those patients in the conventional therapy group
(21% absolute reduction in mortality / 40% relative reduction)
- **Greatly improved** blood pressure, kidney function and reduces need for vasopressors

JAMA. 2009; Vol. 301 No. 23, 2445-2452

The critical importance of measuring Endotoxemia to guide PMX treatment

| <i>In septic patients with similar clinical findings:</i> | EAA<0.4 Low | 0.4<EAA<0.6 Intermediate | EAA>0.6 High |
|---|---------------------------|---|----------------------------|
| N | 9 | 18 | 28 |
| EAA level | 0.23 ± 0.02 | 0.50 ± 0.06 | 0.77 ± 0.12 |
| MAP (mmHg) | 81 ± 13 | 79.7 ± 6.7 | 80.0 ± 14.9 |
| CI (l/min/m²) | 4,07 ± 1,19 | 3,92 ± 1,18 | 3,64 ± 2,10 |
| SVRI (dynes/sec/cm-5/m²) | 1806 ± 437 | 1403 ± 855 | 1455 ± 397 |
| Gram+/- | 50%/12% | 25%/29% | 20%/23% |



The First Theranostic Trial in Sepsis

The EUPHRATES Trial

Evaluating the **Use** of
Polymyxin B Hemoperfusion
in a **Randomized** controlled trial of **Adults**
Treated for **Endotoxemia** and **Septic shock**

ClinicalTrials.gov
Identifier: NCT01046669

The First Theranostic Trial in Sepsis

Pivotal Phase III Trial

- Trial Design:
 - Combined treatment, using the EAA™ diagnostic and the Toraymyxin therapeutic device
- Target Population:
 - Critically ill patients with septic shock and a high endotoxin level
- Double blinded, randomized controlled trial of standard care versus Toraymyxin (plus standard care)
- 360 patients
- 30 U.S. and Canadian sites
- Primary End Point: 28 day mortality
- Mortality reduction from 35% to 20% ($p = 0.05$)



Inclusion Criteria

1. Age \geq 18 years old
2. Documented or suspected infection with definitive or empiric antibiotic administration
3. Evidence of at least 1 new onset organ dysfunction that is considered to be related to current sepsis illness:
 - Mechanical ventilation (on life support)
 - Thrombocytopenia (changes in coagulation)
 - Acute oliguria (kidney failure)
4. Hypotension (Shock) requiring vasopressor support:
 - Requirement for at least one vasopressor for at least 2 continuous hours
5. The patient must have received adequate intravenous fluid resuscitation
6. EAATM \geq 0.6

Trial is Positioned for Success

**World Renowned
Sepsis Experts**

Top Clinical Sites

**International Clinical
Research
Organization**

**Clinical and
Regulatory Experts**

| GROUP | POSITION | NAME | ROLE |
|-------------------------------------|------------------------|------------------------------------|--|
| Data Safety Monitoring Board | Chair | Dr. Bert Spilker | ○ Interim safety |
| | Biostatistics | Dr. Chengjie Xiong | |
| | Critical Care | Dr. John Kellum | |
| | Nephrology | Dr. Ron Wald | |
| | Infectious Disease | Dr. Steve Opal | |
| Global Steering Committee | Sponsor | Dr. Paul Walker | ○ Design protocol ○ Define population, study outcomes ○ Primary manuscript |
| | Principal Investigator | Dr. Phillip Dellinger | |
| | International | Dr. John Marshall (Canada) | |
| | | Dr. Massimo Antonelli (Italy) | |
| | | Dr. Paul Palevsky (United States) | |
| | CC-MD | Dr. Steve Trzeciak (United States) | |
| | CC-CTS | Christa Schorr (United States) | |
| CRO | | | ○ Regulatory ○ Final protocol ○ CRF, contracts ○ Study monitoring ○ Database |

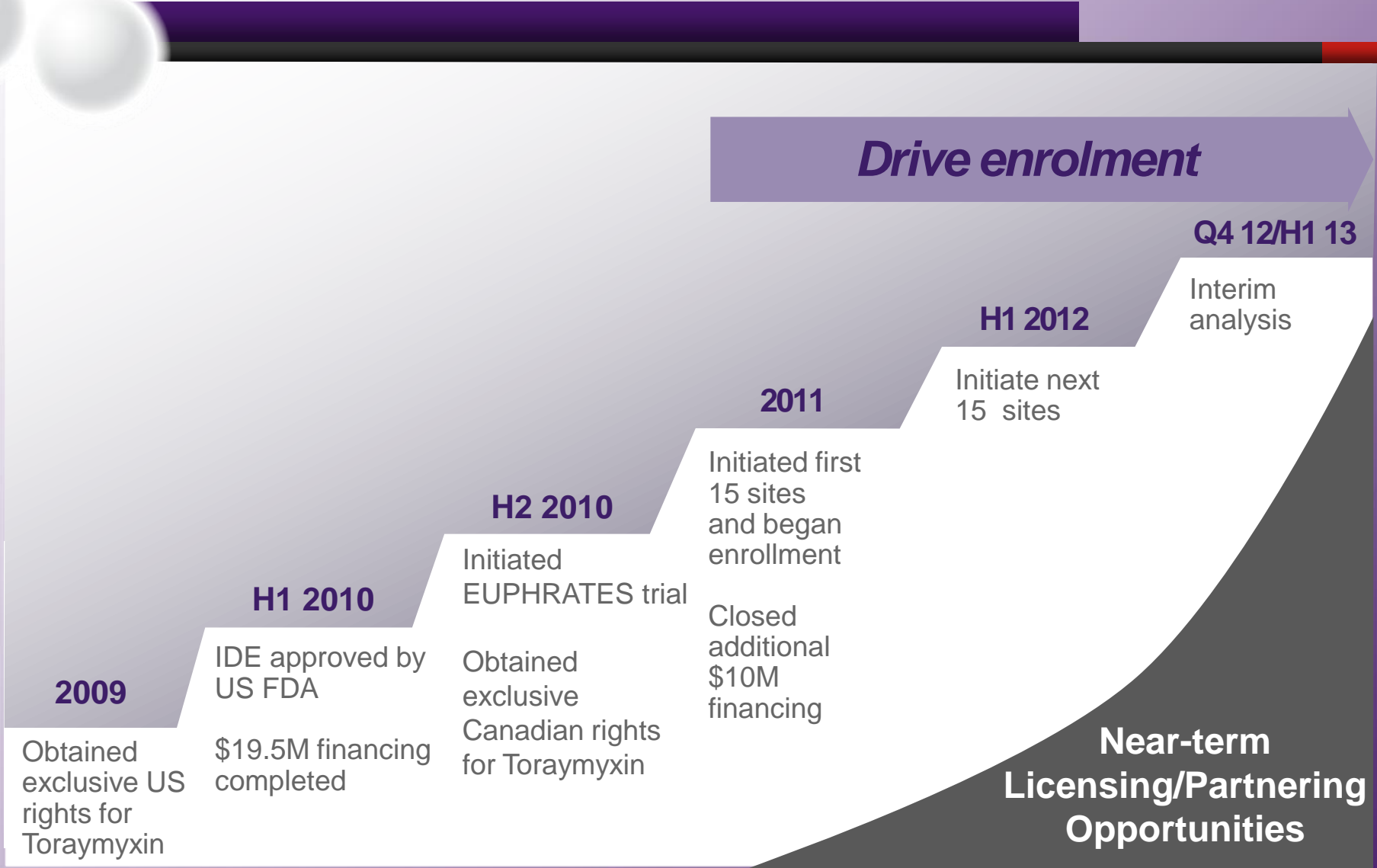


FDA Update

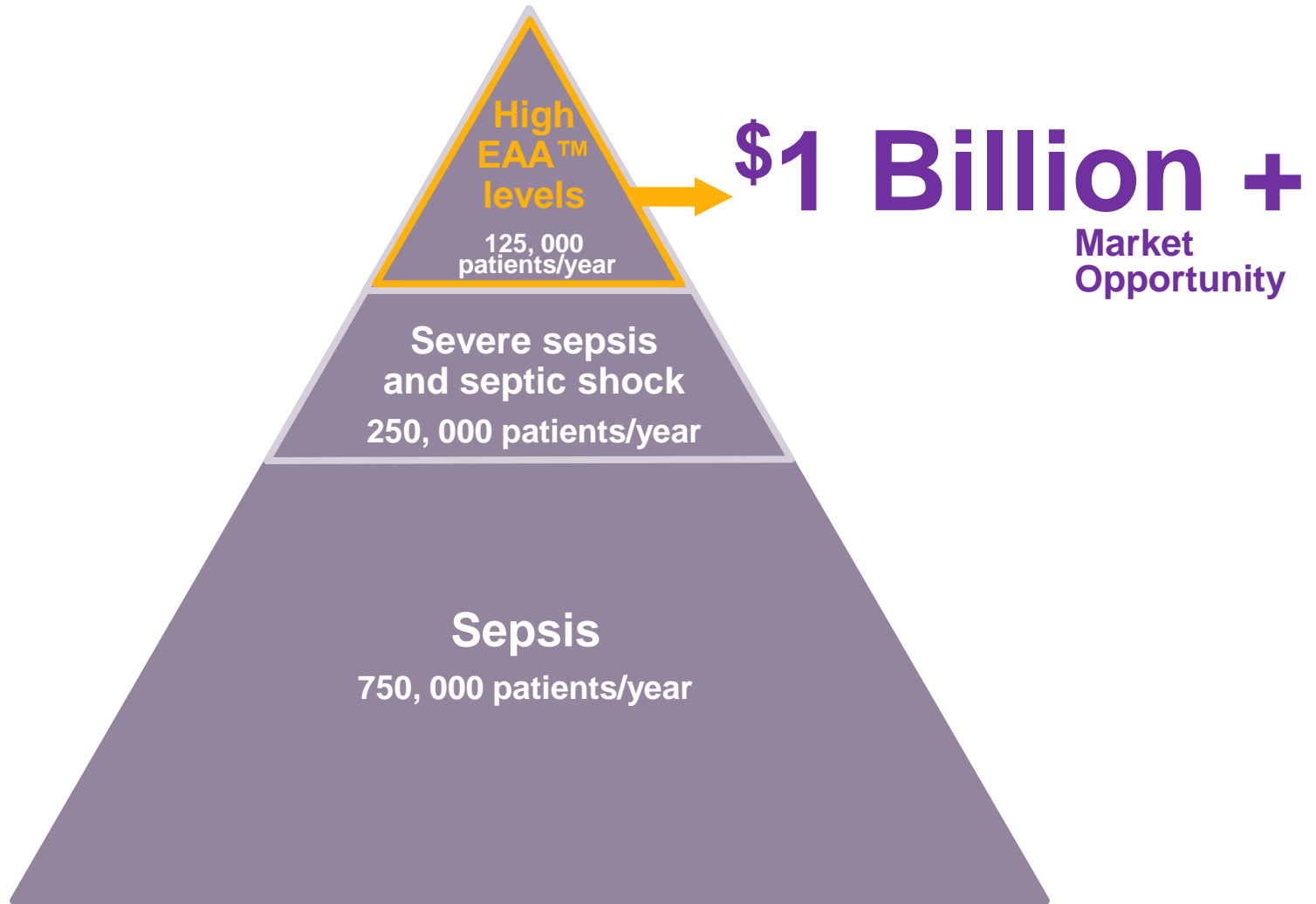
Recent amendments approved by the FDA:

- Entry criteria now less focused on vasopressors and more on earlier high endotoxin levels
- Increase in number of investigative sites
- Agreement on use of international sites if desired

Commercialization Strategy and Milestones



Market Opportunity in North America



The Commercial Opportunity

Exclusive North American rights for Toraymyxin

- 20 + years material supply agreement with Toray Industries Inc.
- Spectral has sole rights to sub license, sell, transfer or assign
- Pricing of \$10,000 per treatment in the U.S., based on independent consulting study and existing reimbursement code
- ~ 70% gross margin
- Very attractive to potential commercial partners

Spectral controls EAA™ worldwide

Opportunities to expand EAA™ /Toraymyxin worldwide



Investment Highlights

- The first Theranostic for severe sepsis and septic shock
- Toraymyxin is safe, effective and has already treated >80,000 patients
- A large unmet medical need worldwide
- Well designed pivotal Phase III trial run by world-class experts
- Blockbuster potential in an underserved market
- Near-term licensing/partnering opportunities
- Significant valuation upside



Management and Board of Directors

Paul Walker, M.D., Ph.D. FRCSC
President & Chief Executive Officer

Anthony Busiskas, C.A.
Executive Vice President & CFO

Robert Verhagen, B.Sc., MBA
Vice President, Business Development

Debra Foster, RN, B.Sc., CCR
Vice President, Clinical Development

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President & CEO of Spectral Diagnostics Inc.

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CEO of American Medical Systems

Guillermo Herrera
Former SVP of Abbott Laboratories

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